

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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COMMISSIONERS PRESENT:

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1 P R O C E E D I N G S

2 MR. HACKBARTH: Okay. I apologize for the late
3 start. Thanks to those of you in the audience who have come
4 to see us work.

5 With this session, we now leave what has
6 preoccupied us for the last couple sessions -- namely,
7 updates to the various payment systems -- to talk about a
8 set of interesting and challenging policy issues. On
9 today's agenda, we have got shared decision-making, benefit
10 design, improving quality and efficiency in hospitals, in-
11 office ancillary exception, and GME. And my head hurts
12 already thinking about it, but they are obviously all very
13 important issues and things that we have touched on in the
14 past, and I hope to make some progress towards
15 recommendations on some of these.

16 First up is shared decision-making, and, Joan, are
17 you leading the way?

18 DR. SOKOLOVSKY: Yes. Good morning. This morning
19 we're going to focus on the beneficiary with two
20 presentations. First, Hannah and I are going to look at the
21 role of shared decision-making. And then in the next
22 session, Rachel is going to talk about benefit design.

1 It has been a year since we last talked about
2 shared decision-making, and at that time, I described how it
3 works. Today I just want to remind you of what it is.
4 Shared decision-making is a process that involves giving
5 patients personalized information about their condition,
6 possible treatment options, and the probabilities of
7 benefits and harms for those options, and then allows the
8 patients to communicate to their physicians how they value
9 the relative importance of the benefits and harms, and then
10 the patient can participate with the physician in decision-
11 making. For example, breast cancer patients learn that
12 there is no difference in survival rates for lumpectomy
13 versus mastectomy but that there are other tradeoffs with
14 both procedures that they should consider. Shared decision-
15 making includes the use of patient decision aids, and these
16 are tools that give patients objective information on all
17 treatment options for a given condition.

18 Shared decision-making is not appropriate for all
19 decisions. You obviously cannot use it in emergencies or
20 when the medical evidence is unambiguous. It is used most
21 often for preference-sensitive procedures when medical
22 evidence suggests that there are several possible treatment

1 options. The goal is to reduce unwarranted variation by
2 ensuring that the procedures are chosen by informed patients
3 who value their possible benefits more than their potential
4 harms.

5 Let me just quickly go over our key findings.

6 Proponents of shared decision-making argue that it
7 can help beneficiaries take a more active role in their
8 health care. To better understand how it works, staff made
9 four site visits and conducted numerous interviews with
10 individuals employing the programs and companies that
11 produce the materials that are used shared decision-making.

12 We found potential in the model but also some
13 conditions that must be met before shared decision-making
14 can be widely employed throughout the health care system.

15 First, physicians must support shared decision-
16 making, and for that to happen, it must not interfere with
17 office work or add to the time they have available to see
18 patients.

19 We found that it is more easily incorporated in
20 specialty care when there is a discrete, time-sensitive
21 decision that a patient must make. However, primary care
22 physicians as a group express support for the idea.

1 To be successful, a program must use objective,
2 up-to-date, and easily understandable patient decision aids.
3 Clinical IT is important to find patients at the right
4 moment to make a decision and to make it simple for
5 physicians to prescribe the decision aid.

6 Now Hannah is going to talk to you about the
7 beneficiary need for better communication about their health
8 needs.

9 MS. NEPRASH: We know that beneficiaries face
10 challenges when making health care decisions. Compared to
11 their younger counterparts, they're more likely to be
12 poorer, less educated, cognitively impaired, and faced with
13 multiple chronic conditions. They're also more likely to
14 have low health literacy. This is defined by the IOM as
15 "the degree to which individuals have the capacity to
16 obtain, process, and understand basic health information and
17 services needed to make appropriate health decisions."

18 Research indicates that health literacy declines
19 with age and is lower for certain segments of the population
20 including the elderly, Medicare or Medicaid recipients,
21 racial and ethnic minorities, and low-income adults.

22 One factor that contributes to low rates of health

1 literacy is the inability to understand the meaning of
2 numbers, which leads to confusion about the risks and
3 benefits of health care procedures and, in turn, affects how
4 patients make decisions.

5 Many patients especially don't understand the
6 difference between a relative versus an absolute risk
7 presentation and are more likely to view a treatment
8 alternative positively if the benefits are expressed as a
9 relative risk reduction. So, for example, saying that a
10 cancer screening test every two years will reduce the chance
11 of dying from that cancer by one-third over the next ten
12 years is a relative risk presentation. And the equivalent
13 absolute risk presentation would say that the same test will
14 reduce your chance of dying from that cancer from around 3
15 in 1,000 to 2 in 1,000.

16 Low health literacy affects health outcomes.
17 After controlling for demographic and socioeconomic factors
18 including income, numerous studies show that elderly adults
19 with poor health literacy were more likely to be in poor
20 physical and mental health; knew less about their chronic
21 disease; were less likely to receive preventive care; and
22 were hospitalized more.

1 Additionally, some of the literature finds a
2 reduction in racial disparities for the use of preventive
3 services when you control for health literacy.

4 So if health literacy is the ability to obtain and
5 process health information, patient activation is the
6 capacity to self-manage one's health and one's health care.
7 An active patient is more likely to receive preventive care,
8 implement healthy lifestyle changes, adhere to treatment
9 plans, and ask questions about his or her health care.

10 Like health literacy, low-income and minority
11 populations are less likely to be active patients, but
12 ongoing research indicates that patients can become more
13 active through tools like shared decision-making. Some
14 studies suggest specifically that minority and low-income
15 patients can become more active, making them more engaged
16 participants in their health and health care decisions.

17 A more active patient may be a very good thing for
18 both patient and provider, who may not always exchange
19 necessary information during an office visit.

20 Researchers at the University of Michigan surveyed
21 patients and providers to assess their rankings of key facts
22 and goals for 14 treatment decisions. When providers were

1 asked to choose the top three things patients should know
2 about chemo and hormonal therapy for breast cancer, not one
3 selected side effects or risks; whereas, almost one quarter
4 of patients expressed wanting to know about serious side
5 effects of the treatment.

6 When patients and providers were asked to choose
7 their top three goals and concerns for the same 14 treatment
8 decisions, they identified very different goals. Providers
9 had a tendency to cluster around only a few goals, such as
10 keeping the breast and living as long as possible for breast
11 cancer decisions; whereas, patients were more diverse in
12 their goals.

13 I will turn it back over to Joan.

14 DR. SOKOLOVSKY: Shared decision-making programs
15 that try to bridge this disconnect are expanding, but
16 challenges remain significant. Initially, programs began at
17 academic medical centers, but currently there are many
18 demonstrations going on at community based clinics. The
19 highest adoption rate has been at breast cancer centers
20 where 50 centers are actively distributing the aids and have
21 programs built around them and a number of others are
22 considering it.

1 When we asked how the programs are working, we
2 have some evidence, not enough. Results from 55 randomized
3 controls found that patients using shared decision-making
4 with decision aids consistently show more knowledge of their
5 condition, they are more actively engaged in their care and
6 have a more realistic idea of the likely outcomes of
7 treatments. They are more likely to choose less invasive
8 options. Cost implications are difficult to come by. In
9 the Group Health demonstration project, which I reported
10 about in your paper, after one year, they found a 10-percent
11 reduction in knee replacement surgery, a 20-percent
12 reduction in hysterectomies, and no change in hip
13 replacement rates.

14 Surveys have shown that physicians generally have
15 a positive attitude towards shared decision-making. For
16 example, one survey of orthopedic surgeons found that the
17 majority thought shared decision-making was an excellent or
18 good idea. The most important benefit they cited was that
19 it increased patient understanding of their condition and
20 the potential treatment options. But few had attempted to
21 implement it within their practice. They reported that the
22 most important barrier was the fear that it would take lots

1 of time and interfere with their work flow.

2 Similarly, in a national survey, 93 percent of
3 primary care physicians said shared decision-making was a
4 good idea, but again named lack of time with patients as the
5 main barrier to its use. We found that with most current
6 programs, there were physician initiatives, but that didn't
7 mean that the physicians were involved in the day-to-day
8 operations of the program. In fact, our interviewees
9 repeatedly told us that programs could only work if they
10 could fit into the way physicians practice. If the program
11 created more work or interrupted the work flow in the
12 office, it was unlikely to be widely adopted.

13 Physicians are not equally receptive to shared
14 decision marking. We found some evidence that physicians in
15 high-volume specialties are more receptive. For example,
16 orthopedists were high adopters in a number of practices.
17 They found that it resulted in fewer patients who were poor
18 candidates for back surgery or knee replacements and that
19 patients had more realistic expectations about treatment
20 results. So this is some information, but this is something
21 we would need to look at more closely.

22 Physicians often stress the importance of

1 implementing shared decision-making in primary care, but the
2 difficulties are significant. Specialists are more likely
3 to have a limited number of decision aids to prescribe for
4 their patients. Primary care physicians deal with a wider
5 range of issues. For example, program organizers at
6 Massachusetts General Hospital identified 22 decision aids
7 that are available for use by their primary care physicians.
8 And the physician is less likely to know before a patient
9 visit exactly which decision aids would be appropriate.

10 Secondly, patients may find decision aids provided
11 by specialists more salient than decision aids used in
12 primary care. Specialists prescribe decision aids at a time
13 when the information is most useful to patients -- before
14 meeting with the physician to make a treatment decision, for
15 example, on cancer treatment or back surgery. The physician
16 can then spend more time with the patient answering
17 questions and discussing the options and less time
18 explaining the basics of the diagnosis and treatment
19 options. On the other hand, patients may not be willing to
20 invest the same amount of time to understand the advantages
21 and disadvantages of different cancer screening options.
22 Specialists are also more likely to get the results from a

1 patient's use of shared decision-making, so there is more of
2 a feedback loop there.

3 I want to talk about some potential policy
4 options.

5 Patient decision aids are the foundation for
6 shared decision-making. They present the risks and benefits
7 and help patients understand how likely it is that those
8 benefits or harms will affect them. They can be written,
9 web-based, or video. Some are multimedia, combining many
10 ways of presenting information, including video clips of
11 patients who have used the information and how they made
12 their decisions.

13 In 2003, an international collaboration of
14 researchers, practitioners, patients, and policymakers from
15 14 different countries began a consensus process to develop
16 quality criteria for decision aids. The criteria, described
17 in your mailing material, also include a checklist to see
18 whether a particular aid meets the criteria. Decision aids
19 have multiplied in recent years. More than 500 aids have
20 been identified including at least 200 that meet at least
21 one of these criteria.

22 Those involved implementing programs stress the

1 need for national quality standards for decision aids. A
2 national standard supported by Medicare would establish the
3 framework for shared decision-making based on objective,
4 timely, and comprehensible material. It also would help
5 consumers identify materials that are based on accepted
6 clinical evidence.

7 So one policy option for you to consider today is
8 to have the Congress require the Secretary to establish
9 standards for decision aids and accredit aids that meet
10 those standards.

11 Information technology is also important in
12 facilitating the use of shared decision-making. It allows
13 program organizers to track patients who could benefit from
14 specific aids. It allows physicians to order aids by
15 clicking a button on a patient's medical record. It
16 minimizes the steps needed to disseminate aids. And
17 sometimes it tracks patient response to the aids. We have
18 yet to find a practice-wide program without a strong IT
19 infrastructure.

20 As a result of the ARRA, providers will be
21 receiving about \$36 billion over the next six years to
22 encourage the adoption and use of electronic health records

1 that meet criteria for meaningful use. The Health IT Policy
2 Committee -- a federal advisory board that makes
3 recommendations for meaningful use -- included provider
4 access to patient-specific educational resources in everyday
5 language. However, when CMS issued its proposed rule on
6 meaningful use, patient education capacity was not included.

7 Development of shared decision-making would be
8 facilitated if the Secretary requires systems to add this
9 criteria in their final rule. And I did just want to add
10 that this is not only about shared decision-making. For
11 example, the current criteria say that lab values have to be
12 available to patients on their electronic health record, but
13 without the patient capacity, the physician doesn't have any
14 easy way of letting the patient understand what the lab
15 value means, which could lead to a fair amount of panic and
16 perhaps unnecessary doctor visits.

17 I would like to conclude the presentation now, and
18 we welcome your discussion.

19 MR. HACKBARTH: Thank you, Joan, Hannah.

20 I'm really delighted that we have this issue on
21 the agenda. When I was at Harvard Vanguard -- this was
22 probably around 14, 15 years ago now -- Dr. Al Mulley from

1 Mass. General came and made a presentation to our clinical
2 leadership on this subject, and what he said still rings in
3 my ears. He presented this as an ethical imperative, and
4 his argument was that there were many medical services for
5 which the right answer was entirely dependent on the
6 patient's preferences, their assessment of risks and
7 benefits and how they valued different potential outcomes,
8 and a system in which that was invested in the physician
9 without any systematic effort to bring the patient into the
10 discussion was, in his view, an ethically flawed system.

11 And then he went on to present evidence that when
12 patients are engaged in a systematic way, in fact, they do
13 make different choices than patients left to their own
14 devices might make. And so this I think is a very, very
15 important topic.

16 Okay. We will open it up for Commissioner round
17 one clarifying questions. I would ask that Commissioners
18 really discipline themselves. I have had several
19 Commissioners come to me and say, you know, "A lot of the
20 round one stuff is really overly broad. I'm patiently
21 waiting and people are basically jumping the queue by not
22 following the ground rules of round one. So round one

1 questions are simple, clarifying questions: "What did you
2 mean by X?"

3 With that as a preface, we will start over here
4 with Bruce.

5 DR. STUART: I just want to echo what Glenn said
6 about the importance of this chapter. Not only is the
7 subject matter important, but the way you presented it is
8 really good.

9 My question is on Slide 4, and it is the last
10 point about relative versus absolute risk. I will betray my
11 views on this in terms of this is a personal bete noir, but
12 there is a comment that you made and a like comment in the
13 text that indicates that individual patients respond more
14 positively to relative risk than absolute risk. And I think
15 I understand why: because relative risk looks big when
16 absolute risk is small. Is that what you meant by this? Or
17 does it take into account the level of absolute risk?

18 In other words, relative risk to me doesn't mean a
19 thing unless you know what absolute risk is. If absolute
20 risk is high, then relative risk is important. If absolute
21 risk is really low, then relative risk is really misleading.

22 MS. NEPRASH: You've characterized it perfectly.

1 The example I presented about the hypothetical cancer
2 screening with the relative and the absolute risk reduction,
3 the equivalent presentations, was also presented to
4 patients, and overwhelmingly, when it was as relative risk
5 reduction, they said that they would opt for that screening
6 versus the equivalent absolute risk reduction.

7 DR. MILSTEIN: Could you clarify whether the
8 current physician payment system does or does not expect as
9 part of the payment that physicians have done a thorough job
10 of explaining to patients the pros and cons of a therapeutic
11 option? In other words, is this something that is already
12 expected as part of the definition of what we are paying for
13 in the fee schedule but it is not happening? Or is this
14 something that wasn't contemplated when the physician fee
15 schedule was put together?

16 DR. SOKOLOVSKY: I don't know if there's a
17 specific component in the fee schedule that would reflect
18 that, but there is the issue of informed consent, which is
19 something that, in fact, we were thinking that we would
20 bring to you in April, which is definitely something that
21 before a procedure is provided.

22 You always, including at the dentist, sign an

1 informed consent rule, and some of the issue here is: Is it
2 really informed consent.

3 DR. MILSTEIN: My question was a little unfair
4 because it wasn't -- it is embedded in this, but there may
5 be someone else on the staff who can answer.

6 MS. BOCCUTI: I think there is a way that you can
7 bill for some extra time. I think Kevin has left the room,
8 or maybe Karen -- so there are ways. Now, it doesn't mean -
9 - you know, if the patient needs extra counseling, then
10 there is a code that you can do for that one. It is face to
11 face, and you can add on to your visit. And there are other
12 ways for visits to be accounted for, not just by it is one
13 code but you can have sort of add-ons. But it is not
14 specifically one for shared decision-making.

15 Karen, did you --

16 DR. BORMAN: [Shaking head negatively.]

17 DR. BERENSON: Basically the definitions of office
18 visits have -- and there is now -- I am sure you have heard
19 about these documentation guidelines at what has to happen.
20 They are focused on history, physical, and decision-making,
21 sort of the doctor's decision-making. In those
22 circumstances where counseling makes up more than half, what

1 I believe is the guidance, of the time of the visit, that
2 can be the dominant reason for the code. So there is no
3 expectation that shared decision-making will happen. The
4 focus is really on doctor stuff. Some of us think those
5 definitions, maybe it is time to relook at that. But for
6 those physicians who want to engage in shared decision-
7 making, there is this approach that you just heard about
8 which permits them to bill a higher level than they can
9 justify simply by the history, physical, and decision-making
10 activities that they engaged in, if that makes sense.

11 MR. GEORGE MILLER: I also want to echo your
12 comment at the beginning of the session about how important
13 this issue is. And I guess my question dealing with the
14 question about health literacy and tying that to health
15 disparities, and if you were able to show a correlation
16 between the health disparities and health literacy and how
17 those may tie together, this may lead to, I guess, a round
18 two question, really, and I apologize if I have strayed into
19 the weeds about that issue.

20 MS. NEPRASH: What I mentioned refers to a few
21 studies that have looked at regional and ethnic disparities
22 in the use of especially preventive care services. And when

1 the researchers can adjust for health literacy levels --
2 which is usually based on two specific tests of health
3 literacy -- those disparities are much less significant.

4 MR. HACKBARTH: Okay. Other clarifying questions?

5 DR. KANE: Is there a distinction between shared
6 decision-making and patient education? I mean, I am
7 wondering which one we are really talking about here,
8 because your example about a patient getting a lab value and
9 needing to understand what it meant is not really
10 necessarily a decision so much as just understanding. So I
11 am guessing you are talking about the broader topic, but I
12 just want to clarify which topic you really are --

13 DR. SOKOLOVSKY: In that situation I was talking
14 about the broader topic, but it is the same criteria in
15 meaningful use would facilitate both.

16 DR. BERENSON: You talked about and in the paper
17 specifically mentioned that researchers in the field
18 stressed the need for national quality standards for
19 decision aids. I am a little nervous about going down the
20 road of a national accreditation program for decision aids.
21 But do we have any examples of misleading decision aids, you
22 know, proprietary-induced decision aids that are moving

1 people into a certain direction that might not be viewed as
2 fair and balanced?

3 DR. SOKOLOVSKY: There's so many examples, I don't
4 exactly know where to start, but one thing I can say is
5 during the snowstorms I spent a lot of time watching local
6 news; many, many commercials which end with "and call us,"
7 your pharmaceutical company or device manufacturer, "for a
8 discussion guide that you can take to your physician."

9 MR. HACKBARTH: Further clarifying questions?

10 MR. KUHN: Joan, a quick question. You had
11 mentioned the various modalities that are available -- you
12 know, web-based, video, I assume one-on-one. Is there any
13 research that shows that one is stronger than the other in
14 terms of impact with patients? I am just curious what is
15 working best out there right now.

16 DR. SOKOLOVSKY: There are a number of studies
17 that try to get at that, but they are too small, I think,
18 for you to really draw any conclusions from them.

19 MS. HANSEN: Yes. On page 4 -- excuse me, 5, the
20 whole aspect of the people who are at risk perhaps in making
21 these decisions, and even though you found a couple of
22 studies that show that even with more challenging

1 populations, you can reduce -- basically have the decision-
2 making a little bit more effective.

3 My other question is I notice that more community
4 health centers are now beginning to take a study of this.
5 Has there been any research that has come kind of from that
6 grouping of providers?

7 MS. NEPRASH: I think it's still a little bit too
8 early. You know, we're aware of a few studies that are
9 going into community health centers, and especially taking
10 advantage of the time in the waiting room to use decision
11 aids to boost -- you know, to make these patients more
12 active, to help brainstorm questions for them to ask their
13 physicians and ways for them to become more involved in
14 their decisions. But results are still coming in. So I am
15 happy to stay on top of that and get back to you when we
16 know more, but that is a promising area of research.

17 MS. HANSEN: I would appreciate that because so
18 much of some of the issues that evolve come from the factors
19 listed on your Slide 5, you know, which is really a bulk of
20 characteristics that people have relative to their
21 comprehension.

22 DR. SOKOLOVSKY: My sense was that this is kind of

1 the cutting edge of where they're going right now, looking
2 to do things. But one other thing we saw recently, there
3 are some decision aids now that are meant to be used with
4 caregivers. For example, we saw a really good one on fall
5 prevention for the frail population. It's meant for the
6 patient and their caregiver to watch together.

7 DR. DEAN: Is there any index or clearinghouse or
8 any place where the available decision aids have been sort
9 of cataloged or put together where people can go to look for
10 these?

11 DR. SOKOLOVSKY: There is an organization in
12 Ontario that does catalog the decision aids -- I can
13 actually send you that link, if you would like to see it,
14 and you can see what's up there -- that meet some minimal
15 criteria before they will list them there. But, yes, there
16 is a catalog, and I would say it's an ever-growing catalog.

17 MR. HACKBARTH: Any other clarifying questions?

18 [No response.]

19 MR. HACKBARTH: Okay. Let's move on to round two
20 comments beginning with Karen.

21 DR. BORMAN: Just in terms -- there was a lot of
22 this information that was very good and very nicely put

1 together. I have two sort of question and comments. One
2 is, in the materials, you talk about the University of
3 Michigan study and what came out of the encounter with the
4 physician -- the shared decision that was initiated by the
5 physician. And we say that for every intervention examined,
6 discussions with the provider tended to emphasize the pros
7 over the cons and involve a recommendation about what the
8 provider thought best.

9 I am going to leave aside right now the pros over
10 the cons piece, because I think that is problematic, but
11 that notion that involves a recommendation about the
12 provider thought best, to my mind, the way this is written,
13 it sounds a little bit pejorative about the recommendation,
14 and frankly, your doctor should be making recommendations.
15 They need to be well structured, well thought through,
16 objective, evidence-based recommendations, but what I think
17 we have something of a problem with is that we oftentimes
18 aren't making a recommendation.

19 And so I would like to see us maybe rethink or
20 reword or do some wordsmith some in that way to get across
21 the concept that we think a recommendation that is based on
22 good background is, in fact, an appropriate part of the

1 doctor-patient encounter, or physician assistant or
2 whomever, but that it is a proper part of the encounter, and
3 this just has a little bit of flavor of suggesting
4 otherwise, which I doubt is what you meant, but that was
5 one.

6 And then if you could help me understand, because
7 I understand, I think, what health literacy is and I can
8 bring up lots of patient connotations in my mind about low-
9 and high-literacy patients that I have dealt with. The
10 activation part and the linkage to the literacy part is
11 where I am struggling a little bit, because you mentioned
12 that something -- it almost sounds as though you are
13 suggesting that an activated patient compensates for less
14 literacy without becoming more literate, and it just seems
15 illogical to me that if you have somebody who is activated
16 or becomes activated, that in order to meet the definition
17 of an active patient, almost by definition, they are
18 becoming more literate. Is that -- or have I
19 misinterpreted?

20 MS. NEPRASH: I don't think you have
21 misinterpreted. There is a little bit of research that
22 looks at patients with low health literacy, and if they are

1 scoring high on patient activation measures, they are asking
2 questions and may be more likely to adhere to treatment
3 regimens, and so they are compensating a little bit for the
4 health literacy. But I am not sure I would say that there
5 isn't a change in their literacy. Does that help?

6 DR. BORMAN: What I am trying to envision is it
7 almost sounds in reading the chapter that you could be very
8 activated but very low health literate, and I am just having
9 a little trouble envisioning what that patient is who is
10 very engaged and does these things and who is low literacy.
11 It is almost like we are judging the quality of what they
12 know, which I think goes way beyond what we can measure.

13 DR. CHERNEW: Like Grandma.

14 MS. NEPRASH: I will go back to the text and work
15 on clarifying that.

16 DR. BORMAN: Okay. There you go. Okay.

17 DR. STUART: I would like to follow up on my first
18 point here. I know there is other research on absolute
19 versus relative risk, but the concern that I have in terms
20 of presenting it in somewhat neutral fashion is that we know
21 that providers, some providers give risks in relative terms
22 because they know that that looks like the impact is bigger

1 than the absolute impact is. In fact, they know that if you
2 gave absolute risk differences, that patients would behave -
3 - would respond differently than if you do it in terms of
4 relative risk.

5 So what I would like to see here is some statement
6 to the effect that if, or when risk-based information on
7 benefits and harms is provided to patients, and if it is
8 provided in relative terms, it is also couched in absolute
9 difference terms. And there is research supporting that.
10 So it is just saying -- this sounds like a little part of a
11 much larger picture, but when you really get down to it,
12 almost everything that you are talking about in terms of
13 shared decision making, choice A, choice B, you can frame in
14 these terms. Physicians and researchers have traditionally
15 used this metric of relative risk and I think that it is
16 problematic mathematically, but even more importantly, I
17 think it is problematic because it could be misused to
18 promote services that have relatively low value.

19 DR. CASTELLANOS: First of all, I appreciate you
20 bringing this up. I think it is a pertinent topic. Like
21 Glenn stated this morning, this is not a new concept. This
22 has been something that has been emphasized in the medical

1 community for a very long period of time. And as Karen
2 said, perhaps because both of us are surgeons with informed
3 consent, this is something we commonly try to do as best as
4 we have with our limited knowledge.

5 I think that another place this can be put is in
6 our recommendations in graduate medical education, that this
7 be emphasized.

8 Like Bob, I am a little concerned about where we
9 are going with this, especially where you suggest perhaps
10 this policy, the Secretary could incorporate it into a
11 meaningful use criteria. You know, I am worried that we are
12 getting another Medicare bureaucracy, increased costs,
13 increased lawyers to review, more costly, et cetera.

14 Perhaps we could do something like a Good
15 Housekeeping Seal of Approval type of process rather than
16 trying to really get it down and dirty.

17 MR. BERTKO: First off, it is a nice chapter and
18 I'm all in favor of shared decision making. I mean, how
19 could anybody not be, right? Then comes the cynical
20 comment, which is this seems to be, by itself -- I am
21 looking at page 11, Slide 11, and the recommendation that
22 the Secretary establish standards as being an ineffective

1 standard -- it strikes me as we are pushing on a rope.
2 Glenn, you gave the example at Harvard Vanguard, you were in
3 a capitated health care system, and so your system had a
4 direct advantage to doing this. In fee-for-service
5 Medicare, what is the advantage for the individual fee-for-
6 service physician? Relatively little.

7 And there's a second part of this and it's the
8 pushing on a rope of getting consumers activated,
9 beneficiaries activated. I think you guys made mention here
10 of one example where there's a cash incentive for some group
11 of patients. Wasn't that in the background literature? So,
12 I mean, do we need to have more investigation of that to get
13 beneficiaries interested in doing this?

14 I think what I am suggesting to be a little bit
15 less cynical is that we suggest more research on the best
16 ways to get this done as opposed to saying, just do it,
17 because the "just do it" part says, oh, sure, let's all walk
18 more. Let's travel less. For my taste, let's fly on
19 airplanes less, things like that, all well-meaning thoughts
20 that don't happen automatically.

21 DR. SOKOLOVSKY: I actually thought we were being
22 much more conservative than you are being here, because we

1 weren't saying just do it. We were saying, okay, let's put
2 standards in place, like have NCQA have standards. As I
3 said, there's a lot of work for that already. But there are
4 programs that do incentives, but I feel like we could say
5 that -- particularly in fee-for-service -- that there was
6 enough infrastructure to say, okay, let's make incentives
7 and people will go do it.

8 MR. BERTKO: Okay. So incentives in the -- or
9 rather, standards in the absence of incentives, I think, are
10 weak or ineffective, and perhaps we should think about other
11 things. I mean, everybody has heard about Safeway and what
12 they have done with their employee population, the guy there
13 who has been dramatic in his getting that message out,
14 whether it is accurate or not. Do we need to have more
15 research on whether the incentives work and how big the
16 incentives should be and whether there should be incentives
17 on this side? I just, again, don't want us to suggest doing
18 things just for the sake that they sound good.

19 MR. HACKBARTH: Can I just pick up on that for a
20 second? So you used the term there should be standards.
21 That can be interpreted in a couple different ways. One
22 type of standard is, it's a regulatory requirement. You

1 can't do it if you don't do it this way. Another approach
2 is a purely voluntary accreditation, the Good Housekeeping
3 Seal of Approval model. Which of those do you have in mind?

4 DR. SOKOLOVSKY: The second.

5 DR. MILSTEIN: A couple comments here. I mean,
6 it's important to realize that the -- for me, I think it's
7 useful to realize a couple things. Number one, patient
8 activation and shared decision-making are not one in the
9 same. Shared decision-making is a form of patient
10 activation. Maybe on another day, in another session, we
11 should discuss patient activation because there's actually
12 some reasonable research in credible scientific journals
13 that suggests that, especially Medicare patients, live
14 longer if activated. It was the Caplan-Greenfield paper,
15 and that's sort of a technology, a method of producing
16 health care that is documented, but for obvious reasons has
17 not been rapidly taken up like perhaps a biomedical
18 technology innovation might have been taken up. But it is a
19 basis of improving value, in this case, longevity for
20 patients irrespective of their baseline level of health
21 literacy. So it is a separate topic.

22 Now, with respect to this particular form of

1 patient activation, shared decision-making, I think that
2 when Medicare was initially laid out and as it's been
3 refined along the way, one of the areas that has not been
4 kind of well conceptualized is whether or not Medicare ought
5 to be paying for services that would be unwanted by an
6 uninformed -- that would be unwanted by an informed
7 beneficiary. That is really what this is targeting, because
8 there's a certain percentage of Medicare services that if
9 the patient were to be given a well-structured opportunity
10 for shared decision-making, they would not want.

11 The review article by Annette O'Connor that I
12 believe was cited and suggests that across, I think, 50 such
13 studies in various countries, predominately the U.S., it
14 turns out that patients, when they go through this process,
15 decline what their doctor recommended about a third of the
16 time. I think that's the mid-point. And so that's a fairly
17 substantial fraction of decision-making-relevant services
18 that are currently being delivered that would not be wanted
19 by a well-informed patient. That's a lot of money.

20 I don't know how the -- I'm not sure that the
21 original definition of medically necessary, or when Medicare
22 wants to pay for services ever thought about this, but for

1 me, one of the other options on the board besides the ones
2 we've talked about is to basically say, it's not covered.
3 It's not a covered service if a shared decision-making aid
4 that has met a certain standard for its scientific and
5 decision-making merit is applicable and was not used,
6 because then we essentially -- there's roughly a one-third
7 chance that Medicare would end up paying for a service that,
8 had the patient been well informed, they would not have
9 wanted.

10 So add that. This is not something that I think
11 that Congress, if they had a chance to think about, would
12 want to be paying for, because of these things that an
13 informed patient would not want, but a lot of patients are
14 not informed.

15 And the last comment is in terms of thinking about
16 how we might go about, irrespective of which tool we pick,
17 you make it a requirement to be a participating provider,
18 you make it a voluntary Good Housekeeping, you incorporate
19 it in P4P, you know, there's two ways of going about that.
20 One is essentially you go through a certification process to
21 say whether or not your method of making sure patients were
22 well informed before they came to a decision were good

1 enough.

2 Another that I know that has been developed, I
3 have heard presentations of in various settings by leaders
4 in this area like Al Mulley, is a notion of just on a sample
5 basis actually testing beneficiaries with respect to what
6 did they understand on the eve of proceeding with the
7 procedure, because that, separate and apart from telling you
8 whether or not the structural elements of the decision,
9 shared decision process were good enough, it actually tells
10 you, at the end of the day, did the patient make the
11 decision with a reasonable understanding of the risks and
12 benefits of treatment A versus whatever was the alternative
13 treatment. So another way of going about it is not a
14 certification process but rather a random sample, sort of a
15 survey of patients on the eve of these procedures to see
16 whether they did or did not grasp what the pros and cons
17 were of the treatment they were about to embark on versus
18 the alternative.

19 So I think it's three somewhat distinct points.

20 MR. HACKBARTH: Could I just ask for a
21 clarification on the first one. So the first point, as I
22 understood it, was a policy option is Medicare shouldn't pay

1 unless an appropriate shared decision-making tool was used,
2 and the important thing is the tool was used, not what
3 decision the patient made, but their use of the tool.

4 Now, the way I interpreted what Hannah and Joan
5 were presenting was a conservative sort of first step. A
6 first step that might lead to that ultimate approach would
7 be let's get certified decision-making tools in wide use.
8 Am I interpreting your approach correctly?

9 MS. NEPRASH: Yes.

10 MR. HACKBARTH: Okay. Arnie?

11 DR. MILSTEIN: That, I completely agree with that.
12 That is a contrast with what I suggested. And I will say
13 that one of the -- in broad brush, one of the things that I
14 think is relevant to this discussion but relevant more
15 broadly is the weight on the side of supplying services is
16 not subject to any kind of conservative approach. There is
17 very little regulation once a -- on certain service volume.
18 I mean, we don't do well on that. And so when we have
19 methods or techniques that weigh on the other side in terms
20 of balancing against service volume, the danger of always
21 proceeding in small increments is that we never are agile,
22 fast, and strong enough to offset the relatively non-

1 conservatively ramped-up forces in favor of service volume.

2 MR. GEORGE MILLER: I want to thank Arnie for his
3 points, because I hope that will help, at least in my mind,
4 frame my comments. I'm in favor of the first bullet point
5 on the standards for decision, particularly around the
6 notion that I raised earlier concerning disparities in
7 health care. In my mind, I think making those standards for
8 decisions aids will be important to address that issue. But
9 like Bob and John, I don't believe there needs to be
10 accreditation for those standards. I think the statement
11 needs to be made they should be part of a process, and as
12 Arnie well described, that if one-third of folks if they are
13 fully informed may not choose to have that procedure done,
14 then Medicare would not pay for that. I strongly support
15 that notion.

16 But just to reclarify the point, I don't think an
17 accreditation body aids or serves the purposes well. I
18 think that that conversation between the physician, it does
19 deal with the informed consent, have a meaningful
20 discussion, and I like the concept of testing afterward,
21 before the procedure, did they fully understand, and that
22 would lead to -- in my mind, it would lead to a better

1 understanding and would help to eradicate some of the
2 disparities, which is my major thinking about how this would
3 possibly affect disparities in health care in a very
4 pronounced way.

5 DR. KANE: Yes. I mean, I'm very supportive of
6 this notion, although I'm a little daunted by the challenge
7 of the comprehensibility of a lot of these types of things.
8 I'm just wondering if there's a way to think about how the
9 program itself might target where it's really important to
10 have these types of decision aids. I mean, I was just
11 looking, glancing at the article you left us about
12 copayments and hospitalizations, and obviously some very
13 poor choices were being made there where health plans
14 increased copayments for outpatient visits, and so patients
15 said, okay, I won't follow up on my hypertension, diabetes,
16 or my MI, I will just sort of hope it doesn't happen again,
17 and they end up being hospitalized more.

18 So clearly, there's some poor decision making
19 going on, particularly around when there's financial
20 incentives that make people make poor choices. So I'm just
21 wondering if there's things we can't target.

22 And the other one that comes to mind would be end-

1 of-life care, where there's clearly a lack of family
2 provider and patients' willingness to go through the
3 understanding of the options in a timely manner before it's
4 too late. So the whole idea of what are your -- and I know
5 this is a sensitive subject, but there's really a need for
6 some sort of a tool that helps people through those choices
7 and that really reflects what they most want and value as
8 opposed to what maybe even their family member wants and
9 values.

10 So I'm just wondering if there could be some
11 priorities or targets, because otherwise, this is a huge
12 subject. And then if you were going to then tack on
13 something like, we won't pay for that unless you have done
14 this, then it would relate to driving programmatic goals for
15 Medicare rather than just this broad, wide open, you know,
16 any kind of education counts-type thing.

17 DR. SOKOLOVSKY: Let me just say two things about
18 that. One is in Minnesota, they are considering
19 legislation. They have identified 14, I believe,
20 preference-sensitive decisions, and within the State
21 Medicaid and State employers-employees health plan, they
22 won't pay for those procedures unless the shared decision

1 making has, in fact, happened.

2 DR. KANE: And that is being driven by public
3 policy makers saying, these are the important areas, whereas
4 this is a -- I mean, I just think this is very big and I am
5 just kind of overwhelmed by the possibilities, whereas I
6 think there are some real program areas where we know that
7 the patients and their families are not making the best
8 decisions, and maybe even the providers need a little
9 education and maybe that should be articulated or made -- if
10 we are going to try to go this direction, that there should
11 also be an effort to create a priority list.

12 DR. SOKOLOVSKY: And then the other, in response
13 to your other comment, there is an advance directives shared
14 decision-making tool and it is one that's one of the ones
15 most popular for primary care doctors.

16 DR. KANE: And should we try to make that a
17 requirement at some point, at some stage of life or some --
18 I don't know. I mean, again, thinking about how can we
19 advance program goals with these aids as opposed to just
20 saying they are a great idea and they should meet certain
21 standards.

22 DR. BERENSON: Yes, just a couple of points to

1 follow up on my technical question that I asked about
2 standards. I haven't come to a conclusion of where I come
3 on this. The problem I'm having is that there are literally
4 hundreds of thousands of communications a day between
5 doctors and patients and in no way do we have standards for
6 those communications. There is the direct-to-consumer
7 advertising which would not meet the standards that you
8 would lay out for decision aids, and yet we are going to
9 pick this sort of subcategory and have standards. It just
10 seems sort of the tail wagging the dog kind of thing. I am
11 not necessarily opposed to it. Maybe these are discrete
12 enough and maybe we can make an advance in this area even if
13 we can't do anything directly in all those other areas, but
14 I would need to be convinced.

15 I also would want to explore the question of why
16 we would necessarily need the Secretary to direct that there
17 be an accreditation as opposed to the market asking for an
18 accreditation to happen, which is what typically happens
19 when NCQA or somebody else finds that there's a demand for
20 an accreditation, but maybe again there is a reason in this
21 area to do it. I just would be asking those kinds of
22 questions.

1 I guess that's the basic point I wanted to make.

2 DR. CROSSON: So I think one of the questions that
3 I would ask myself, and it ties back to what Glenn first
4 said, and I think Ron said the same thing, these tools have
5 been around a long time. This way preceded pay-for-
6 performance and many of the other ideas that we have talked
7 about here, and sort of the question is, well, so why is it
8 that 15 years later, we are actually talking about how can
9 we get this tool employed?

10 And as I look at my own organization, I have to
11 ask the same question. So as I look at the pattern of
12 quality improvement activities that have taken place in that
13 15 years' movement towards patient safety, preventive
14 medicine, early detection of disease, focus on better
15 outcomes, process improvement in the hospital, all of these
16 things have just sort of moved along.

17 This one has been relatively slow in my own
18 organization. I talked to Matt Handley from Group Health,
19 who was the physician who spearheaded this, and said, you
20 know, you have done a great job with this. So what do you
21 really think? And he said, I tell you, we got this done but
22 it was very hard, because even in our setting where there is

1 no negative incentive for the physicians, we continually
2 deal with the fact that many physicians really believe in
3 what they do, and so they have sort of an underlying
4 resistance to saying, gee, really, we ought to go through
5 this process to sort of second-guess what I think ought to
6 be done as a physician. I am not saying they are right. I
7 am just saying there is a human element to this that goes
8 beyond financial incentives and I think that may suggest
9 that this ought to go in -- if we really want to push it, it
10 may need to go in one of two directions.

11 I also had, about a year ago, a session where I
12 brought together leaders of group practices, both prepaid
13 and fee-for-service, and employers, large employers, to talk
14 about what would be areas of common interest, and I had
15 prepared this issue as one of the major discussion points,
16 and it kind of just laid an egg. I was really kind of taken
17 aback that what I would view as progressive group practice
18 leaders are kind of looking aside and down at the table and
19 saying, well, you know, this is kind of hard to do. And
20 even the employers were saying, gee, I'm not sure really our
21 employees would like this.

22 So there's a lot of sort of passive resistance to

1 this that belies the value of it, and I think -- so where
2 that takes me is that maybe, if we really believe in this,
3 either we're going to have to ramp up incentives for the
4 patients, the carrot thing, or go down the direction that
5 Arnie said, which is to progressively build it someday into
6 the regulatory environment or the incentive environment in
7 such a way that it overcomes that resistance.

8 This is not -- I'm not saying that physicians are
9 opposed to this or that it's principled resistance or even
10 strong resistance, but that there is a human element here
11 which transcends incentives that I think has made this
12 rather slow to progress.

13 And just one last point on the standards thing. I
14 think the other point to make in terms of the feasibility of
15 this is that you can't sort of just do this one time. I
16 mean, the elements that go into, for example, in situations
17 where there are many different modes of therapy, the
18 evidentiary-based changes frequently and the relative risks
19 and benefits of these things change. So you would need not
20 only a body to do this once. You would need somebody, some
21 set of people to be updating it all the time to make sure
22 that it continually reflected the evidence.

1 MR. HACKBARTH: Let me just pick up on that. I
2 referred to Harvard Vanguard's looking at this. Our
3 clinical leaders decided not to do it, and it wasn't because
4 they were in any way philosophically opposed. In fact, it
5 struck all the right chords philosophically for our clinical
6 group. We had a couple of our departments look at the
7 specific tools that were being proposed by Al Mulley, and
8 the way they looked at it is, if we are going to do this,
9 this really needs to be integrated into our practice. It is
10 not there is a library of tools that patients are referred
11 to and then they come into the office and we tell them
12 something completely different. It has to be part of how we
13 practice medicine so there is a consistent message delivered
14 to the patient.

15 And trying to get to that point is just a huge
16 undertaking. There were disagreements about how some of the
17 evidence was presented and it just sort of died of the
18 weight of trying to integrate it into our practice in a
19 meaningful way, despite all of the philosophical belief in
20 the approach.

21 MR. BUTLER: So one more comment on the provider
22 focus versus the consumer focus, which was kind of a theme

1 that has been picked up and, I think, a way -- it applies,
2 by the way, not just to this, to other things like, say,
3 medical homes. We give money to the provider side. Why
4 don't we incentivize the consumer to participate?

5 So if you look in the private insurance side,
6 major employers are increasingly activating their employees
7 through financial incentives. It starts with the risk
8 assessment online, then you get your cholesterol checked,
9 and then if you have a chronic illness, if you engage in the
10 program, and it goes on and on. I think it's starting to
11 show some results.

12 And so how we get Medicare beneficiaries similarly
13 incentivized, I think it doesn't address the narrower shared
14 decision-making around specific, you know, targeted areas,
15 but it does activate the enrollee in a broader way.

16 And I could even say on the last issue of the IT,
17 why just do the stimulus dollars? Why don't you reward the
18 consumer who picks a physician who provides direct online
19 access to their health records? And it is a different --
20 somehow economically different. And that would further
21 incentivize those offices to provide that service, not just
22 by the government providing dollars for putting it in place,

1 but patients would pick you instead of somebody else.

2 MS. HANSEN: Thank you. I appreciate a lot of the
3 specific examples that have come along with this second
4 round of comments. Directionally, you can probably
5 anticipate that I like the direction of this, but I see how
6 large a topic this is. And then when I think about the
7 incentives of places that are actually set up to do this, if
8 we could go to Slide 11 for a moment -- oh, sorry, I meant
9 Slide 7 -- I think what the hard work is that Jay brought
10 up, and I think why Harvard Plan didn't do it, is the last
11 bullet which says that patients and providers identified
12 very different goals.

13 And my sense is that when physicians are moving in
14 a direction of evidence-based practice and the latest things
15 that come up, oftentimes, that doesn't translate necessarily
16 to the goals that the patient might have. And then when the
17 research that comes out that if given the choices, perhaps
18 even with whatever the evidence has that the patient
19 selection may be different and reducing to one-third of
20 those choices, that sets up a real tension as to whose
21 decision trumps, the standard of quality that would be
22 measured here.

1 So therein for me lies a nexus of the tension of
2 do you weight the consumer-beneficiary decision after
3 knowing the relative risk and decision-making but have some
4 incentives at the same time to pick the best evidence-based
5 provider in, say, technology or something like this? It
6 requires a different profile.

7 And then an outlier comment that I have, that I'm
8 always curious that when we have another body of work of the
9 most efficient providers for best value, the work that was
10 done, like how did they do that, the group of you who worked
11 on that. How does that correlate to anything here, if at
12 all? But it is just like there are bodies of work of where
13 it is the best quality, best value. Were there any
14 considerations of how the beneficiary progressed in that?
15 And it is just another cross-tab of thinking about this
16 issue.

17 But I think part of the difficulty is, ultimately,
18 it's both the technical knowledge and the beneficence value
19 that comes from the part of the provider-physician, and
20 whereas the patient-beneficiary appreciates that, but still
21 may have other options even with the given information. And
22 I don't know how we weight that in deciding what the

1 ultimate best and right decision is. So it's like you have
2 two different things going on. Patients want something
3 different despite the information that is provided, or even
4 with the information that is provided.

5 So again, I may be making this more complex, but
6 it just strikes me, why is there that resistance?
7 Certainly, a 15-minute office appointment doesn't allow for
8 this kind of work to be done.

9 DR. CHERNEW: So as you might imagine, I am very
10 supportive of this and I think it is brilliant to have this
11 followed by the next chapter. I think that is great. So I
12 very much like the idea of consumer decision stuff.

13 That said, I guess I'm a little skeptical about
14 involving more government role, bureaucracy in here,
15 although I do believe that there probably are some select
16 areas where one might be able to -- if one picked up. So
17 one question I have which I'll let you get to in a minute is
18 how many clinical areas do we really think are clean enough
19 that one now has the ability to say something about both
20 what a balanced and accredited decision aid is, and we could
21 do something stronger. Now, maybe we could have more over
22 time and maybe I would be supportive.

1 But what I am worried about is there's a lot of
2 value judgments. If you look on page 24 at the list of
3 things that is what makes this accredited, good, is it
4 balanced, it's very hard to figure out. I imagine we would
5 have a problem with any for-profit entity trying to promote
6 this, right? But I can just see with the orthopedic
7 surgeons we have a decision aid and the decision aid cuts
8 out a third of back surgeons. We have decided it is
9 unbalanced, and someone else thinks no, but who is going to
10 decide? And then you have the specialty groups, which are
11 kind of now like the decision aid rucks, that are putting
12 together their decision aids as to what happens and how we
13 manage all that, and it just strikes me as a challenging
14 endeavor.

15 I am even worried, just taking the very simple
16 example which Bruce gave, which I agree with completely,
17 incidentally, about the relative versus absolute risk and
18 how to deal with that, but there is a fair bit of, say, Amos
19 Traverski evidence that people down-weight absolute risk.
20 They underweight low risk differentials more so than they
21 might if they were, quote, "rational" in the way people make
22 decisions.

1 And it's not that I want to have a debate about
2 relative or absolute risk, both of which I think are hard,
3 as much as I am worried that the implementation of an
4 accreditation, Good Housekeeping, other sort of seal puts
5 the government or CMS in a position that no matter what they
6 do, they are going to be inevitably seen as driving clinical
7 practice one way or another.

8 So while I am very supportive, as our health
9 affairs paper said, about better education around end-of-
10 life care, I would run to the hills if there was a
11 government-sponsored end-of-life -- or maybe government
12 accredited is not the same as government-sponsored, so I
13 understand the difference, but still, I would be scared,
14 really personally, to have to defend what might come out of
15 a decision aid if the various sides disagree about how one
16 gives this type of information.

17 So while Al Mulley, who taught in the same course,
18 I have a lot of respect for how this bubbles up in
19 organizations like Harvard Pilgrim or in other places, I am
20 really very supportive of these things, I think before one
21 moves forward to have sort of an official Federal role in
22 this, one really has to be careful as this could be

1 perceived, in fact, maybe correctly, but in any case,
2 perceived -- I will stick with that -- as a step towards
3 suddenly influencing the practice of care in a way that
4 might be opposed by relevant, although perhaps biased,
5 constituents.

6 So I think it requires a lot of thought and
7 caution before one moves forward unless we take particular
8 clinical areas where we say, this is an area where we think
9 the evidence is so good and the problems are so bad that we
10 could do a good job of that. And that is my biggest
11 concern.

12 MS. BEHROOZI: I think that -- sorry. A lot of
13 what I wanted to say was said before, but now, Mike, you
14 make me want to say a lot more. I think that there really
15 has been quite a lot of work done around these areas.
16 You've got states mandating -- right? -- that decision aids
17 be used, and these decision aids, they're not just -- you
18 know, they've been around for 15 years or more. There are
19 recognized organizations, bodies that have various advisory
20 committees that, you know, are vetted up, down, every which
21 way, and the point is that they're most effective when there
22 isn't a right answer. They're most effective when

1 information is all over the place, and they're most
2 effective when the entity giving the information does not
3 have skin in the game. And I think that is what we are --
4 oh, sorry, the slide is not up now, but that is what we're
5 talking about when we're talking about accrediting these
6 things. It's not this is the right decision aid but,
7 rather, this decision aid tells you there is no right
8 answer. And, really, the process that I was most impressed
9 with -- I attended one of the site visits with Joan and
10 Hannah, and what I was really most impressed with was the
11 elicitation of the patient's own values.

12 We contract with Health Dialog for our nurse
13 helpline, so we have a lot of those decision aids available
14 for our members, but it's not connected to, you know, the
15 clinician. It's that the members can get it themselves. So
16 I've seen some of them, and they're very good and they're
17 very helpful, and the information is out there. And, by the
18 way, I would rather get information about whether to get --
19 you know, how often to get a mammography from that kind of a
20 presentation than this sort of shrill backlash after the
21 recent controversy or, you know, evidentiary findings about
22 frequency of mammograms. I'd rather have it presented in a

1 dispassionate way all in one place, these are the two sides.

2 Screenings I recognize are not as easily -- it's
3 not as easy to implement these things with respect to, you
4 know, the kinds of standards that Arnie is talking about
5 where you wouldn't pay for something unless the process had
6 been gone through. But, anyway, so I think it's important
7 that we do this because we are talking about giving people
8 information, and to step back and say, well, it's just too
9 complicated to figure out what's the information to give
10 them when there has been so much development of the
11 information in this area and it is about there being no
12 right answer.

13 We say all the time, IOM, everybody says all the
14 time, among other things, care should be patient-centered.
15 That's what this is. And as Arnie says, we don't want
16 Medicare dollars going for things that patients ultimately
17 don't want. So I think one of the things that I would
18 suggest in the paper is to stress how these tools assist
19 physicians in doing what we think they ought to be doing.
20 Whether that's expressed by way of the fee schedule or not
21 yet, I think it should be more expressed that these are
22 things -- or it is sort of implicit that these are things

1 that we want providers to do, and these are tools to help
2 them do it, and do some of it outside of that 15-minute
3 consultation so it is not a burden.

4 Now, I recognize that just because I say that
5 doesn't mean physicians are going to accept it and, you
6 know, think that, okay, well, there's one patient who wants
7 it so I'll do it because she said so. But I think we do
8 have to start with national accreditation so that it's
9 elevated to a level of recognition, and hopefully
10 acceptability, and then provides a foundation for doing
11 things like setting requirements.

12 One other thing that I would add in terms of, you
13 know, the negative incentives or the reluctance of
14 physicians, one thing that is mentioned in the paper is that
15 in Washington State, where they have implemented legislation
16 on shared decision-making, it includes legal protections for
17 physicians who engage in shared decision-making, which makes
18 a whole lot of sense, right? When somebody is really
19 informed and has really made the choice, the physician is
20 entitled to that protection, and that might provide a little
21 more incentive for physicians to get on board.

22 DR. DEAN: Well, Mitra just made most of my

1 points. I would take a little issue with what Mike said for
2 the very reason that Mitra just raised, that these are very
3 difficult, complex decisions, but the proponents of the
4 procedures, for instance, they're not going to be timid
5 about the validity of what they promote, like Bob said.

6 And so I think as hard as it is, these decisions
7 are going to get made, and I think as a public body or
8 whatever our role is to try to be sure there is some balance
9 there, as hard as that is -- and it's terribly hard, and
10 it's controversial, and we are going to make mistakes and
11 all that stuff. But I was going to raise the issue of the
12 whole liability implications of this. I don't know if that
13 came up in your research, and maybe it's not developed
14 enough, but it would seem to me that that would take away a
15 lot of the fear that drives a lot of physician behavior if
16 they had that protection to know that this individual really
17 was informed and that the validation of that comes from the
18 fact they went through this process, not just because I told
19 them that about the risk, because we know that's not a
20 terribly valid thing.

21 So, you know, it probably maybe is too early to
22 make that judgment, but it would seem to me that that would

1 be a powerful force.

2 DR. SOKOLOVSKY: My plan was to hit you all with
3 that next month.

4 [Laughter.]

5 DR. DEAN: Just one quick thing. I ran across one
6 of these decision aids, and the complexity of this -- this
7 is in a completely different context, another activity I'm
8 involved in, and I thought this was really a good decision-
9 making aid. I sent it to Joan, and she thought it was
10 terrible. And it has to do with, you know -- it's just a
11 comment on how complex this process is.

12 MR. HACKBARTH: Okay. Well, we've got something
13 short of a complete consensus on how to proceed here, but I
14 do think we have the beginnings of at least some
15 constructive thoughts about how to proceed. So we'll have
16 more on this later. Right now we have to press ahead with
17 the next item on our agenda, which is improving Medicare's
18 benefit design.

19 DR. SCHMIDT: Joan and Hannah talked about giving
20 beneficiaries a more active role in their health care
21 through information. I'm going to talk about beneficiaries'
22 incentives for using care and how they may be affected by

1 benefit design.

2 The Commission has been evaluating fee-for-service
3 Medicare's benefit design for several years now through
4 illustrative cases of redesigned benefits and an expert
5 panel about value-based insurance design that included Mike
6 Chernew before he was a Commissioner. And last year, Chris
7 Hogan of Direct Research analyzed the effects of
8 supplemental coverage on Medicare spending.

9 We are talking about it again today because this
10 is an important and complicated topic. Where possible, we
11 have rough estimates of spending and the distributional
12 effects, but note that these are subject to change.

13 The Commission devotes a lot of attention to
14 reforming providers' incentives through their payment
15 systems, but improving incentives for beneficiaries may be
16 just as important to address long-term goals for the
17 Medicare program. Changes to the fee-for-service benefit
18 could offer an opportunity to make Medicare's benefit
19 package better for individuals who have very high health
20 care spending and cost sharing.

21 For the long term, Medicare needs to be
22 transformed to improve incentives for delivering and using

1 high-value care. Given the program's problems with
2 financial sustainability, it's likely there will need to be
3 changes. For example, we may need to consider whether
4 Medicare's benefit design should be different for future
5 cohorts beneficiaries. We may want to discuss ways of
6 introducing management tools into fee-for-service Medicare.
7 As we develop a better understanding about the relative
8 value of alternative treatment options, we may also want to
9 explore value-based insurance design, matching individuals'
10 cost sharing to their clinical needs in order to encourage
11 them to use high-value therapies. In this session, we will
12 focus primarily on approaches for redesigning the fee-for-
13 service benefit and for redefining the role of supplemental
14 coverage.

15 The structure of Medicare's benefit has
16 shortcomings in coverage that leads most beneficiaries to
17 take up secondary insurance. This chart is just to remind
18 you about the distribution of supplemental coverage in 2006
19 among all Medicare beneficiaries. About 91 percent had
20 supplemental coverage and 9 percent did not. Employer-
21 sponsored coverage was the most common type, followed by
22 individually purchased Medigap policies, private Medicare

1 plans, and Medicaid.

2 When looking at how beneficiaries use Medicare
3 benefits, there are two different sets of incentives to
4 consider. The first is their decision between enrolling in
5 a Medicare Advantage plan or in fee-for-service. In the
6 commercial world, when a consumer has different options for
7 health insurance, premiums can act as a signal of the
8 breadth of coverage and provider options. For example, we
9 usually expect plans with relatively tight networks of
10 providers to have lower premiums.

11 In the Medicare program, premiums are not a good
12 signal of information. In fee-for-service Medicare, there
13 is one benefit design, a uniform Part B premium, and
14 patients may choose among any willing provider. In the
15 Medicare Advantage program, premiums have been artificially
16 lowered because of how the Part C payment system operates
17 and the use of rebate dollars. So in the choice between
18 fee-for-service Medicare and MA plans, premium signals that
19 consumers typically use to help them make choices do not
20 help very much.

21 The second set of beneficiary incentives deals
22 with behavior at the point of service, which can be affected

1 by cost-sharing requirements. The amount that a patient
2 must pay at the point of service can sometimes affect
3 whether she chooses to seek care in the first place, which
4 provider she sees, and which treatment she uses. There is
5 an extensive literature showing that cost sharing can affect
6 the use of both necessary and unnecessary care, and we don't
7 want to discourage necessary care. Trying to encourage the
8 use of high-value care is the great challenge of benefit
9 design.

10 Last year, Commission-sponsored work shows
11 evidence that when elderly beneficiaries are insured against
12 Medicare's cost sharing, they use more care and Medicare
13 spends more on them. That analysis found some notable
14 patterns. For example, having secondary insurance was not
15 associated with higher spending for emergency
16 hospitalizations, but it was associated with 30 percent to
17 50 percent higher Part B spending for services such as minor
18 procedures, imaging, and endoscopy.

19 Looking within each category of supplemental
20 insurance, paying little out of pocket seemed to be
21 associated with higher Medicare spending. The analysis
22 suggests that if supplemental coverage did not fill in as

1 much of Medicare's cost sharing, the structure of fee-for-
2 service cost sharing could be used to help beneficiaries
3 choose high-value care.

4 Another part of last year's analysis found that
5 lower-income beneficiaries are moderately more sensitive to
6 cost sharing than higher-income ones. One would expect
7 filling in Medicare's cost sharing to be more valuable to
8 low-income people, and it might have a stronger effect on
9 their willingness to seek care.

10 In general, the analysis found that when either
11 lower-income or higher-income beneficiaries had supplemental
12 coverage, their Medicare spending was higher than
13 individuals without supplemental coverage and similar
14 income. However, the presence of secondary insurance had a
15 moderately stronger effect on Medicare spending for lower-
16 income beneficiaries.

17 The Commission has explored problems with
18 traditional Medicare's benefit design. The fee-for-service
19 benefit alone does not provide financial protection against
20 very high levels of out-of-pocket spending. Compared with
21 other types of coverage, Medicare's benefit has a high
22 inpatient deductible and low outpatient deductible. These

1 features lead to a highly concentrated distribution of
2 Medicare's cost sharing.

3 The one form of supplemental coverage that is
4 available to all elderly Medicare beneficiaries --
5 individually purchased Medigap policies -- are often
6 expensive, with administrative costs of 20 percent or more,
7 and premiums for them can vary a lot.

8 The most popular types of supplemental policies
9 fill in nearly all of Medicare's cost sharing. By
10 effectively masking price signals at the point of service,
11 supplemental coverage may affect beneficiaries' choices
12 related to care -- whether to seek it, which provider to
13 use, and which therapy to use.

14 Short of the long-term changes that I alluded to
15 earlier, we may want to take some incremental steps to begin
16 changing beneficiary incentives. The aims of these nearer-
17 term measures include:

18 Out-of-pocket cap to reduce beneficiaries'
19 financial risk. Above that cap there could be nominal cost
20 sharing, as in the Part D benefit. At the same time, set
21 limits on supplemental coverage so that Medicare's cost
22 sharing could discourage beneficiaries from using lower-

1 value services. Since low-income beneficiaries are
2 moderately more responsive to cost sharing, design
3 assistance with their cost sharing that does not deter them
4 from using higher-value care.

5 Move forward with the Commission's recommendations
6 on comparative effectiveness to establish an independent
7 public-private entity that would produce and provide
8 information to compare the clinical effectiveness of
9 services with their alternatives.

10 And another aim may be to begin examining ways to
11 use information and financial incentives to encourage
12 beneficiaries' adherence to high-value therapies.

13 You can think of the next several slides as a
14 thought exercise that goes through pieces of potential
15 changes. These are not mutually exclusive. They lead to a
16 combined illustrative package. We are presenting them over
17 a series of slides in order to help us the distributional
18 effects.

19 Consider the effects of adding an out-of-pocket
20 cap to fee-for-service Medicare. We will look at some
21 specific dollar examples in a minute, but the general points
22 to take away are it would provide some relief to

1 beneficiaries with the highest cost sharing and also tend to
2 lower supplemental premiums for many beneficiaries.

3 Medicare would start paying for some of the costs
4 now covered by secondary insurers. Since beneficiaries who
5 have Medigap policies pay the full premium for the
6 supplemental benefits of everyone in their insurance pool,
7 including some with high Medicare cost sharing, all
8 beneficiaries who have Medigap policies would see lower
9 premiums.

10 The downside is that simply adding an out-of-
11 pocket cap would lead to higher Medicare spending at a time
12 that the program already has problems with financial
13 sustainability. It would also lead to somewhat higher Part
14 B premiums since B premiums are set as a percentage of
15 Medicare spending for Part B services.

16 Having no more cost sharing above an out-of-pocket
17 cap could lead to somewhat higher utilization. One way to
18 counter this might be to follow Part D's example. It has an
19 out-of-pocket cap, but above that cap beneficiaries still
20 pay some nominal cost sharing.

21 To give you a sense of the magnitude of spending
22 involved, here are data from CMS that show the distribution

1 of Medicare cost sharing in 2008. This reflects what
2 beneficiaries owed providers, but in most cases, their
3 secondary coverage paid for much of this. Most people did
4 not pay these full amounts out of pocket.

5 Forty-two percent of beneficiaries had less than
6 \$500 in Medicare cost sharing, and on average, they each
7 paid about \$250, so that would basically cover the Part B
8 deductible and the 20-percent cost sharing for several
9 office visits.

10 At the other end of the spectrum, 2 percent of
11 beneficiaries accrued \$10,000 or more in Medicare cost
12 sharing, with an average amount of more than \$15,000 a
13 person. Hospitalizations tend to drive this amount of cost
14 sharing. These are beneficiaries who likely had several
15 hospital stays during the year and probably had to pay the
16 Part A deductible several times, along with Part B cost
17 sharing for physician care in the hospital as well as for
18 their office visits.

19 Since a lot of Medicare's cost sharing stems from
20 having a hospital stay, I should point out that this
21 distribution is just for a one-year snapshot. In any given
22 year, about one in five Medicare beneficiaries has a

1 hospital stay, but over several years the odds of having one
2 or more hospital stays go up considerably. For example,
3 among beneficiaries who were in Medicare in 2004 and were
4 alive in 2008, about half had a hospital stay at some point
5 over that five-year period. So an out-of-pocket cap could
6 have benefits over time for more people.

7 As an example, in the year 2008, if Medicare's
8 benefit had capped cost-sharing liability at \$5,000 per
9 person, about 6 percent of beneficiaries would have been
10 affected if they owed \$5,000 or more in Medicare cost
11 sharing. But many other beneficiaries who owed less cost
12 sharing would still have benefitted because their premiums
13 for supplemental coverage would have gone down.

14 In the case of people with Medigap policies, a
15 rough estimate suggests that, on average, Medigap premiums
16 would have been about 15 percent lower, or about \$300 in
17 2008. However, specific effects on Medigap premiums would
18 depend on the specific pool of people covered. It is less
19 straightforward to quantify exactly what would have happened
20 with other forms of supplemental coverage like employer-
21 sponsored retiree plans and Medicaid.

22 Under this example, beneficiaries would have owed

1 at least \$10 billion less in Medicare cost sharing, so
2 Medicare program spending would have been higher to cover
3 that expense. Part B premiums would also have paid for some
4 of this additional benefit, an increase on the order of \$4 a
5 month.

6 Now consider adding both an out-of-pocket cap and
7 a combined deductible that applies to both Part A and Part B
8 services. Today Medicare has a high inpatient deductible,
9 about \$1,100 -- exactly \$1,100 in 2010, and a relatively low
10 outpatient deductible, \$155. By comparison, one combined
11 deductible that applied to both inpatient and outpatient
12 services distributes cost sharing more evenly over the
13 insured population. It's the approach used with many
14 commercial policies.

15 Because of concerns about the added cost of
16 providing an out-of-pocket cap, let us assume that we need
17 to set the combined deductible at a level high enough to
18 keep Medicare program spending the same. But we just saw
19 that the costs of providing an out-of-pocket cap are pretty
20 high. The example I gave of a \$5,000 out-of-pocket cap was
21 \$10 billion a year for one year. If we made no other
22 changes in Medicare's benefit design, all beneficiaries

1 would need to pay a relatively high combined deductible to
2 pay for the additional capped benefits.

3 In our example from 2008, Medicare beneficiaries
4 would have had to pay a combined deductible on the order of
5 \$950 to cover the additional benefit cost. Again, remember
6 that as we project to future years, the size of the
7 deductible would be larger. This is an example for 2008.

8 These two illustrative changes would still provide
9 cost-sharing relief to the sickest beneficiaries, and since
10 we designed this to be budget neutral, Medicare program
11 spending wouldn't change. The Part B premium would probably
12 go down a bit. If Medigap policies were allowed to fill in
13 the combined deductible, the average premium across all
14 Medigap policies would probably remain about the same.
15 Adding an out-of-pocket cap to Medicare would lower
16 supplemental costs, but covering the combined deductible
17 would raise them, perhaps netting out.

18 It may seem counterintuitive to let supplemental
19 coverage fill in the combined deductible, but I'll come back
20 to this in a moment.

21 There are important downsides of these two changes
22 to consider. First, obviously, the combined deductible

1 amount is pretty high. And, second, we need to be concerned
2 about how beneficiaries who do not have supplemental
3 coverage would react to this combined deductible. We
4 already know that these individuals use less care on
5 average, and the worry is that they would use even less
6 necessary care. And this is a very important concern to
7 bear in mind as we go through this thought exercise.

8 One way that could help to lower the combined
9 deductible while keeping an out-of-pocket cap involves an
10 excise tax on insurers with supplemental policies that fill
11 in most of Medicare's cost sharing. Only applying a tax to
12 these types of policies serves several purposes.

13 First, the tax would help in part to recoup some
14 of the additional Medicare spending associated with that
15 more complete coverage, and it is similar in the approach
16 used in Part D where beneficiaries who enroll in plans with
17 supplemental benefits must pay additional premiums for their
18 higher use of services.

19 Taxes would be paid by Medigap insurers directly
20 to the Medicare trust funds through the same Medicare
21 administrative contractors that already process claims.
22 Presumably, insurers would pass an excise tax along in the

1 premiums of those more complete plans. In turn, this would
2 provide incentive for beneficiaries in those plans to
3 voluntarily consider other types of Medigaps that have lower
4 premiums but require paying more of Medicare's cost sharing.
5 Policymakers may want to also consider giving policy holders
6 a one-time option to move into Medigaps that are not subject
7 to the excise tax on guaranteed-issue basis.

8 This slide shows the distribution of Medigap
9 policies in 2008. Plans C and F are the most popular with a
10 combined 55-percent market share. They cover both
11 Medicare's Part A and Part B deductibles.

12 Plan types K and L are newer standard policies
13 that cover part of the Part A deductible, none of the Part B
14 deductible, and have lower premiums, but so far not many
15 beneficiaries have purchased them. Not many at all.

16 This summer, Medigap insurers may start marketing
17 new plan types M and N that also essentially trade off more
18 beneficiary cost sharing for lower premiums. Plan N will
19 use co-pays for office visits and emergency room use.

20 If there were an excise tax only on Medigap
21 policies, it probably would not raise enough revenue to
22 lower the combined deductible that we have been talking

1 about by much. If the tax were applied only to those
2 Medigap policies that cover both the Part A and Part B
3 deductibles, a 10-percent excise tax might raise on the
4 order of \$1 billion per year. With that amount of revenue,
5 a redesigned benefit could still have a \$5,000 cap, but it
6 would still also require a pretty high combined deductible
7 to remain budget neutral. The revenue would probably lower
8 the combined deductible by less than \$50.

9 If the excise tax encouraged beneficiaries to move
10 into the newer Medigap policies that require paying more of
11 Medicare's cost sharing at the point of service, that could
12 lower the growth in Medicare spending and, in turn, more of
13 those resources could be used to get to a lower combined
14 deductible.

15 A legitimate question is why let supplemental
16 coverage fill in a combined deductible. It is inconsistent
17 with the idea that we want less masking of price signals at
18 the point of service.

19 Well, another approach could be to simply restrict
20 supplemental insurers from covering the combined deductible.
21 It would lower program spending considerably, but analysts
22 have raised this idea for a long time, and it has never been

1 well received, probably because beneficiaries tend to like
2 Medigap Plans C and F a lot. So in our thought exercise, we
3 have let supplemental coverage continue to fill in
4 deductibles, but also included the excise tax as a way to
5 encourage beneficiaries to move voluntarily to some of the
6 newer plans that have a bit more cost sharing.

7 Another variation would be to make all
8 supplemental insurance subject to an excise tax, not just
9 the ones that provide first-dollar coverage. So, for
10 example, the excise tax might apply to all Medigap policies,
11 not just the C and F plans. This would potentially provide
12 more revenue that could get to a lower combined deductible,
13 but it would not necessarily encourage beneficiaries to move
14 toward the newer plans that have more cost sharing. Maybe a
15 little bit on the margin.

16 We have focused on Medigap policies, but another
17 approach would also make employer-sponsored coverage subject
18 to an excise tax. How complete is the coverage offered by
19 employer-sponsored plans? For many years, surveys have
20 shown that employers often include cost sharing in their
21 retiree benefit packages, but it's unclear whether these
22 cost-sharing arrangements apply to all retirees or primarily

1 those who are in younger cohorts.

2 A few years ago, Actuarial Research Corporation
3 analyzed 2005 data from the Medical Expenditure Panel Survey
4 for the Commission, and at that time about 20 percent of
5 beneficiaries with supplemental coverage through an employer
6 had no out-of-pocket spending other than their premiums.
7 The retiree plans paid for their Medicare cost sharing.

8 In other Commission-sponsored work that used 2005
9 data from the Medicare Current Beneficiary Survey, 50
10 percent of fee-for-service beneficiaries with employer-
11 sponsored coverage paid 5 percent or less of their Part B
12 spending out of pocket.

13 To summarize, we have discussed adding an out-of-
14 pocket cap to the fee-for-service benefit in order to
15 protect the sickest beneficiaries from very high financial
16 liability. However, unless we made other changes at the
17 same time, Medicare's program spending would be quite a bit
18 higher. We discussed how adding a \$5,000 out-of-pocket cap
19 in a budget-neutral manner would require a relatively high
20 combined deductible, for 2008 on the order of \$950.
21 Additional measures could help to lower that combined
22 deductible somewhat.

1 For example, we discussed an excise tax on
2 insurers that offer supplemental plans that cover nearly all
3 of Medicare's cost sharing. The tax revenues alone might
4 not lower the combined deductible by much. However, if they
5 encouraged beneficiaries to move into newer Medigaps that
6 require the policy holders to pay more of Medicare's cost
7 sharing, this could also free up resources to lower the
8 combined deductible.

9 There are other issues that we will continue to
10 explore. For example, there may be other ways to change the
11 fee-for-service benefit design, making cost sharing more
12 uniform across all types of services. For future cohorts of
13 beneficiaries, Medicare's benefit design may need to be
14 restructured in a different way, and their options for
15 supplemental coverage may need to be different as well.

16 We can explore using pilots or demonstration
17 programs to try out new approaches with supplemental
18 coverage. For example, we might want to encourage new types
19 of Medicare SELECT plans, Medigap policies that charge lower
20 premiums or provide premium rebates when beneficiaries use
21 network providers. So far, these have been limited in
22 scope, only establishing networks of hospitals, not

1 physicians. Insurers might be more interested in
2 establishing physician networks for SELECT products if they
3 shared some of the savings from doing do.

4 Another topic that could be the subject of a pilot
5 or demonstration is value-based insurance design, perhaps by
6 tailoring Part D cost sharing requirements to individuals'
7 clinical needs, and this would be an opportunity to test
8 whether value-based insurance design could help to achieve
9 lower Part A and Part B spending.

10 The overarching goal of this thought exercise is
11 to make the fee-for-service benefit a better benefit.
12 Changes could improve the benefit package for those
13 beneficiaries who today have repeated hospital stays and
14 face unlimited financial liability under Medicare's cost-
15 sharing requirements. But at the same time, we would need
16 other reforms that affect a broader number of beneficiaries
17 in order to avoid worsening the program's financial
18 sustainability. Changes from the status quo are very
19 difficult, but they could potentially encourage
20 beneficiaries to choose higher-value services.

21 For your discussion, I'd appreciate hearing what
22 additional analysis you'd like us to pursue and what

1 direction you would like to take.

2 MR. HACKBARTH: Okay. Thank you, Rachel. Like
3 Mike, I think the juxtaposition of this with the preceding
4 session on shared decision-making is good. In fact, from
5 time to time I think that what we need is sort of a thematic
6 report, like a June report that is about different ways that
7 we might seek to engage patients in promoting a high-value
8 delivery system. You know, 90 percent of our conversation
9 focuses on how we pay providers and all that, and clearly
10 that's important. But I think also engaging patients in
11 that effort is equally important. In fact, my fear is that
12 if we neglect that piece of it and we just change what the
13 providers do and patients are not involved, you set up, you
14 invite a backlash, much as we had with managed care in the
15 1990s.

16 So I am glad we are starting to take a look at
17 some of these patients issues. They are, however,
18 complicated issues, and, you know, for example, the issue
19 about the effect of increased cost sharing on low-income
20 beneficiaries is a very important issue that I worry about.

21 Okay. We will start over on this side this time.
22 Let me see hands for round one clarifying questions.

1 MS. BEHROOZI: Hi, Rachel. I'll save my response
2 for what you said about the juxtaposition of sessions until
3 round two, but just on Slide 9, the people with the highest
4 spending, the sickest beneficiaries, take the last two
5 sections, I guess, the 4 percent and the 6 percent. Of the
6 total Medicare beneficiaries, you told us that 9 percent
7 have no supplemental coverage. Do you know what that figure
8 is with respect to that 6 percent?

9 DR. SCHMIDT: No, I do not. I know it is a higher
10 proportion. The pie chart I showed you actually includes
11 MA, and if we just looked at fee-for-service, it's maybe 11
12 percent do not have supplemental coverage. And it is higher
13 yet within those highest spenders, but I don't know the
14 exact number. I can look into that more.

15 DR. CHERNEW: When you calculated the excise tax
16 for your examples, how does the magnitude of that compare to
17 the spillover of the supplemental policy on the fiscal
18 liabilities of the Medicare program? Do you understand the
19 question? I just wasn't sure if the excise tax was having
20 beneficiaries pay more than what they were costing the whole
21 system in extra use or less.

22 DR. SCHMIDT: It was considerably less. I gave a

1 hypothetical 10-percent excise tax taking into consideration
2 political problems associated with having a tax.

3 DR. CHERNEW: But if you were really going to
4 charge them the full amount that buying that policy cost the
5 Medicare program, it would be more.

6 DR. SCHMIDT: Considerably more.

7 MR. HACKBARTH: How much more?

8 [Laughter.]

9 DR. SCHMIDT: Way to put me on the spot. If we
10 used the estimates that Chris Hogan came up with last year,
11 it was getting close to 100 percent, 75 percent tax, which
12 seemed like something that was completely infeasible.

13 MR. HACKBARTH: [off microphone] Other clarifying
14 questions?

15 MR. BUTLER: This is obviously very specific to
16 Medicare in this country, but I am just curious. Is there
17 absolutely anything to be learned from other countries that
18 cover large populations that have tweaked with economic
19 sharing, you know, for the beneficiaries? Do we know of any
20 data that would help, what has happened in other areas?

21 DR. SCHMIDT: I frankly would need to come back to
22 you with a little more look at the literature before I could

1 answer that well, but I am happy to do so.

2 MR. BERTKO: Peter, I would only offer that having
3 read a couple of the recent books on it, it actually goes in
4 the other direction, and the protections for people that are
5 critical care users are generally much better, that is, co-
6 pays on drugs and other kinds of things drop to zero after
7 some -- and I'll use the words "out-of-pocket limit" gets
8 hit. So it is in the other direction.

9 Of course, their payment rates are so much lower
10 that they can have lower out-of-pocket's compared to our
11 payment rates for the same level of services.

12 DR. KANE: I am just curious to know what kind of
13 -- does Congress or anybody now regulate the Medigap
14 policies beyond -- I know they specify the different benefit
15 levels, but can they --

16 DR. SCHMIDT: Oh, yes --

17 DR. KANE: Is it already pretty much something
18 easy to do to go ahead and start configuring, reconfiguring
19 the Medigap and the employer-sponsored plans?

20 DR. SCHMIDT: It's a very complicated topic you
21 raise. There are a series of reg -- the Federal Government
22 has set standards for what the policies might look like, and

1 there's also medical loss ratio standards that the insurers
2 need to abide by. They're regulated by each state in
3 addition. If you were to make changes to the structure of
4 these, certain bodies within the Congress would need to pass
5 laws that would ask the National Association of Insurance
6 Commissioners to set up changes to those standards. In
7 fact, some of that is contemplated in the Senate health
8 reform bill, I believe.

9 DR. KANE: How about the employer-sponsored plans?

10 DR. SCHMIDT: The employer-sponsored policies are
11 regulated in a different manner. Many of them are under
12 ERISA so they're not subject to the same types of
13 regulation, state level. And it's also a different set of
14 entities within the Congress that would be acting on that.

15 There might be a tie-in to Medicare that's
16 mentioned in the mailing materials with respect to Part D,
17 the retiree drug subsidy, where many employers continue to
18 provide primary prescription drug coverage and receive a
19 subsidy from the Medicare program. So there is a link there
20 that one might possibly use.

21 MR. HACKBARTH: Just to follow up on what you said
22 about the employer-sponsored, they are not regulated by the

1 State insurance commissioners. They are covered by ERISA.
2 On these issues of basically benefit design, I think that
3 means that they are largely unregulated. There are no
4 federal standards in lieu of state regulation. This is
5 basically entirely up to the employer on advice and counsel
6 of their consultants and health plans.

7 DR. SCHMIDT: [off microphone] Correct.

8 MR. GEORGE MILLER: A question on Slide 5. You
9 mentioned in your presentation that with supplemental
10 coverage Medicare spending increased about 30 percent, if I
11 remember correctly. Do you know how that may be broken down
12 by physicians and specialties? Do you have that
13 stratosphere? And does it slope up just like -- and Bob --
14 well, I guess not Bob, but a presentation earlier by the
15 Urban Institute. Or do you know?

16 DR. SCHMIDT: In some of the work that Chris Hogan
17 presented to the Commission last March, he had some fairly
18 detailed tables about differential effects across types of
19 care and settings of care and the like. In general, the
20 existence, the presence of supplemental coverage is
21 associated with greater use of specialty care, of certain
22 minor procedures, of imaging. I'm happy to show you the

1 tables from his work again.

2 MR. GEORGE MILLER: Yes, thank you.

3 MR. BERTKO: Okay. Two questions or comments.

4 The first one is on nine, and I think I know what you have
5 done, Rachel, but I wanted to be certain. I interpreted
6 this as this being the cost sharing for Parts A and B
7 without any D types of things in there.

8 DR. SCHMIDT: That is correct.

9 MR. BERTKO: Okay. So just for everybody to know,
10 there are a very small subset of people that would shoot
11 into that \$10,000 or more coverage due to high-cost
12 biologics and others. The rest of Part D, I think, would
13 only modestly bump the number or the percentages upward a
14 little bit. And I think everything we are talking about
15 here in terms of redesign is only on the A-B coverage and
16 not on the D coverage.

17 DR. SCHMIDT: That is right. There are some
18 difficult challenges --

19 MR. BERTKO: Yes.

20 DR. SCHMIDT: -- associated with thinking about
21 how to combine A and B and D, given that we use stand-alone
22 prescription drug plans.

1 MR. BERTKO: And if the Chair lets me, I won't
2 offer an opinion, but I would like to offer another option
3 to your options slide, if we could, if we can go to that
4 one. And I will come back. I will save my other comments
5 for two.

6 So here are potential improvements. I would offer
7 a different one that I think could be, at worst, cost
8 neutral, and at best, cost savings, and that would be an
9 out-of-pocket cap with minimum cost sharing on all Medigap
10 and retiree types of things. And so I'll just now, if you
11 let me, make a minor editorial comment that we know the cost
12 of the out-of-pocket cap is the \$10 billion from Chris
13 Hogan's work, which seemed to be the amounts recoverable, or
14 actually, I should say, excess demand within the
15 neighborhood of \$40 to \$60 billion out of Part B on the 100
16 percent run-up, if I recall that number correctly, and
17 minimum cost sharing, such as \$5 PCP, \$25 specialty, \$100
18 emergency room might slow that down remarkably.

19 DR. SCHMIDT: So can I just make sure I understand
20 what you are saying? So rather than trying to change the
21 combination of supplemental coverage and the Medicare
22 benefit, you would just change the structure of the Medicare

1 benefit?

2 MR. BERTKO: No. It's the supplemental coverage,
3 and the recovery part of that. So I would do one thing to
4 the current Medicare coverage, that is, only put an out-of-
5 pocket cap on it, because I believe your comments about the
6 combined deductible and the problems with access to
7 professional services are very big. And then, secondly, I
8 would save the money by putting in minimal cost sharing on
9 all supplemental coverages. I think it's conceivable, at
10 least, I'll look for your reaction and the panel's later, on
11 the fact that that could easily recover \$10 billion and
12 might recover \$20 or \$30 billion in terms of reducing the
13 induced demand from zero cost share supplemental coverage.

14 MR. HACKBARTH: Okay. That's a thought-provoking
15 round two comment.

16 MR. BERTKO: Sorry. [Off microphone.] I'm
17 bottomed out.

18 MR. HACKBARTH: Ron, and then Bruce.

19 DR. CASTELLANOS: In the material you sent to us,
20 you talked about select networks for physician services.
21 How does that differ from basically the MA plans?

22 DR. SCHMIDT: You mean the Medicare Select

1 policies, those plans? They are Medigap products, so they
2 operate in the context of fee-for-service Medicare. And
3 generally, it includes a network of hospitals at this point.
4 It does not tend to include physician networks.

5 DR. CASTELLANOS: [Off microphone.] I think in
6 the material, at least how I interpret it, you are thinking
7 about developing a network just for physicians.

8 DR. SCHMIDT: Well, the notion was to maybe do a
9 demonstration to see whether any insurers that are offering
10 Medicare Select products would be willing to take on the
11 added costs of setting up a network of physicians if they
12 perhaps shared in some of the savings that the Medicare
13 program might accrue from having network providers. That is
14 the idea.

15 DR. STUART: I'd like to echo what Glenn said
16 about the importance of this chapter. I think you've got a
17 great start and I have some suggestions for expanding this
18 in my round two comments.

19 In round one, as you know, a year ago when Chris
20 Hogan was here and I had questioned some of the estimates of
21 induced demand and price responsiveness, and I just looked
22 at the face sheet -- now, obviously, I have not had a chance

1 to read the article that all of the Commissioners were
2 given, but it's instructive, and if I do some back-of-the-
3 envelope calculations, what I come up with is an estimate
4 that for every ten percent increase in price, you would get
5 a one to two percent decrease in use of ambulatory services
6 and hospital services, which is, by the way, spot on with
7 what the RAND Health Insurance Experiment came up with.

8 And so my question is, if you were to use the
9 elasticity estimates that are implicit in this article,
10 would that have changed your estimates about the impact of
11 raising the -- or combining the deductibles?

12 DR. SCHMIDT: Let me again qualify that the
13 estimates here are really rough ones and do not take into
14 account the thought of higher inpatient utilization, which
15 is suggested by this Travetti article.

16 DR. STUART: To just take one half a minute, that
17 would mean, then, that your estimates assume that there is
18 no price responsiveness, that that would not have a
19 behavioral impact.

20 DR. SCHMIDT: At this stage, but --

21 DR. STUART: At this stage. Okay.

22 DR. SCHMIDT: -- it was to give you a basic

1 understanding --

2 DR. STUART: All right. Okay. Thank you.

3 DR. SCHMIDT: -- but I plan to come back with
4 more.

5 MR. HACKBARTH: Okay. Round two? Mitra?

6 MS. BEHROOZI: We've had some discussion about
7 this before, Rachel, so I'll be brief. Your work is very
8 thoughtful and thorough. I appreciate that.

9 I still have a question about why this topic links
10 together protecting the highest spending beneficiaries with
11 so-called the incentives at the front end. It's a laudable
12 goal. I absolutely don't want the sickest people to go
13 bankrupt because of circumstances beyond their control. But
14 even if it's ten percent of that six percent of fee-for-
15 service beneficiaries, that's 0.6 percent of fee-for-service
16 beneficiaries that we should do something for. But to wrap
17 that in, to take the cost that mostly is being paid by
18 Medigap insurers, frankly, and put it at the front end,
19 leaving aside the fact that you're assuming that much of
20 that will be covered by Medigap insurers anyway, I have a
21 real objection to doing more of that, to loading more costs
22 up front, which I've expressed before, and I'll just say a

1 couple of things about that.

2 I think that the -- I know there are a lot of
3 economists here. I don't operate as an economist.

4 DR. CHERNEW: Yet.

5 MS. BEHROOZI: Yet, he says. Oh, I'm getting
6 farther from it, actually.

7 It's not first-dollar coverage, and I know this is
8 really swimming upstream and my fins and tails and whatever
9 are getting all shredded going up against that stream, but
10 it's really not first-dollar coverage by itself that's the
11 culprit. It's the lack of management. It's the lack of the
12 ability to have any other levers to control behavior. And
13 so we use dollars as a mechanism for controlling behavior.
14 It's a cost shifting, really. It's a proxy for management.

15 If everybody were in the same economic
16 circumstances and made their decisions on a fully-informed
17 basis, as we talked about in the prior session, then okay,
18 fine. I guess we could just revert to an economic model and
19 assume that people would make economically rational
20 decisions that aligned with clinically rational decisions.
21 But where people have different perceptions, even, of their
22 own ability to afford things, whether they think they can't

1 afford it or whether they think they can afford it, they're
2 not going to make clinically rational decisions. If they
3 think they can afford the extra imaging tests and the full-
4 body scans and all of that stuff, that's not a clinically
5 rational decision, right, and that's more spending for the
6 Medicare program, just in the same way that it matters --
7 and so I care about that from the Medicare program's end.

8 But I also care about the beneficiaries and,
9 frankly, the Medicare program, who aren't poor enough for
10 Medicaid, may not even be, on the face of it, poor, but live
11 in a high-cost area, have lots of people they are helping,
12 you know, pay the rent or whatever, who feel like they can't
13 afford the costs that are shifted to them.

14 So ideally, to drive the most clinically
15 appropriate behavior, it seems to me that we should be
16 imposing costs where a particular choice is not of clinical
17 value, right? That's the kinds of things that we've been
18 talking about in lots of different ways in different types
19 of topics that we cover, and that's what I was saying,
20 Glenn.

21 I would add to your comment and others' comments
22 about how this topic flows so well from the shared decision-

1 making topic. I would have put the value-based design at
2 the other side of it, because that, to me, is the beginning
3 of the approach to how to really get people to -- to support
4 people in making clinically rational decisions.

5 And just on the last point, so we have talked
6 about cost shifting generally, but I would say that
7 deductibles are the bluntest, crudest form of behavior
8 modification via dollars. John's point about more targeted
9 types of copayments, I can live with. I still don't think
10 it's as effective as management, because like I said, the
11 \$25 copayment for a specialist for somebody who thinks they
12 can afford it, they'll go to six of them. So it doesn't
13 necessarily effectively manage. And somebody else who
14 really needs to see an endocrinologist won't go.

15 So I really have a strong reaction, I think, to
16 the notion of even if it's true that we don't have a lot of
17 other levers right now besides dollars, I really object to
18 it being in the form of deductibles.

19 MR. HACKBARTH: Let me just pick up on Mitra's
20 comment for a second, and I want to get Rachel to help us
21 out with some of the existing research on this topic, and
22 then I want to ask Mitra a question to better understand her

1 point on the research.

2 Of course, one important piece of research on this
3 is the RAND Health Insurance Experiment, and my recollection
4 of the RAND findings were that cost sharing mattered. There
5 were significant reductions in utilization, as Bruce was
6 saying.

7 A second finding was that there was a reduction in
8 both appropriate and inappropriate services in roughly equal
9 measure. In other words, faced with cost sharing, people
10 weren't saying, oh, I am just going to get rid of the
11 inappropriate stuff. They were unable, pretty much, to
12 distinguish between the two.

13 A third finding was that for most of the
14 population in the experiment, the fact that they couldn't
15 discriminate between appropriate and inappropriate didn't
16 seem to affect their health status.

17 But the fourth finding was that the exception to
18 that was for low-income people.

19 DR. SCHMIDT: Right. It was, in particular, low-
20 income and people in poor health.

21 MR. HACKBARTH: Yes.

22 DR. SCHMIDT: That combination. They tended --

1 they had lower blood pressure levels in the existence of no
2 cost sharing. That was the clinical measure they looked at.

3 MR. HACKBARTH: Yes. Yes.

4 DR. MILSTEIN: Glenn, you need to recognize the
5 RAND Health Insurance Experiment was for under-65 people.

6 MR. HACKBARTH: Yes.

7 DR. MILSTEIN: It was not -- and I suspect that
8 people over 65 have a different elasticity of demand.

9 MR. HACKBARTH: But it may also be that the
10 potential risks are greater for the over-65 than for the
11 under-65 population covered in the experiment.

12 So now I wanted to ask Mitra my question. So what
13 I heard you express concern about was across-the-board cost
14 sharing, as exemplified by a big increase in the deductible.
15 But I thought I also heard you say you have less problem
16 with it if it is, for example, cost sharing -- you pay more
17 for a service of unproven value. If you choose the new drug
18 that hasn't been proven to be more effective, you ought to
19 pay significantly more for that. Did I hear you correctly?

20 MS. BEHROOZI: That is an example of how to target
21 cost shifting so that you are incenting behavior in a
22 clinically rational way.

1 Can I just say something about --

2 MR. HACKBARTH: Yes.

3 MS. BEHROOZI: I am sorry. I forgot to mention --
4 actually, Bruce mentioned it -- the recent New England
5 Journal article on a study done at Brown University only
6 among Medicare Advantage beneficiaries finding changes,
7 increases in copays--where the copays already existed, it
8 wasn't a matter of going from zero to something, which John
9 has told us has a dramatic impact, but it was from something
10 to something more -- yes, reduced outpatient spending, but
11 there is some evidence that of the reduction of appropriate
12 care because they actually indicate that there was an
13 increase in inpatient utilization -- an increase in
14 inpatient utilization -- and they extrapolated that they
15 think that the increasing cost to the plan is \$24,000 for
16 every 100 health plan enrollees.

17 Rachel and I had some discussions about some
18 issues that may not -- that may undermine some of the
19 findings here, but I actually am rereading it and I am
20 feeling like it says a lot that we hadn't looked at before,
21 particularly in terms of Medicare beneficiaries and changing
22 copayments, not adding copayments, certainly nothing as

1 dramatic as going from a \$150 deductible before you get any
2 coverage to \$950 of deductible before you get any coverage.

3 DR. CHERNEW: So I want to echo even more strongly
4 how important I think this issue is, and apart from any of
5 the details, which I will say something about in a second, I
6 think it raises a fundamental question about the role of
7 patients in the future of Medicare as we address the
8 Medicare problem.

9 And the question is, in part, do we sort of
10 balance the back and reform Medicare simply on the back of
11 providers through various payment rate reforms, or do we
12 include patients in some way to deal with this, and how we
13 deal with that is a challenge.

14 My one broad comment is, going forward, of course,
15 in a broader thematic view, the interaction of these two
16 things matters. So one could envision a system where you
17 have very strong payment rates. Then you might not need all
18 these same consumer incentives, although you do have the
19 conflict that patients want this and they don't have to pay
20 and now you have clamped down on the providers. So there is
21 room for a lot of thoughtful work, not just about the role
22 of the patient incentives, which we don't talk about as

1 much, but also how that interacts with all the things we've
2 said on the payment side, because they're not mutually
3 exclusive. I think that, broadly speaking, is a really
4 important thematic way to go for big picture issues.

5 On the specific substance, let me say first what I
6 think the status quo is, because the status quo, in my
7 opinion, is not the pictures that you showed up there. The
8 status quo for people who retire ten years down, maybe less,
9 is going to be substantially less Medigap coverage, whether
10 it be Medigap coverage because premiums have risen.
11 Employers, I think, are pulling back dramatically. I was
12 with Paul Fronstin the other day who said that in our work
13 we are doing with the Urban Institute, we should assume that
14 in third years, no one gets employer-based coverage. And
15 now people say, what about public employees? Well, that
16 might lag a little bit.

17 But for the most part -- and as it happened, the
18 next day, I went to the benefits committee that I just was
19 appointed to with my employer, and I won't say the details
20 of that, but I might be upping some of my savings.

21 [Laughter.]

22 DR. CHERNEW: Because, essentially, some of the

1 promises -- I think if you look actuarially at some of the
2 promises that were made by employers to individuals are not
3 tenable. And we can pretend they're tenable by looking
4 about what's going now, but my opinion is they're really
5 not.

6 And then if we reform Medicare Advantage, which
7 we've discussed in a way that I think is reasonable, I think
8 you find that Medicare Advantage as an outlet to a way to
9 get this coverage will be less generous than it may have
10 been in the past, because right now, we are spending a lot
11 of money to get some of these gaps filled in that way.

12 So my view is the status quo for many people that
13 I know is that it's not as generous a picture going forward
14 that it is now. So when we talk about reforming it, we
15 can't talk about reforming what it would look like today,
16 and it looks like we're making things a lot worse for people
17 by putting in a deductible or all this, which I understand.
18 But it might be the case, and I won't go so far as to say
19 this, that, in fact, some of these things are going to look
20 a lot worse for individuals and we really need to think
21 about how to do that.

22 And the big challenge that I think is raised here

1 extraordinarily well is that we have to balance our desire
2 to maintain access to the things we think are of value and
3 discourage access to the things that we aren't. We want to
4 make that overall, and it has very strong implications for
5 issues related to disparities.

6 One of the challenges that I think arises in all
7 of the work that we do is how to think about it in the
8 following way. Mitra's comment, which I am supportive of,
9 is we would want to charge people more for the things of
10 lower value. What I think is actually more likely to
11 happen, whether we want it to go this way or not, is we
12 would see coverage deteriorating in various ways and we have
13 been struggling very hard to at least try and carve out
14 those areas that we know are high-value to protect them. We
15 don't know what they all are.

16 So the status -- we've only argued for lowering
17 barriers to high-value things, but that's against the
18 backdrop of coverage getting a lot less generous by and
19 large, and I think even if the Medicare benefit doesn't
20 change, I think beneficiaries are going to perceive the
21 Medicare benefit as becoming less generous over time. And I
22 think through the benefit package structure, we have to

1 think about how to manage that, and one way could be through
2 solving all the problems with physician payment changes, and
3 that solves the cost problem, we can keep copays down, but
4 I'm not sure how well that will work. And I think that
5 interplay is why the beginnings of this chapter, which is
6 one that I hope gets revisited, I think, is going to be
7 fundamental.

8 MS. HANSEN: Well, I cannot be more articulate
9 than I think both Mitra and yourself combined here. I do
10 think that there's the immediate term, the design, as well
11 as looking at the trajectory of what's coming down the pike,
12 and I certainly have brought that up with kind of the
13 growing older population who will actually use more services
14 regardless at the moment of this design.

15 But I do think that in the interim period, the
16 blunt instrument factor of the \$950 on the front end,
17 especially for a group that I've oftentimes also spoken
18 about, is this less than Medicaid population but at great
19 risk, is something that we should think about.

20 I think perhaps just as a backdrop of pure
21 economic dollars, I think I've raised this, also, but if we
22 just also think of the context of the typical Medicare

1 retiree and what their normal income is. So we can talk
2 about absolute dollars, but what percentage does that affect
3 their total ability to manage their costs so that we get
4 also a full or constant picture of the impact to the system,
5 the Medicare system now, the Medicare system in the future.
6 But the concomitant erosion that will occur with the
7 absolute dollars, what in future dollars, what that is, let
8 alone today's dollars, where half of the Medicare
9 beneficiaries live on probably less than \$22,000 a year for
10 everything.

11 So those are the things. I just wanted to have
12 that robustness of that picture painted.

13 DR. SCANLON: I would just sort of add sort of my
14 sense of the importance of this, and I think that we really
15 can't think of Medicare as insurance unless it's got some
16 catastrophic protection. And that, I think, just leads to
17 the point of thinking that there has to be a cap of some
18 sort, a cap with some nominal cost sharing sort of beyond
19 that certainly is a reasonable thing.

20 It also seems, and it's always been the case, that
21 it makes no rational sense to be heavily subsidizing an
22 insurance product for the beneficiary population and

1 simultaneously allowing for supplemental coverage which is
2 adding to the cost of that insurance product. So taking
3 some steps with respect to supplemental coverage, I think,
4 is very important, and not just Medigap but also the
5 employer. Even though the employer coverage may be
6 withering, it's there now for the time and it's there. We
7 shouldn't be incurring those unnecessary costs.

8 The thing I would stress is that we really have to
9 take into account what Jennie raised the issue about, sort
10 of the portion of the beneficiary population that is lower
11 income. And defining things in nominal terms, either a
12 deductible or some copayment, I think misses the point that
13 for some people, those are very big numbers.

14 We have the Medicare savings programs that cover
15 cost sharing up to poverty, okay. Poverty is about \$11,000
16 or \$12,00 for an individual, \$15,000 for a couple. Those
17 people in poverty, they have a very different -- are just
18 above poverty -- they have a very different sense of what
19 these dollar amounts means. So I know it's much more
20 complicated to think about defining a program with income
21 tiers, but it's something that we, I think, can't avoid when
22 we talk about improving the Medicare benefit.

1 DR. CROSSON: Yes. First of all, I agree with
2 Bill. I think we've talked about the need for a
3 catastrophic cap for some time. It seems to me that the
4 idea of someone covered by Medicare going bankrupt because
5 of out-of-pocket costs is something, if we can do it, we
6 ought to try to prevent.

7 Among the options, the one that we have on the
8 table that causes me the most heartburn, like some others,
9 is the combined deductible. So, I mean, for most Medicare
10 beneficiaries in the average year, that results in an
11 effective deductible for outpatient services of \$950, which
12 is a lot, and it's a lot for certain populations, as I think
13 has been brought up.

14 So I have sort of a specific question. You
15 mentioned earlier that in the bill that passed the Senate,
16 the health care reform bill, there are some provisions that
17 are directed at trying to change the allowable benefit
18 structures in the Medigap policies, presumably for the same
19 reason of reducing program costs. So I guess my question
20 is, could we look at -- and it may be or may not be by the
21 time we look again that something may have happened along
22 those lines and this could be along the path of becoming law

1 -- would it be possible to look at projections of whether
2 those provisions, if passed into law, would allow, without
3 dealing with the combined deductible piece, would allow for
4 a catastrophic cap either at the \$5,000 level, which costs
5 \$10 billion, or solving half the problem, at the \$10,000
6 level, which appears to cost \$3.9 billion a year?

7 DR. SCHMIDT: Let me say what those provisions are
8 and then I'll get to your specific question. As I read the
9 Senate health reform bill, what it contemplates is as of the
10 year 2015, standards for Plans C and Plans F, which are the
11 most popular types of Medigaps, would need to be revised by
12 the NAIC to incorporate nominal copays for office visits. I
13 think they're on the order of \$20 or so is what's
14 contemplated for office visits for primary care, somewhat
15 higher for specialty care. I think it's kind of left a
16 little unclear exactly what those levels might be. And also
17 emergency room visits.

18 One thing about those provisions is that it would
19 affect people who are just now becoming elderly, entering
20 the Medicare program and contemplating the purchase of a
21 Medigap. It would not affect the stock of current folks in
22 the Medicare population. They would be grandfathered,

1 presumably, and could keep what they have. So the savings
2 initially from having those in place presumably would be
3 relatively small.

4 There is some out-of-pocket cap that might be
5 provided with that, but I would suspect it is pretty high.
6 Over time, the savings relative to a world where those
7 Medigap policies did not change would grow, and presumably
8 that would pay for more. We could try to do some
9 projections if that would be helpful.

10 DR. CROSSON: One point of personal privilege.
11 Becoming eligible for Medicare and becoming elderly are two
12 separate things.

13 [Laughter.]

14 DR. SCHMIDT: Forgive me.

15 MR. HACKBARTH: But the Senate health reform bill
16 only addresses prospectively Medigap. It doesn't do
17 anything with ERISA, exempt employer --

18 DR. SCHMIDT: Correct. It is only with Medigap.

19 MR. HACKBARTH: Okay.

20 DR. BERENSON: Yes. I will share everybody else's
21 view that this is very important and I like the direction of
22 where your proposals were going and, essentially, let's get

1 a real stop-loss and catastrophic coverage and then create
2 incentives for people not to buy first-dollar supplemental
3 but to face some cost sharing. This article gives me some
4 pause and I'm going to have to understand it a little
5 better.

6 I'd make two points about why at least my going-in
7 view -- two points that haven't really come out. One is
8 implicit, having to do with value-based benefit structure.
9 Virtually every discussion I have about medical homes with
10 people trying to figure out how to encourage beneficiaries
11 to participate but not lock them in or assign them into what
12 appears as a gatekeeper, the glib thing is, oh, we'll just
13 waive their cost sharing, to which I glibly respond, they
14 don't have any cost sharing, at least 90 percent of them
15 don't. So there's right now some real practical issues
16 around trying to promote certain kinds of behaviors because
17 everybody has first-dollar coverage.

18 The second point I would make, which hasn't come
19 up, is an issue around the beneficiary, the beneficiary's
20 family, and fraud and abuse or mistakes. In my own
21 situation, I will recount this, my mother died a few years
22 ago. As part of her acute illness, she had a transfer from

1 a hospital two miles away to another hospital and there was,
2 after months of going through things, I found that there had
3 been a supposed helicopter moving her from one to the other
4 at \$6,000 when, in fact, there was no helicopter. It was
5 simply an ambulance. And I had no reason to -- I mean, it
6 was all paid for. The hospital billed. Medicare paid that.
7 It got transferred over to the Medigap insurer that paid the
8 rest of it, and I sat there saying, I really need to look
9 into this, and yet I haven't still. I will, now that I am
10 saying it very publicly here.

11 [Laughter.]

12 DR. BERENSON: So one thing I believe they do in
13 France, where people, at least for physician services,
14 people do have first-dollar supplemental coverage but they
15 have to pay the copayment in the office, see what they're
16 being charged, and then on the back end collect, I just
17 think we need to think of -- I know AARP over a decade ago
18 had a whole campaign about sort of being part of and ability
19 to care about bad billing, whether it's intentional,
20 fraudulent, or whether it's a mistake, which I would hope
21 happened in this case. It's hard to imagine how, exactly.
22 I do think there is a reason to have -- I mean, it's an

1 aspect that I think -- and anything you can find about what
2 sort of behavior change happens with patients and their
3 families as they have to face bills, even if they're not
4 ultimately liable for the cost, but sort of how the bills
5 move, how the claims move, I think would be helpful in this
6 discussion.

7 DR. KANE: Maybe a finder's fee for finding fraud
8 in the bill?

9 I just wanted to support the concept of having all
10 of these numbers presented as a percentage of household
11 income and not necessarily just as -- there's actually two
12 people involved here, too. It's usually not just one
13 beneficiary. I mean, a lot of these people are couples, and
14 so you multiply that by two on household income, not just
15 one. I think that would help us get a better sense of how
16 powerful some of these things are to families.

17 And I guess I don't quite understand -- it would
18 be helpful to get a sense of how the Medigap policies value,
19 because they're doing catastrophic, aren't they? Some of
20 these Medigap policies have a catastrophic --

21 DR. SCHMIDT: Well, some do, and they effectively
22 are picking up all of the cost sharing, so --

1 DR. KANE: Just actuarially, what does that mean
2 to them? And I guess how would that -- it's a little hard
3 to understand how you value the catastrophic coverage in
4 terms of -- I know there's a certain amount, but does it all
5 -- do people also end up using more services when they have
6 catastrophic coverage?

7 DR. SCHMIDT: Yes, they do.

8 DR. KANE: So that's not in here yet?

9 DR. SCHMIDT: That's not in there yet.

10 DR. KANE: I just find it really hard to kind of
11 follow this in the little pieces when there is a big
12 behavioral effect that could also swing in if you start
13 putting in catastrophic coverage. And then how would you
14 offset those costs?

15 DR. SCHMIDT: Right. And, again, we hope to come
16 back with more detailed information for you.

17 DR. MARK MILLER: But you also said in your
18 presentation that you could use the Part D construct, where
19 once you hit the catastrophic cap, there's still at least
20 some nominal co-payment that stays in place. You did say at
21 least that much.

22 DR. MILSTEIN: I support all the prior comments

1 about the notion if we want to have a reasonable chance of
2 closing the so-called value gap, you know, that we've got in
3 the health care system and in Medicare, we probably need two
4 engines, you know, operating the provider side of it and the
5 patient side, and you want both to be value-seeking in their
6 orientation more than is the case now.

7 That being said, I think, you know, it's funny, we
8 have certain metaphors for what's difficult to do, and, you
9 know, John was saying pushing a rope uphill. I think we'd
10 probably put in that came catalog of metaphors applying a
11 75-percent excise tax to Med. supp plans.

12 [Laughter.]

13 DR. MILSTEIN: That's probably harder than pushing
14 a rope, but, anyway, so I think what it really boils down to
15 is what we want is we'd like to within reason and within
16 what is reasonable to expect of Medicare beneficiaries to
17 have beneficiary incentives to make higher-value decisions
18 and engage in higher-value behaviors. That is the overall
19 concept. And then you sort of say that then raises two
20 questions that were in some ways answered in various ways by
21 some of the prior comments.

22 One is which behaviors and decisions would have

1 the most leverage on affordability and quality. You know, I
2 think the choices look something like this: First of all,
3 treatment options, you know, which treatment option. That's
4 sort of what we've done with drug formularies, right? And
5 that certainly could be extended to non-drug treatments.

6 But people who catalog cost-effectiveness and/or
7 comparative effectiveness studies say that we have a little
8 bit of building to do before that -- the cupboard is not as
9 full as it would need to be if we wanted to have a big
10 impact. So for the time being, that's a little bit
11 challenging.

12 Second is self-management behaviors, you know,
13 engage in various programs to reduce your health and,
14 therefore, health cost risk. That is, I think, a little bit
15 more challenging in the Medicare population than it is in
16 some of these pilots in younger populations. But also my
17 sense is the evidence doesn't suggest that that is a big
18 opportunity to lift value in the Medicare population, more
19 than has been recognized in the past, but it's not a big
20 number.

21 Then last is, I think, something actually we've
22 talked about before, which is choice of higher-value

1 providers. Now, there's a behavior in the decision where I
2 think there's reasonable evidence you could get a pretty big
3 lift, and where value is defined as we have defined it here
4 in the past.

5 And so you say, well, what -- then I think to
6 myself, well, you know, what mechanisms. Well, you know,
7 one would be the GAO mechanism that was advocated in a
8 couple of their reports, which is if we do have evidence
9 that there is a subset of physicians that are way off the
10 market in the Medicare program with respect to their
11 resource use, that is, unfavorable resource use, and
12 hopefully measuring, you know, available measures of
13 quality, one idea would be to say, well, let's have more
14 favorable -- you know, lower patient cost sharing for
15 patients that agree to select among physicians that are not
16 in the -- I think the GAO words for this was "distant
17 outlier" category. That is one option.

18 Another would be to tied this in with our
19 mainstream recommendations and say, look, if a beneficiary
20 is willing to select an accountable care organization or an
21 accountable medical home that is taking accountability -- I
22 mean, not just upside but downside accountability for

1 moderating, for improving value by lowering the spending
2 trend and improving quality, then they should get some kind
3 of a benefit incentive.

4 Now, in terms of what incentives you offer, that's
5 where I think we probably -- I wish we had more research on,
6 you know, what the relationship is between certain economic
7 incentives and certain people's behaviors, particularly in a
8 way that is kind of sensitive to people's income and
9 education levels. But if we're going to talk -- if what's
10 on the table is, you know, establishing or much better out-
11 of-pocket protection or better deductible, you know, my
12 intuition would be that's something we haven't -- it might
13 be something better fit for the non-affluent Medicare
14 beneficiaries, and we do have some precedents in the federal
15 programs for giving a little bit more of a benefit or having
16 -- to people of lower income or asking people at higher
17 income to pay a little more. That has begun to creep into
18 the Medicare program, and that could be, if you wanted to
19 moderate the need to raise taxes, you know, to give rewards
20 in the form of lower -- introducing maximum out-of-pocket
21 and lowering deductibles, we might want to start with
22 people, you know, who are below a certain income level.

1 MR. HACKBARTH: As is often the case, Arnie, I
2 really like the way you framed that, and you did something I
3 was trying to do, but not nearly as well as you did it.

4 You know, these are tough decisions about
5 increasing beneficiary cost sharing. This isn't the first
6 time we've looked at this, and people haven't exactly run up
7 and grabbed it and embraced it as the way for Medicare to
8 go. And that's because there are a lot of legitimate issues
9 about its impact on the Medicare population.

10 It seems to me that maybe if, as opposed to just
11 latching onto this and pursuing it to its end, whatever that
12 might be, if we first said here is the array of tools that
13 might be used to engage patients and try to do some
14 assessment, like Arnie suggests, you know, here are the
15 high-leverage, high-value, and how this fits in that
16 framework and compare it to other opportunities, I think
17 that might be a fresh approach to it and potentially a more
18 compelling approach, both maybe for people around this table
19 and for the Congress. So thank you, Arnie. I like that
20 framing.

21 MR. BERTKO: So I am now going to take my
22 opportunity to opine a little bit, keeping in mind my --

1 MR. HACKBARTH: You did that already.

2 [Laughter.]

3 MR. BERTKO: No, and I've got more opinions than
4 that, Glenn. Come on. But I'll try to be quick. So
5 recapping here, a \$5,000 out-of-pocket, \$5 primary care, \$25
6 specialty, \$100 emergency room visit.

7 The first comment here is this is urgent, we need
8 to do this without grandfathering.

9 The second comment is -- and I'm going to go
10 towards your comment you just made about increasing cost
11 sharing. The answer is, yes, you're increasing cost
12 sharing, but, secondly, you're not going to really affect
13 beneficiaries very much because the cost of their Medicare
14 supplement premium will come down almost as much as the
15 cost-sharing difference. And if you recall, like Medicare
16 Advantage, except it's worse with Medicare supplement,
17 you're paying \$1.40 out in premium to get \$1 worth of cost-
18 sharing benefit back, because the loss ratios are in the 65-
19 to 70-percent range. So with everything that moves around,
20 it reduces the premiums.

21 MR. HACKBARTH: On average, but there's still a
22 different distribution of those costs.

1 MR. BERTKO: That is a true statement except that
2 the way the premiums are calculated, they come down, on
3 average, and they come down for most people. So 93 percent
4 of Medicare beneficiaries see a doctor a couple times a
5 year. It's very few who have no encounters whatsoever, and
6 the cost sharing for the catastrophic portion affects
7 everybody who's got a Medigap coverage.

8 The second thing here is that this is actually --
9 you like to look for things which have a two-fer or a three-
10 fer effect. This one has got at least that many. So it
11 would -- as Bob said earlier, for medical homes, accountable
12 care organizations, and medical management -- Mitra's
13 question -- you need to have some way to affect cost
14 incentives and channeling so it works there, management
15 tools. Value-based insurance design or whatever you're
16 going to do on that, whether you stick to small stuff like
17 diabetes management at the start or expand to other things
18 later, you've got to have these things so you can say, oh,
19 yes, we went from here to there, and you can't go from there
20 to plus money on paying that.

21 Then, lastly, this actually has some ability,
22 possibly, to reduce the demands on the Part A trust fund

1 because if you can reduce emergency room admissions, you can
2 also reduce admissions to the hospital which then affect
3 directly the Part A fund, because hospitals -- and I don't
4 know if Peter would agree with this wording, or Herb, but
5 they harvest admissions out of the emergency room, for
6 better or worse. And if we can keep people going through a
7 less acute care for these kinds of little-acuity conditions,
8 then that would be great, too.

9 So I think --

10 DR. KANE: John, what's the "this" again?

11 DR. MARK MILLER: Can I just --

12 MR. BERTKO: The \$100 per admission co-pay rather
13 than zero, which says go see your primary care or specialist
14 before -- rather than checking into the hospital to be
15 treated.

16 DR. KANE: But a \$100 co-pay [off microphone].

17 MR. BERTKO: Yes. Separate, outstanding, can't be
18 waived, or filled in.

19 DR. MARK MILLER: So what John is saying -- and
20 this is to connect to his last couple comments. I am sorry.
21 The first ones that he made and then these, and just to kind
22 of pull some of this together because I think you were

1 moving fast, and I am sorry, I'll be as fast as I can.

2 So you're saying, all right, let's drop the
3 deductible idea, let's go to a cost-sharing idea, and he's
4 giving examples of cost sharing for an ER visit, a primary
5 care visit, and a specialty visit. And these are co-payment
6 amounts, \$100, \$5, and \$25. Just talking, right? That kind
7 of thing. At the same time, as a catastrophic cap, correct?

8 MR. BERTKO: Correct

9 DR. MARK MILLER: Okay. So that's the approach
10 instead of a deductible and catastrophic cap, you have this
11 cost sharing through arranged visits with a catastrophic
12 cap. And then what I think some of your other comments
13 were, from the ER you might get a secondary effect of fewer
14 hospital visits. And then he was also saying to Bob's
15 comment over here that then you could say to the
16 beneficiary, I will relieve or not relieve you of these
17 things in order to incent you to go to an ACO or a medical
18 home, just to connect that dot.

19 And I had just one quick question. And you're
20 also saying for Medigap and why the premium falls is Medigap
21 cannot fill these.

22 MR. BERTKO: That's right. Medigap would be --

1 this would be minimum cost sharing. Medigap couldn't pay
2 for it, which brings down Medigap premiums, and because of
3 the 140 percent or \$1.50 to pay \$1 in claims, it doesn't
4 close it all the way, but it will be a near dollar-for-
5 dollar reduction. More cost sharing lower premiums.

6 DR. SCHMIDT: Could I ask John a question here?
7 That is, this notion of having the co-pays, would that just
8 be on Medigap policies? Or are you envisioning employer-
9 sponsored care plans?

10 MR. BERTKO: Well, Medigap I am certain has the
11 big bang. You mentioned, I think, in your presentation that
12 20 percent of retiree health care have this. I would put it
13 in there as well. I would also consider an income-related
14 one for Medicaid in much the same way. But, you know,
15 again, this is a straw man. Everything is subject to
16 looking at.

17 DR. SCHMIDT: Right. The reason I raise that is
18 that the cost of even a \$5,000 cap, I gave \$10 billion,
19 which did not have a behavioral effect and was for 2008. It
20 would be more money in future years. And I'm wondering if
21 just, you know, a change to the Medigap population alone
22 would be enough resources to pay for that.

1 MR. BERTKO: Given your numbers and the size of
2 the population covered by Medigap, namely, 25 percent of it,
3 I think the answer is yes. But I'm aware at least of only
4 one instance -- and this is by anecdote -- of where some
5 retiree health coverage with near 100-percent coverage was
6 twice the AAPCC-induced demand. And so, yes, it would have
7 an effect on that. I would do it everywhere that it made
8 sense.

9 MR. HACKBARTH: Okay. We're down to our last few
10 minutes here.

11 DR. CASTELLANOS: It's very difficult to follow
12 John. I live in the real world. I'm a practitioner, and
13 I'm just going to talk about some -- as a urologist, I feel
14 somewhat impotent when I bring up my comments.

15 [Laughter.]

16 DR. CASTELLANOS: I do want to mention that cost
17 sharing really does affect the real world. You know, we can
18 criticize the RAND study because it is below 65. We can
19 criticize the Brown study because it only was MA patients.
20 But in the real world it affects, and we do need to do
21 something about increasing the barrier for the treatment of
22 unnecessary services. And we certainly need to do something

1 about lowering the barrier for the necessary services.

2 Cost sharing does make a difference, and I think
3 it's important to put -- I think the beneficiary needs skin
4 in the game. I'm sorry, but I think they need skin in the
5 game. We need to protect some of the high-risk populations,
6 the people in poverty, the ethnic minorities, and the
7 catastrophic sick patients which we call the train wrecks.
8 They really, really need help.

9 And, lastly -- and Arnie opened up the issue about
10 higher level of providers -- the provider needs tools, just
11 like Glenn said. We need comparative effectiveness, and we
12 really do need tort reform. I have a patient who came in
13 the office Monday that didn't need a CAT scan and didn't
14 need a bone scan, but her comment was, "I have insurance and
15 I demand it, and if there's something wrong, I'm going to
16 come back to you and I'm going to sue you." I need some
17 protection.

18 DR. STUART: I know that woman.

19 [Laughter.]

20 DR. STUART: No. I'm not going to repeat all
21 this. I think there's a broad consensus, and I think that
22 looking forward in terms of what the insurance market will

1 look like is the way to go.

2 There's a danger, I think, in saying, well,
3 Medicare is behind the 8-ball because it doesn't have a
4 combined benefit with a single deductible and coinsurance
5 feature. I think we understand that. But if you read the
6 trade press, everybody is looking at value-based designs. I
7 saw the results of a survey of insurers and self-insured
8 plans that said that 30 to 40 percent either had some
9 element of that now or were planning it next year. So this
10 is something that's happening right on the -- it's
11 happening, and it would be useful to have that summarized in
12 the chapter. And it would also be useful to have -- now, I
13 have no idea of this. Maybe John or Jay know how many
14 Medicare Advantage plans are using some kind of value-based
15 technique. But I think that that would be useful.

16 But I think that Mitra is on to something in terms
17 of, you know, it's not just economic incentives that matter
18 here. And, in fact, if you look at the value-based design,
19 what you'll see is that the programs that are touted as
20 being the most effective are ones that combine some form of
21 disease management or behavioral modification together with
22 the change in price. Those are the ones that really move

1 behavior. And so it would be interesting to see the extent
2 -- it would be interesting to talk about that because I
3 think that utilization management is a really important
4 element of this.

5 Then I will end by saying, although I recognize
6 that we will never learn anything from the French, that the
7 French do do one thing that is designed to reduce
8 unnecessary costs, which is to charge for no-shows to
9 physicians.

10 MR. HACKBARTH: Okay. Thank you, Rachel.

11 * We'll now have a brief public comment period.

12 [No response.]

13 MR. HACKBARTH: Seeing none, we will reconvene at
14 1:15.

15 [Whereupon, at 12:23 p.m., the meeting was
16 recessed, to reconvene at 1:15 p.m., this same day.]

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1 area.

2 This panel discussion emanates from our work on
3 considering whether Medicare can do more to accelerate
4 quality and efficiency improvement. We've been focusing on
5 what we're calling Medicare's quality infrastructure, and to
6 date we've held an internal panel on this issue back in
7 October, and we've had two public discussions with you --
8 one in November about technical assistance and what
9 Medicare's role is in that, and then back in January we
10 talked a little bit more about technical assistance and then
11 also conditions of participation.

12 Overall, our logic for taking on this topic has
13 been that Medicare has a responsibility to both motivate and
14 support quality and efficiency improvement. To motivate
15 improvement, MedPAC has recommended numerous payment changes
16 including pay for performance, penalties for high rates of
17 readmissions, bundling, medical home, and we've also
18 recommended public reporting of quality data.

19 But it may be that payment incentives and public
20 reporting alone are not sufficient to induce the magnitude
21 of change needed. Support may be needed to enable the full
22 spectrum of providers to respond to these incentives. Some

1 providers may simply not know how to improve, and some may
2 face particular challenges. Also we wanted to consider
3 other levers Medicare has to motivate and support improved
4 performance, and here we have focused on conditions of
5 participation and whether they could be leveraged more to
6 accelerate improvement.

7 With respect to technical assistance, we've raised
8 several questions and possibilities for change. Among them
9 are: Should technical assistance resources be targeted to
10 low performing providers or communities? Here we've talked
11 about the wide variation in quality of care. And we've also
12 talked about how targeting assistance in this way could help
13 address racial and socioeconomic disparities in the quality
14 of care since low performing providers tend to serve a
15 disproportionate number of minorities and economically
16 disadvantaged people.

17 We have also asked who should provide the
18 assistance? Currently, Medicare contracts with quality
19 improvement organizations, QIOs, in each state to provide
20 assistance to providers. Interviews with stakeholders and
21 research have raised questions about the efficacy of this
22 program. Also, in the last decade, more private sector

1 organizations have begun offering technical assistance. So
2 an alternative to consider, to the current structure, would
3 be to allow more types of organizations to participate as
4 technical assistance agents, and these could include
5 exemplary provider organizations functioning as mentors.

6 And lastly, what type of assistance is needed? Is
7 it process reengineering? Is it building relationships
8 between providers? Should we also consider providers' need
9 for Medicare data, particularly across episodes? And this
10 may be critical as providers try to reduce their readmission
11 rates and avoidable emergency room visits.

12 With respect to conditions of participation, we
13 have discussed creating voluntary higher standards for
14 providers. Higher standards could provide additional
15 motivation for high and middle performing providers to
16 continue to improve as they seek ways to distinguish
17 themselves in the marketplace. Another option is to create
18 mandatory outcomes-oriented standards for select procedures,
19 akin to the current requirements for transplant centers.
20 And lastly, the COPs could be expanded to require efficiency
21 improving activities and updated to increase the chance that
22 adherence really results in measurable quality improvement.

1 To help you determine if this discussion of policy
2 options leads you to a recommendation, Hannah, John and I
3 will continue to research the issues surrounding them,
4 including the ones that you've brought up over the last
5 couple of meetings. But we also wanted to work to provide
6 you a provider's perspective, and that's what leads us to
7 today's panel discussion.

8 I also wanted to let you know that we're
9 complementing this panel with our own more in-office and
10 site visit conversations with providers, now and also
11 through the summer. In the fall, we'll report back to you
12 on our findings and continue to address any questions you
13 may have. Our thought, subject to your feedback, is that we
14 will have an initial discussion of these issues in this
15 June's report to Congress, but we will make no
16 recommendations.

17 So now let me turn to the panel. We are very
18 fortunate to have Dr. Philip Mehler, Chief Medical Office
19 from Denver Health, and Dr. Ron Anderson, President and CEO
20 of Parkland Hospital in Dallas, to talk with you today. You
21 have their bios, so I won't use the time to introduce them
22 other than to say that both organizations have been widely

1 recognized for their commitment to quality while serving a
2 diverse population and have been mentioned specifically by a
3 number of commissioners as organizations we can learn from.

4 I think this is likely to be a broad conversation,
5 touching on a variety of issues, but for your reference this
6 is a list of some of the topics that we've asked them to
7 address. I won't read it. Instead, we'll just go straight
8 to the panel, and I believe Dr. Anderson will be starting us
9 off.

10 DR. ANDERSON: I'd like to thank you for inviting
11 us here. We have a lot to detail in 12 minutes, and I'll
12 slip through some of these slides and leave them for you to
13 review, trying to get to the questions and answers where
14 really the meat is usually there.

15 But we are a safety net hospital in Dallas. We
16 fill a lot of gaps in trauma, for example. I know Karen
17 Borman was one of our trauma surgeons here, and we still
18 miss her. And we do about 16,000 deliveries for babies per
19 year, and about 55 percent of the doctors in Dallas actually
20 trained at Parkland. So we fit a lot of the needs for the
21 community as a safety net.

22 And we have a very diverse population, very

1 heavily minority population. That has changed, more toward
2 Hispanic than African American, over the years I've been
3 there. I've been CEO for 29 years.

4 This is a very busy hospital. It's the busiest in
5 Dallas County, and you see the growth that's occurred with
6 population growth in every place except the ED. In the ED,
7 you actually see a reduction. As the population virtually
8 doubled from 1980 to last year, we actually decreased from
9 182,000 visits really to 130,000, and that's because we've
10 put clinics out in the community where the patients live and
11 provided a really better mousetrap and instituted a medicine
12 model called community-oriented primary care.

13 We have built our surgical volume by building day
14 surgery, those kinds of things -- just constantly growth.
15 We're like an HMO except you can enroll on December 31st
16 with a gunshot wound. So it doesn't -- always open.

17 This is an important slide. It's one of the keys
18 to where we've been successful. In community-oriented care,
19 we've gone out into the community, working with the
20 community, trying to manage the in-betweens -- between our
21 hospital, between our primary care, the sub-specialty areas,
22 but also where people actually live, trying to work in a way

1 that they might actually be able to help care for
2 themselves, decrease demand. And that's by going out and
3 doing the public health work to determine what's going on in
4 the community, developing interventions with the community's
5 participation, doing the interventions, looking at the
6 results, giving it back to the folks that are there, having
7 them comment on that, and then doing a continuous quality
8 improvement program.

9 We're located throughout Dallas County, but if you
10 know Dallas County, we're located in the low income areas
11 with now 11 health centers, 8 women's clinics. Oftentimes,
12 they're conterminous. We go to schools, homeless shelters,
13 and basically try to de-emphasize the hospital if we can,
14 but do a lot of things in nontraditional settings.

15 We've had a program called the Cancer Prevention
16 and Intervention Program where we've done low or no-cost
17 mammography. Just to show you what's been accomplished
18 there, in green, those that are screened, their state of
19 presentation -- his is work done by Marilyn Leitch and Skip
20 Garvey, two surgeons in our place -- and those that didn't
21 screened prior to the provision of free and low-cost
22 mammography.

1 So sometimes it turns out to be much cheaper for
2 us since we're the insurer of last resort, like Medicare,
3 many times. We're caring for a population, oftentimes
4 Medicare, Medicaid or charity. It's to our advantage to
5 spend the money and to take the barriers down and get the
6 people cared for.

7 We do a homeless outreach program to 28 homeless
8 shelters, 6 of which are mainly focused on domestic
9 violence. That's also saved us quite a lot of money.

10 And we've had an outreach program for 30 years in
11 prenatal care. We now deliver prenatal care to 98 percent
12 of the women who actually come to Parkland to deliver. You
13 can see the results are a reduction by almost two-thirds in
14 stillbirth, neonatal deaths, intracranial bleed and days in
15 the NICU. So it saves us a lot of money. When we're asked
16 why we provide prenatal care to undocumented women, the
17 economic argument outdoes everything, but the humane
18 argument should.

19 This is a look at disparity. We're doing some
20 work also looking at African American infant mortality. You
21 can see we've brought it down nearly to that of the
22 Caucasian population -- again, nothing you could turn on a

1 light switch with, something that took many years to
2 develop. Even if you provide incentives, you have to gain
3 the trust of the community, and you have to go out there in
4 the vineyards quite a long time. I think you hear similarly
5 from our colleagues at Denver, that this really is not just
6 a light switch situation even if you give us incentives to
7 do so.

8 This is my Jaw of Life chart. It shows that as we
9 increase the amount of prenatal care, we decrease
10 prematurity. Prematurity, as you know, in the United States
11 is going up. We actually have seen a reduction over the
12 last 20 years, and again this is something that many public
13 systems might be able to teach the private sector. We think
14 it's important.

15 We were gifted the jail, so we used it for public
16 health intervention. We screen tuberculosis, sexually
17 transmitted diseases. We try to work on care management of
18 mentally ill patients. Sadly, we have 1,400 inmates a day
19 out of 6,000 or 7,000 that are mentally ill, and care
20 management for those is really important. Otherwise, they'd
21 just through a revolving door and cost a lot of money.

22 These are some of the things that we're actually

1 doing, and we're trying our best to kind of do outcomes
2 research to see where we're going, and that's important.

3 We own our own HMO which has over 50 percent of
4 the market. That's to help us integrate care as much as can
5 and do care management.

6 We now have over 4,500 children in an asthma
7 program. We've decreased hospitalizations by over 50
8 percent, ER visits by over two-thirds at our children's
9 hospital, and so this care management actually works very
10 well.

11 I'm going to quickly go through the trauma portion
12 of this and the prevention that we do to emphasize the need
13 to go upstream, to recognize as a payer of last that we want
14 actually to intervene early, take all the barriers down that
15 we can, to try to have an impact that we want. And we've
16 tried to shift our paradigm toward integrated preventive
17 health care and promoting financing that makes sense, that
18 doesn't discourage prevention. You know now if we prevent
19 something in a fee-for-service model, we actually lose money
20 and revenue? That's a fatal flaw.

21 We want to equip people, so they'll be able to be
22 motivated and have the skills necessary to help with self-

1 management. And we make prevention an element at the very
2 crossroads in the health care interactions that we have, and
3 we think chronic disease management, where maybe 10 percent
4 of the patients cost 90 percent of the money, is where we
5 ought to really be focusing a lot of our attention.

6 I want to go over now to where we've worked in
7 quality, where we've been. We were proud to be Parkland.
8 We had no clear method of measuring quality. We had no
9 ability to basically determine if we were actually achieving
10 what we wanted to. We tended to be siloed in departments,
11 and we had great individual effort, but no systematic
12 approach.

13 We are in a journey, and we are working with
14 people like IHI. We're working with UHC to compare
15 ourselves to our cohorts. We worked with the Texas Health
16 Foundation, the agency in Texas that really works with this,
17 on things like one-day admissions. But mostly, we've worked
18 with outside private groups to try to catch up with where
19 they're at, and so that's, we think, very important to do.

20 But we also had to change our own board. Our
21 board had played a lot of attention to fiduciary
22 responsibilities, but we have to convince them that quality,

1 safety and access is a fiduciary responsibility. They made
2 a safety and quality committee basically parallel to the
3 finance committee. They spend as much time on that, and so
4 from the very top of a governor-appointed governance board
5 we started paying attention to that.

6 The medical school has paid more attention to it,
7 as they've owned their own university hospital and had to.
8 But we used to assume that we were good because we were the
9 medical school's hospital. I would never assume that; we
10 never would.

11 But these are some of the things that we did to
12 raise consciousness, to really put in a system of
13 accountability, to actually put in rewards to the physicians
14 for achieving goals in quality, and looking at outcomes more
15 and more, and not just throughput. Too many places look at
16 throughput. They don't go ahead all the way and look at
17 outcome, and I think that's an important thing.

18 So now where we're currently at is organizational
19 analysis, trying to provide right care at the right time and
20 the right place, trying to look at prevention and look at
21 quality improvement programs.

22 We have a program on readmission for congestive

1 heart failure. We found that the biggest reason for
2 readmission is socioeconomic, not a physical finding, not a
3 laboratory test, not an injection fraction study. It's the
4 fact that they lived in a poverty area, and they're more
5 likely then not to have the support they need from social
6 services. So we try to identify those on the day of
7 admission, and then by the time the patients get out, get
8 them into a primary care home, have them seen within a week
9 or two because most readmissions occur before the patient is
10 actually even seen, and to try to have that sort of
11 embracing service with social services, dietary and other
12 people there to help them.

13 I think that's very important, but that's not
14 right now recognized by CMS -- no social severity of
15 illness. We look at medical severity, but I think we need
16 to migrate toward social severity and understanding that.

17 But the power of the electronic medical record and
18 being able to do outcomes and be able to hold us more
19 accountable, hold ourselves accountable I think is very,
20 very important, and we spent over \$70 million in the last 5
21 years. That's one thing I'm worried about with public
22 safety nets. Many of them, particularly rural hospitals,

1 don't have the ability to do that, and that's going to be a
2 very important place for you to provide some support.

3 We redesigned our own ED, and we cut dwell times
4 in half by doing systems engineering with an MBA MD person
5 who we've trained.

6 We also decreased left without being seen, from 2
7 years at 15 percent, to 3 percent or less and actually found
8 that those people who left weren't less sick. They
9 basically were sick because our admission rate has gone up
10 as we had more of them stay and be seen and the throughput.
11 So they weren't non-sick people who were just coming there.
12 But I think the biggest key is if you provide another place
13 for people to go, like the clinics we do and walk-in clinic
14 that sees 300 people a day, they will use those in lieu of
15 the emergency room, and you can be quite successful.

16 But the biggest thing I think is we need to add to
17 our extensive primary care systems a care management system
18 and disease management system, and those things together we
19 think will have the kind of impact on outcomes that we're
20 seeing in some isolated models. We'd love to see some of
21 the models and projects funded. They're really important to
22 try, and I think we'd learn a lot from each other and then

1 disseminate the information.

2 Again, I'd like to thank you, and I'd be open for
3 questions later. Thank you.

4 DR. MEHLER: Likewise, I'd like to thank you for
5 inviting Denver Health to share with you some of the things
6 that we've put in, in the last few years.

7 I apologize, I got a cold yesterday on the way
8 here.

9 Very quickly, I'm going to go at it a little bit
10 different than Dr. Anderson, but this is Denver Health very
11 quickly. Similar to what he said, it's sort of the right
12 care at the right place at the right time. So you see there
13 the main medical center, Denver Health Medical Center, which
14 is a 500-bed, Level 1 trauma center.

15 But the key to our success I believe, over the
16 last five years, is really the fact that: We have public
17 health integrated within Denver Health Medical Center. We
18 have nine federally qualified health center to provide
19 primary care. We have our own HMO. We have Denver Cares
20 which is a non-medical detox, so all these patients that
21 used to come to the ER are now taken to this other facility
22 and detox over there. We have correctional care. We also

1 have school-based clinics which allow us to take the care to
2 the students at the place that they are, rather than having
3 them come down to the hospital. And then we run our own 911
4 center.

5 But the two keys I think, and the takeaway
6 messages, are that: We have an employed physician group.
7 We're a closed medical staff. We employ all our physicians,
8 and by doing so it really gives you leverage to effectuate
9 care versus having private docs come into your hospital.

10 Then, similar to what Dr. Anderson said, we've
11 invested over \$300 million in the last 10 years into IT. We
12 have a fully developed CPOE model, other IT advancements.
13 The combination of the employed medical staff, HIT and then
14 having an integrated system with an extensive array of
15 health centers across the community has allowed us to
16 achieve the success we have.

17 We care for over 150,000 individual patients. One
18 in four patients gets their care at Denver Care. About 40
19 percent of Denver babies are born at Denver Health, 35
20 percent of Denver's children use us, and we actually take
21 care of, through our trauma mission, patients from every
22 Colorado county.

1 Who do we serve? Well, we really serve a
2 vulnerable people. This makes it tough because there's
3 unlimited demand for services and they don't have, as Dr.
4 Anderson said, a lot of the ability to take care of
5 themselves when they get out of the hospital. So you have
6 to be creative in order to effectuate good outcomes and
7 prevent readmissions.

8 We take care of the poor. We have a large non-
9 English speaking population, high-risk pregnant women,
10 victims of violence. We take care of a lot of homeless
11 people, public inebriants.

12 Chronically mentally ill is a big challenge for us
13 at Denver Health. There are very few psych beds within
14 Denver right now. There are only about 50. Five years ago,
15 there were three-hundred psych beds. That's one of the
16 biggest challenges going forward is the ability to integrate
17 mental health within the acute care model because if they're
18 not adherent to their psych issues, they're not going to be
19 adherent to their medical issues.

20 We also take care of prisoners and victims of
21 infectious disease.

22 Similar to Dr. Anderson, a very ethnically diverse

1 population: 52 percent of our patients are Hispanic, 13
2 percent are African American, 25 percent are Caucasian.

3 We have provided over \$4 billion in unsponsored
4 care in the last 20 years. Almost 50 percent of our
5 patients are uninsured. We only have 10 percent of the beds
6 in Denver, but we provide over 40percent of the unsponsored
7 care in the Denver metropolitan area, and despite those
8 challenges we've remained in the black every year since
9 1991.

10 We go beyond the uninsured. We're the major
11 Medicaid provider for the state, which is important for us
12 as a source of income. We're the major provider for CHIP.
13 We have an increasing role in Medicare. About 14 percent of
14 our revenue comes from Medicare. We're the busiest trauma
15 center in the state. We're a major correctional care
16 provider. And we have a number of competitively won grants
17 of about 20 million for disaster preparedness after 9/11.

18 Despite the challenges of taking care of a poor
19 population, we have been very cost efficient. Our charges
20 are some of the lowest of any peer metro Denver hospital in
21 25 of 35 categories that are looked at.

22 We were number 4 out of 102 hospitals and

1 university health consortiums for length of stay divided by
2 total expense per hospital discharge. For 2009, our
3 admissions were 7 percent over budget, but despite that fact
4 our average length of stay actually fell from 4.6 to 3.8
5 days. And, as you know, even a 0.1 decrease in your length
6 of stay is very substantial.

7 Despite taking care of a vulnerable population,
8 our readmission rate vis-a-vis UHC is in the top 10 percent
9 of all UHC hospitals.

10 Very quickly -- I'm sorry if you can't read this
11 well -- these are some UHC data that would support the fact
12 that we've really gone on this quality journal over the last
13 few years and have really had terrific results. This shows
14 our O/E ratio in the top third of the slide there, and, as
15 you see, our observed to expected mortality ratio for our
16 total inpatient is 0.53 -- so, a 47 percent decrease risk of
17 dying from similar illnesses when you come to Denver Health
18 despite the protoplasm that we take care of at Denver
19 Health.

20 These are some data from the American College of
21 Surgeons looking at all the trauma centers across the
22 country. I don't know who the other people are, but Denver

1 Health is the little green dot all the way on the left. We
2 had the lowest mortality rate for any major trauma center in
3 the American College of Surgeons survey that was published
4 last year.

5 Then UHC does a quality and accountability
6 aggregate where they look at a number of things. Shown
7 here, Denver Health for the last year was number 1 out of
8 106 hospitals in UHC despite the fact that we're taking care
9 of a vulnerable population, and for 3 out of the last 5
10 quarters we've been number 1 in UHC in that regard.

11 So when you sort of distill that down on why
12 there's such a very important, compelling reason to try to
13 improve quality, basically as a result of these, about 133
14 patients did not die as expected, which is a huge,
15 significant outcome. And we're not talking about end-of-
16 life issues and hospice patients; these are patients that
17 come in with typical medical illnesses.

18 Similar to Dr. Anderson, we believe one of the
19 keys for improving quality and where there needs to be a lot
20 of focus is on the outpatient. As you know, as a country,
21 we spend about \$700 billion a year for inpatient care, but
22 about two-thirds of the dollars we spend are actually for

1 outpatient care.

2 In the rest of the country, about 34 percent of
3 Americans have their blood pressure controlled, so about 70
4 million Americans have hypertension. At Denver health,
5 almost two-thirds of our patients have hypertension
6 controlled. This then results in you have less admissions
7 for stroke, less admissions for heart attack, et cetera. So
8 focusing on the outpatient arena in addition to the
9 inpatient arena, in an integrated system, is one of the keys
10 for success.

11 This is something sort of hackneyed, but it's
12 something we're proud of. You know hand hygiene has been
13 talked about. It seems real simple, and it's sort of, you
14 know, just do it. But we really struggled with this, and
15 until we put in programs. I think the important thing that
16 we did here is that we don't want to blame people, but we
17 want to hold them accountable. When you have a surgeon that
18 keeps going into the room time after time, something needs
19 to be done in that regard. We actually put in an online
20 system where anonymously people could report people that
21 they saw not complying with hand hygiene, and I think that
22 was one of the reasons we were able to get up to 90 percent.

1 Our ICU bloodstream infections due to catheters,
2 which is a huge waste of money to treat these infections,
3 just by putting in simple checklists and by putting in a
4 central line insertion cart in all of our ICUs, we've been
5 able to decrease our ICU central line infections markedly --
6 similarly with regard to ventilator associated pneumonias,
7 by putting in the bundles which are so important and sort of
8 learning from other industries that have been successful,
9 like the aviation industries where you have these simple
10 bundles, where you have these simple checklists, and using
11 those and enforcing them and then, perhaps most importantly,
12 putting these data up in the ICU where you're transparent
13 and you're compared to the other ICUs. Doctors tend to be
14 competitive, and that's what drives change, I think.

15 So our quality journal in 2009, we won the NAPH
16 chair award, which is the highest award that they give for
17 quality. This is related to a program that we put in. We
18 didn't go with the flow with regard to rapid response teams,
19 which I don't believe makes sense in teaching hospitals. I
20 think what you've got to do is get the residents to the
21 bedside and empower the nurses to call when they think a
22 patient is starting to become unstable. We put in our own

1 program that integrates the residents into the program.

2 The message here is I think you've got to know the
3 literature. You got to be willing to say we don't agree
4 with sort of the trends out there, and for our hospital this
5 sort of makes sense in order to sort of reduce the
6 inexorable decline that some of these patients are on.

7 We have docs that are on the advisory committee
8 for NQF. We have a couple docs that are on the JNC 8
9 committee. We've been involved in the HIT Senate committee
10 because of the investment that we've made in HIT.

11 We've published a lot of our things, and I think
12 that that, being an academic medical center and trying to
13 predicate theory on evidence-based medicine, is the way to
14 go. We don't tolerate sort of Gestalt and this is
15 anecdotal. We really try to say what's the evidence and
16 let's effectuate that evidence.

17 I really think the investments that we've made,
18 we've tripled our infection control staff in the last couple
19 years -- significant expense, but I think that the return on
20 that investment is key because infections continue to be a
21 big issue in all acute care hospitals.

22 This is just a letter about the clinical triggers

1 program that we put in for the rapid response. Again, the
2 message there is to be brave enough to say that what
3 everybody is doing may not be right for your hospital and be
4 willing to try something a little bit different.

5 Another key thing was being transparent with our
6 quality. Initially, we had a quality scorecard that we
7 started about four years ago that was tallied and sent out.
8 The real big thing that we've done now is that we now have a
9 new electronic interface with a data warehouse. It took
10 about six months to develop.

11 But the key point here I think, which drives
12 quality, is you have to be able to drill it down to the
13 clinic, and you have to be able to drill it down to the
14 physician. We don't believe that physician-related data
15 should be de-identified within the hospital. We want to
16 compare it to the peers in a non-punitive manner and use
17 this quality scorecard on a regular basis, given to the
18 leaders and the physicians of the hospital to drive quality.

19 So this is just a quick snapshot of it, but
20 basically for all of our outpatient indicators -- diabetes
21 care, hypertension care, et cetera -- we have drilled down
22 to the physician within Denver Health. Again, since we have

1 an employed physician staff, you can really drive change by
2 having these data available.

3 Another thing that we've really tried to do is to
4 integrate LEAN within Denver Health, and that's a big
5 message that Dr. Gabow, our CEO, really wanted me to impart
6 here. We've been on this journey with regard to LEAN. LEAN
7 traditionally has been a process measure for finance and
8 other things. I said to Dr. Gabow a couple years ago, I
9 really think that we can use LEAN theory in clinical.

10 Actually, one of the things that we've applied
11 LEAN to is reducing hospital readmissions. We deal with the
12 same issues that Dr. Anderson. A lot of these determinants
13 are social determinants. They're not due to the usual
14 things that you'd think, and therefore you have to be
15 creative in order to reduce these readmissions.

16 One of the things that we've really invested in is
17 to very much augment our UM staff in the hospital, by having
18 more nurses that are there at the time of discharge, by
19 having a discharge lounge where again the medications are
20 gone over with the patient. You get the patient out of the
21 bed, you move them to a different unit, and you reinforce
22 the fact that they need to be taking these medications.

1 This is the number you need to call when you're having a
2 problem. And we also get them an appointment in primary
3 care at the time they're leaving the hospital, rather than
4 relying on chance where they have to make the appointment on
5 their own, which doesn't seem to work.

6 Another big issue that we're worried about at
7 Denver Health is this whole issue of abnormal results. We
8 know that what drives a lot of lawsuits are tests that were
9 ordered and nobody followed up on them. This, we're also
10 using LEAN technology in order to improve our abnormal
11 results tracking.

12 We're also endorsing the Global Safety Score that
13 a lot of hospitals are using across the country right now.
14 It's a group of measures that really indicate there was a
15 bad outcome in a patient, and you simply add these up and
16 continue to track them. So, rather than looking at just an
17 individual one or two indicators, you have this Global
18 Safety Score which is really a surrogate. Is quality in
19 your hospital improving?

20 Another big issue is to take quality out of the
21 department of safety and quality, and diffuse it into the
22 different departments across the hospital. You have to

1 engage the physicians and the nurses and the social workers
2 in quality. One of the big challenges is how do you pay for
3 the physicians who are generally seeing patients or doing
4 procedures. We need to give them salary support in order to
5 engage them in quality. Simply to have a top-down approach
6 doesn't work. You have to engage the different departments,
7 and we believe in that, and we've done creative things
8 within every department to have a quality champion that
9 helps us effectuate things, but also creates things within
10 their departments that other departments can learn from.

11 So, in conclusion, Einstein said, you shouldn't
12 use an old map to explore a new world. We think that we
13 have a new map at Denver Health, and again I think the keys
14 that have been able to help us drive quality across the
15 hospital have been the employed physician group, the
16 integrated system, our investment in HIT and then being
17 creative, similar with our clinical triggers program versus
18 a rapid response team, and similarly with regard to other
19 programs that we've put in that may be a little
20 nontraditional, using LEAN in the clinical arena, being
21 willing to take those leaps to effectuate good care for the
22 population that has a lot of social issues going on and

1 makes it hard at times to really get good care for them.

2 MR. HACKBARTH: Thank you -- two great
3 presentations and right on time. It's really appreciated.

4 So we begin with round one clarifying questions,
5 and let me kick that off with a question for Dr. Anderson.
6 Could you talk a little bit about how your medical staff is
7 organized? Dr. Mehler emphasized the importance of a
8 salaried medical staff.

9 DR. ANDERSON: We're similar to being salaried in
10 the sense that we have the University of Texas Southwestern
11 Medical School, and we're a closed faculty. We spend about
12 \$120 million a year on faculty salaries, and we also pay for
13 the house staff which are our employees. So we work very,
14 very closely with them.

15 And for many years, before they had a university
16 hospital, we were the university hospital. Now they have
17 their own university hospital, but we tend to have Parkland
18 doctors, and they tend to have university doctors. So it's
19 very much, except they're not our direct employees.

20 This is a better model -- direct employment --
21 I'll tell you, because there are many other things in an
22 academic setting too, that people have many masters.

1 They're trying to publish. They're trying not to perish,
2 and that sort of thing. So it is tougher to get them to
3 focus.

4 So we've hired some doctors that focus on quality,
5 who work directly for me or our employees. We've had to
6 supplement that to get where Denver Health because they have
7 the people directly employed. So I think the directly
8 employed is a better model.

9 MR. HACKBARTH: So let me start over on this side
10 and see hands for clarifying questions.

11 DR. MILSTEIN: Why isn't the distribution of
12 performance closer to yours? In other words, what is it
13 that makes it so hard for other organizations to do this?

14 I mean we hear a lot from other organizations
15 saying give me 20 years and a lot more money. Why are you
16 able to do it now, deliver these results now, and not have
17 any particular major subsidy to do it? What's the
18 difference here?

19 DR. ANDERSON: I can tell you part of the
20 difference is leadership. Patty Gabow and Dr. Mehler and
21 others have really had a lot of leadership in there. We've
22 had leadership to try to do some of this.

1 But I think it's also been a drive. It's a
2 culture -- something we've wanted to do a long time because
3 we were the payer of last resort. We had limited dollars,
4 but open enrollment. We had a vulnerable population. And
5 if we save money, it's not like Kaiser. If it's enrollment,
6 I save the money, I get to keep the money.

7 Actually, if I save money by keeping people
8 healthy, I create new capacity, and other people come and
9 use it. There's always a backfill in public hospitals. So
10 it's actually a disincentive sometimes. Like in Canada,
11 they bed-block mainly because they don't want new patients
12 necessarily.

13 We do. We want to actually show better value by
14 being better stewards, and that's been something that's been
15 rewarded for a long time.

16 But I think it comes down ultimately to leadership
17 and also incentives, and we don't have an incentive to use
18 more. We have an incentive to get better outcomes.

19 DR. MEHLER: I would basically agree with Dr.
20 Anderson. I think the only additional thing is that there's
21 an urgency when you're a safety net hospital. I mean things
22 can go bad, and a second payer's sources can change, and so

1 there's an urgency really to do things.

2 I think the other thing is that because we're
3 lucky to be an academic center -- all of our physicians have
4 an appointment at the University of Colorado with the same
5 criteria for promotion as a doc at the university -- we
6 really try to effectuate outcomes that are predicated on
7 evidence-based medicine. We push that throughout the
8 organization, and we push that with the residents, to say
9 what are the data to say that what you're doing is the way
10 to go in medicine. That combination of the urgency, the
11 academic model and the integrated system I think is what
12 drives it.

13 DR. GEORGE MILLER: Thank you. Both presentations
14 were outstanding. I really appreciate your being here
15 today.

16 I'd like to focus my question to both of you about
17 disparities among minority populations and what you've done
18 and what you can see that could be used in a broader sense,
19 to other organizations, from your learning and your
20 understanding and the outcomes you had from them.

21 DR. MEHLER: I think one of the things that is key
22 that I really did, I was the Chief of Medicine at Denver

1 Health for about 15 years, and I still see patients on a
2 regular basis and love doing it. I think one of the keys is
3 that you have to have a provider staff that's diversified,
4 and we take pride in the fact that we have a number of
5 African American physicians, a number of African American
6 nurses and a number of Hispanic physicians. I actually
7 employ two full-time Russian-speaking physicians, who
8 trained in Russia and came to the States because there's a
9 huge Russian population in Colorado. So to be culturally
10 sensitive, you have to have a provider staff and a work
11 staff that's also diversified.

12 In addition to that, we've actually done outcome
13 studies trying to look at our outcomes in our different
14 populations, and our immunization rates are actually -- if
15 you're an ethnic minority, actually our immunization rates
16 are actually better. However, we recently discovered that
17 our lipid control was actually worse in our African American
18 population, and so we're figuring out how we can do better
19 in that regard.

20 But I think the key is to have a workforce that's
21 ethnically diverse.

22 DR. ANDERSON: George, I also think you have to

1 have people interested in doing studies. It's like the
2 alcoholism; you have to recognize you have a problem, and if
3 you recognize it and you see it. Like in the cancer study I
4 showed you, where we decreased from 50 percent in Stage 3
5 and 4 down to 8 percent, we did that basically because we
6 knew there was a problem. Inherently, we saw it. Our
7 doctors said, what can we do? We tried to develop something
8 to address it and do outcome studies.

9 We're looking at GI studies in black males right
10 now and getting colonoscopy out. There's a huge, huge
11 issue, but we can prevent that cancer if we find the polyps
12 and remove them. Finding a way to do that may require out-
13 of-the-box thinking. We may have to use different
14 approaches to colonoscopy or virtual colonoscopy or some
15 other way to do that.

16 If you reward folks for doing the studies and for
17 presenting them, many medical schools haven't thought this
18 is real science. Honestly, if it's not sub-cellular and
19 mitochondrial, it's not real science. This is where we can
20 translate science at the bedside or at the community side
21 quickly, and I think really get impact and payback rather
22 substantially. So I think you've got to reward it, but too

1 many schools have not paid attention to the social
2 determinants of health.

3 There's a recent article by the Blue Ridge
4 Association about the value of social determinants of health
5 and why medical schools should be teaching about this. You
6 know that deals with social justice issues and racism and
7 poverty, and that's huge.

8 Graduating from high school may be the most
9 powerful thing you can do for your lifetime, for your
10 health. So we work with the schools to try to get these
11 kids to graduate.

12 Those are the kinds of things that you have to
13 have the bigger, broader view. Instead, our health system
14 has been more of a sick system instead of a health system.

15 MR. HACKBARTH: Clarifying questions?

16 MS. KANE: With 30, 40 percent uninsured, what are
17 your major sources of subsidy for those patients?

18 DR. ANDERSON: At Parkland, we get about \$400
19 million a year from the local government, from taxes. We
20 get DSH and UPL, about \$170 million which is incredibly
21 important, and we worry about that all the time. But we do
22 \$575 million in charity care cost. So out of, well, a \$1

1 billion expense budget, basically charges don't mean
2 anything. We all know that.

3 We just look at the expense budget side, but we
4 get about 38 percent of our money from local taxes, but our
5 charity care burden is about 50 percent. So I've got to
6 make that up like any other business, and that's why DSH and
7 UPL have been so incredibly important to us.

8 DR. MEHLER: Similar to Denver Health, DSH and UPL
9 are very important to us.

10 We've realized in the last couple years that we
11 need to increase our commercial business a lot more, and so
12 we put in very unique programs, using the terrific medical
13 staff that we have at Denver Health. So, for instance, I
14 have a small program at Denver Health. I've been interested
15 in for about 25 years in the medical complications of
16 anorexia nervosa. So I have a small program, a six-bed unit
17 at Denver Health, that I re-feed people that weigh 30 and 40
18 pounds, from across the United States. All those people are
19 insured. If we can increase our commercially insured
20 population by 1 percent, that's \$17 million to Denver
21 Health.

22 So we have challenges. We have UPL. We have DSH.

1 We have Medicaid/Medicare. But we've also realized that we
2 can't continue to be the old Denver General that people knew
3 from 40 years. We changed our name. We've really tried to
4 compete, and by improving our facilities at Denver Health,
5 we've been able to attract more commercial patients which
6 are very important to us.

7 DR. BERENSON: Just following up on the payer mix
8 issue, Dr. Mehler mentioned that I think Medicare was 14
9 percent of your revenues. Could you, Dr. Anderson, tell me
10 what it is at your place?

11 DR. ANDERSON: It's in that range, about 10 or 12
12 percent, and most of the Medicare business we have are
13 crossover patients in Medicare and Medicaid. So they're
14 actually our target population, and they're the poor. I
15 mean that's typically the population.

16 We're finding more and more it's very difficult
17 for people to get Medicare, a new provider, and so actually
18 we're getting more Medicare business. It's growing because
19 private sector doctors are not accepting Medicare. So we
20 see that as a new population we may have to gear up to do.
21 We have a very busy geriatric program.

22 DR. BERENSON: Is that the same situation in

1 Denver? I've actually heard that Denver is a particular
2 problem of Medicare patients finding doctors. Is that what
3 you --

4 DR. MEHLER: Absolutely. The medical community
5 has disembraced that population. In fact, in Colorado
6 Springs, which is the third biggest city in Colorado, none
7 of the sub-specialists there will take Medicaid as a source
8 of payment, and so we found that our Medicare business has
9 gone from single digits up to 14 percent over the last 4
10 years. We actually view it as an opportunity for us.
11 Especially if we can get them enrolled in our Medicare
12 Select, our own HMO at Denver Health, it actually makes
13 money for us.

14 MR. BUTLER: Okay. So I'm going to borrow a
15 little bit from a topic we're covering later today --
16 graduate medical education -- because you both have
17 referenced it.

18 So, for Ron, you've been there a long time, and
19 you've seen your program increasingly embrace the community-
20 oriented primary care. So first, my question would be to
21 you. How have you aligned, or how have you adapted or not,
22 the GME program to be a facilitator or a supporter of the

1 GME?

2 And Phil, on your side, you've got a little bit
3 more inwardly measurement, LEAN process. How is that
4 filtered or integrated with the graduate medical education
5 training? Are residents getting LEAN techniques taught and
6 so forth?

7 So, same question but kind of different, how do
8 you adapt or use your GME programs in the quality
9 improvement processes?

10 DR. ANDERSON: Thank you, Peter.

11 We have our COPC doctors, who work out in the
12 community, are our employees. The medical school said they
13 really didn't want to go there back in the nineties. Some
14 have gone there. Pediatrics has gone there. Family
15 medicine has gone there. OB/GYN went there in a big way
16 many years ago.

17 But my own department, internal medicine, was very
18 traditional. They didn't want to go off campus. You know
19 doctors can't go off campus. Something bad may happen as
20 you travel from the medical school. You know.

21 However, we have a new General Medicine Director,
22 Ethan Halm, who is very interested in this and wants to do

1 population-based studies. These are wonderful
2 opportunities, laboratories, I mean to understand the public
3 and population-based medicine. And we have a school of
4 osteopathy in Ft. Worth that wants to send their students.
5 So I'm using them to leverage my medical school, to say, why
6 don't you really look at this? This is a wonderful
7 opportunity.

8 In regard to learning about quality, access,
9 safety issues, the compliance issues in the hospital, these
10 students oftentimes are turned loose on the public without
11 having any knowledge at all about what they're going to do
12 when they go into practice. We're trying to expose them,
13 but right now it's again more the hospital pushing it. At
14 the medical school center, our curriculum is so full, and it
15 is full. But it was said once, we had the best residents in
16 the world, and after you retrain them they're even better.

17 DR. MEHLER: At Denver Health, specifically in
18 regard to your questions, we have the chief residents from
19 all the major services participate in a LEAN event, what
20 they call the Rapid Improvement Event. It's a weeklong
21 event to address a clinical issue -- so, the medical chief
22 resident, surgery chief resident, OB, Peds and psychiatry.

1 We're a very inbred program, so a lot of our docs actually
2 have trained at Denver Health and at the University of
3 Colorado. So if you expose them to this way of doing things
4 as residents, then when they become your faculty it's easier
5 for them to integrate into what they do.

6 I think the biggest challenge right now with GME
7 and everything is some of these mandates about the work hour
8 restrictions, which I think the evidence sort of supporting
9 them is somewhat tenuous, and it's really creating havoc
10 within the hospital because of the handoffs that have to
11 happen and the shift work that has to happen.

12 I really worry that the next generation of
13 physicians, we have to rethink how we're training them
14 because in my humble opinion it's way different than it
15 should be right now, and I'm not sure there's a lot of
16 evidence supporting it. So just like I promote evidence-
17 based medicine, and my docs on the medical staff, I think
18 that we need that with regard to graduate medical education.

19 MS. HANSEN: Yes, this is in relationship to the
20 Medicare population that you both serve, and, Dr. Anderson
21 you brought up that you have a robust geriatrics program. I
22 wondered if you could talk about that a little bit and

1 whether or not we have something focused on that. I'm
2 thinking about measures since outcomes are so critical in
3 your commitment, the use of ACOVE measures, the acute care
4 of vulnerable elders in hospitals.

5 And then just you mentioned using a team of
6 people, that is nurses and social workers, to work with the
7 physicians. So I'm just curious about that whole part
8 because we've talked about that in the past here. How do
9 you get to that point?

10 DR. ANDERSON: We, like I think Denver General,
11 see -- the Denver Health hospitals see actually the Medicare
12 population as an opportunity for us. We get a lot. We have
13 the largest house staff training program in Texas. So there
14 would be some incentives for somebody because Medicare is a
15 good payer from the educational point of view. A lot of
16 other people in Texas, Medicaid doesn't help us with
17 education and that sort of thing. So it's important for us
18 to look at that.

19 But it's also the underserved. Who is our
20 underserved population? We have 400 elderly minority
21 patients in a swath where there are no clinics in Dallas,
22 which is less populated, that we actually do home visits

1 for. We go out and we take people from geriatrics to do
2 home visits. You don't really know your patients until you
3 go in their home type of thing.

4 The central campus, where we do the evaluation
5 for, say, Alzheimer's or where they do the very long tedious
6 evaluation which isn't paid for very well, that's always
7 cross-subsidized.

8 But then out in the community, we try to get
9 doctors interested -- family medicine and internists -- in
10 geriatrics because we're not going to have enough
11 geriatricians. We have three on the family medicine
12 faculty. We have about seven on the internal medicine
13 faculty. But we're training fellows in everything, but
14 that's still not enough to really do anything. We have to
15 get added competence and get people to want to do this.

16 I think connections to nursing homes that has been
17 done in Wishard in Indianapolis, where they actually covered
18 nursing homes from the academic setting. Some of the care
19 in some of the homes are not very good, frankly. So I think
20 we could integrate a lot of that better.

21 And some of the managed care products that are
22 coming out in Texas are looking at how to deal with the

1 people who have the high burden of illness, and so I think
2 this is a population we're pretty good, and we can actually
3 care manage those people and really given an opportunity.
4 So we see that as a calling.

5 Thirty-eight percent of the Texas doctors take
6 Medicaid, and probably sixty, seventy percent will take
7 Medicare. It's a problem that we see coming, and we think
8 we have to get ready for it, but just a tsunami in aging.
9 So if we don't prepare for that, we're going to miss I think
10 the real public health aspects of this.

11 But we're looking at PACE as well. We're looking
12 with the Volunteers of America. They're doing PACE
13 programs. That's not our core competence, to do all the
14 social services they do, but it might be that we would
15 provide the medical care and basically use a PACE model,
16 which we think is probably one of the best models.

17 MS. HANSEN: The question of metrics for the
18 ACOVE, do you do that in the acute facility as part of your
19 quality measures?

20 DR. ANDERSON: Yes. Yes, we do.

21 MR. KUHN: I know, Dr. Anderson, you said your
22 statement about the importance with your governance of the

1 quality effort. Could you tell me, and also Dr. Mehler,
2 about how much time do you spend at a typical board meeting
3 on quality issues, and what particular metrics are the most
4 impactful or the board members find so much useful in terms
5 of viewing what you're all doing in performance in this
6 area?

7 DR. ANDERSON: I think the numbers -- sometimes we
8 used to say statistics in public health were the human
9 tragedies with the tears washed away. We actually sometimes
10 bring patients to talk to our board, not just the good ones,
11 but we also present seminal events, never events. We're
12 trying to make that more transparent instead of behind
13 closed doors, which is always the liability the lawyers want
14 you to do.

15 But we also use the same sort of bundles and
16 scorecards, and we've actually -- my incentive salary is
17 tied to quality.

18 But we used to spend half the time on finance, and
19 now we spend about a third of the time on finance and about
20 a third on quality and access, and about a third on
21 compliance and other issues and strategic planning. It's
22 much more balanced than it was.

1 But when you look at people who get appointed to
2 public hospital boards, I mean a lot of them are bankers and
3 a lot of them are people that are very substantial folks.
4 We had recently our chair as an African American woman is a
5 nephrologist trained at Parkland, and I can tell you that
6 she wants to focus on quality and on disparities and other
7 things.

8 I think that really matters, who is on boards.
9 But people tend to do, on boards of hospitals, what they do
10 in real life, so to speak. So, if it's all bankers, it's
11 going to be mostly about that. So I think we have to start
12 enriching these boards, and we need to educate them about
13 governance.

14 If it doesn't start at the very top, but it also
15 has to start with the medical advisory group, and they need
16 to be an empowered group of physicians. In academic medical
17 schools, a lot of times it's the chairs who control, and
18 basically they're in their little silos. So we've had a
19 terrible time trying to go from a medical advisory council
20 to a medical executive council where the doctors at the
21 front, on the line, are actually empowered to make change.
22 Sometimes it's been a peculiar thing to watch because that's

1 what we need.

2 We need doctors at the front who are actually
3 doing this every day, to be involved in fixing this. They
4 come and make reports to the board, and we identify
5 projects. We celebrate projects that have been successful.
6 We also talk about ones that weren't successful. You learn
7 as much from failure as you learn from success, but I think
8 the key is you've got to be willing to talk about it and put
9 out and make it transparent, as you go down to the
10 individual doctor level. We're trying to get to the point
11 where we can go down to the individual doctor level, so that
12 we can do that, not in a punitive way, but in a way where we
13 can open this up as much as we possibly can.

14 But every one of our meetings, we'll have all
15 those bundles. Whether it be pneumonia or bloodstream
16 infections or other never events, they're all displayed
17 basically on something that a lay person can follow.

18 DR. MEHLER: I think it's really the same thing at
19 Denver Health. I think across the country the sort of
20 mantra of board on board is where everybody is going, that
21 it's not only a financial, but it's also a quality fiduciary
22 responsibility.

1 In addition to that, some of the things we do at
2 Denver, similar to what Dr. Anderson said, is we always have
3 two physicians as part of our board members, and one comes
4 from the dean's office at the school, and one is from
5 actually the private community.

6 In addition to that, we encourage the board
7 members to round with us in the hospital, and I think that
8 that's very important, so that they understand the
9 challenges that we have. So, when I attend on the medicine
10 service, which I have for close to 30 years, every day that
11 I'm attending there's one of the board members there that
12 are rounding with me. The patients love it, and the board
13 loves it, and the staff love seeing them there which is
14 important.

15 We also, on the day of our board meeting, we have
16 what's called the EQAC meeting which stands for Education
17 and Quality Assurance Committee, which is a board committee
18 that reports directly to the board. And similar to what Dr.
19 Anderson said, we review all sentinel events that occur.

20 Actually, one of the key things that have been
21 very good over the last couple years is they want us to
22 report on sentinel events follow-up six months later. Show

1 us what's happened to prevent it the next time. So we do a
2 root cause analysis. They want the outcomes from that root
3 cause analysis presented in six months to show what Denver
4 Health has done to try to prevent that sentinel event from
5 happening again.

6 I've been involved in the administration of Denver
7 Health for many years, and there's clearly been an
8 evolution. None of this stuff used to be discussed in a
9 board meeting, over the last number of years it's probably a
10 quarter or a third of what we do at every board meeting.

11 MR. HACKBARTH: Other clarifying questions?

12 Okay, let's go to round two, and I'll kick off
13 round two.

14 So both your organizations are exemplary in terms
15 of quality, efficiency, population health, and you both work
16 in environments where the resources don't come easily
17 because of the populations you serve, among other factors.
18 So what we're looking for -- we often hear in particular
19 from institutions that are challenged in that way, in terms
20 of resources, that, well, we want to get better, but it's
21 really hard for us.

22 So, if you were on the other side of the table, in

1 thinking of, charged with the responsibility of saying, here
2 are the policy levers that could help other institutions
3 achieve what we've been able to achieve, what sort of policy
4 tools do you think ought to be looked at?

5 One example, just my question may be too abstract,
6 is obviously a part of the Medicare program is the QIOs, and
7 there is a notion that we provide resources to the QIOs, and
8 they can help institutions get better. Do you make use of
9 that resource? If not, why not and what other tools do you
10 think might be better than QIOs?

11 DR. ANDERSON: We used the Texas Medical
12 Foundation and worked with them because we had problem with
13 single-day admissions. Part of it was we had no beds, and
14 patients were under observation. We created a better way to
15 handle that, but we concurrently review every admission. So
16 now we actually solved that.

17 But a lot of times our physicians weren't caring
18 about reimbursement. They weren't getting paid more. They
19 were worried about the patient going home. They were
20 worried about a homeless person who couldn't get outside
21 care, I mean didn't have the resources to get home care. So
22 they would put them in for social admissions, those kinds of

1 issues.

2 It's hard to know that the doctor is working in
3 good faith, and then you may be punitive if you don't -- you
4 may have penalty if you put the person in. So we've
5 actually admitted some of those people and just don't charge
6 for them. We just don't submit a bill because we think it's
7 protecting the patient. So we've had to accommodate some of
8 that.

9 But I think the work with IHI, I like their rapid
10 -- they have rapid implementation program you can sign up,
11 and we've done palliative care and things like that with
12 them, where you really see something come out. I will tell
13 you it's much more effective than what I've seen done even
14 with committees and people working in good faith with the
15 CIO. So a lot of people are going private.

16 What would I say to other people who tell me that
17 we can't be as good as you are or whatever? That didn't
18 happen overnight. It happened. It's a journey. Don't let
19 perfect become enemy of good. That's part of the problem.

20 And it would be great to set up an incentive
21 program that people get better, and as they get better they
22 get incentivized to get better because sometimes they can't

1 jump a canyon in one jump. I mean they're going to have to
2 go down the canyon and climb out the other side, and that's
3 what they're afraid of.

4 I see this in Texas all the time at the rural
5 hospitals. They just don't know. There's a huge digital
6 divide between what they can do with information systems,
7 for example. So they're almost waiting for some new
8 technology. Instead of cable, we're waiting for a cell
9 phone, and I don't know if that's coming.

10 In the public hospitals, I'd hate to see you lower
11 our standard, so that we can basically limp along, and we'll
12 be okay, and we'll get paid for mediocre care. You ought to
13 challenge us to provide the best care we can, and we can.

14 But I would say on the other side we may have
15 actually done a better job than some other places have done
16 in the private situation with our patient population, and
17 I'd hate to penalized because my patient population is
18 sicker or poorer. I see a lot of times people don't
19 understand the socioeconomics of the patient population
20 we're dealing with, and the constraints, and I think that's
21 why we need some studies on social severity.

22 DR. MEHLER: I think very similar to what Dr.

1 Anderson just said, it has been a journey. It's nothing
2 that happens overnight. But I think really the message has
3 to be to everybody also out there, if two safety net
4 hospitals can achieve this level of quality, then what's
5 wrong with everybody else, and why can't you do it? I think
6 that has to really be a message that gets out there.

7 In addition to that, I think that to say woe is to
8 me because I'm strapped for resources, I think you really
9 have to look from within and say, where is there waste?
10 There's a lot of waste that happens in hospitals.

11 As we all know, the incentive systems are
12 misaligned right now, and we have to figure out in order to
13 do evidence-based care and not care that just I sort of feel
14 like doing today. The way to do that is to give concurrent,
15 timely, peer-reviewed feedback to the docs, to say, if the
16 other docs in your clinic are achieving 60 percent
17 hypertension, why are you are 30 percent here? And I think
18 that that's very important in order to drive care.

19 In addition to that, I think the way that you sort
20 of tell people how you can make a difference out there is to
21 really emphasize the fact that you have to understand that
22 most of the medical costs are actually in the outpatient

1 arena. Certainly, we spend a lot in the inpatient arena.
2 But getting to integrated care systems and getting to the
3 medical home, the true medical home that everybody agrees
4 makes sense, in a way, that integrated system is a way to
5 achieve good results. When you have fragmented, open
6 medical stats where you don't control a lot of those things,
7 it's difficult to get your arms around it.

8 MR. HACKBARTH: Okay, let me see hands.

9 DR. BORMAN: I wonder if each of you could touch
10 on two things that I think you both have experience with.
11 One is if you were challenged to identify some metrics that
12 would represent quality educational processes, because
13 you're both important elements of university teaching
14 programs, academic medical centers, things that you, for
15 example, some of the achievements that you have, can you
16 relate those to things that could be measured as the
17 quality, that reflect the quality of your education programs
18 as play out in your health systems? That would be one.

19 Are there some things that if we measured you on,
20 you would do well, and we would want to be able to apply
21 those same metrics to other. They're achievable with the
22 right kind of systems that include graduate medical

1 education. So that would be one. Are there any metrics
2 like that? What should they look like?

3 And then secondly, the notion of, and I want to
4 emphasize at least from my knowledge of at least one system
5 at the table here, that they've both I think underplayed a
6 lot the leadership contribution to what has happened in
7 these two places, and they both need to take a lot of credit
8 of that and others in their system they share that with.

9 But thinking about that, how would you recommend,
10 for example, is there a way that we can use the Parklands
11 and Denver Healths as intentional mentors and resources for
12 other like places? And not necessarily even like. Ron, for
13 example, you invoked the multiple rural hospitals in parts
14 of Texas. How can Parkland be a mentor and aide to them,
15 and how can we potentially help you be that through federal
16 programs?

17 So those would be my two things. That is what are
18 quality education metrics as it plays out in your very good
19 systems, and then how would we utilize programs like yours?
20 How do we actively mentor others to achieve where you are?

21 DR. ANDERSON: I think in the past we have had a
22 very good residency program, very competitive. We have

1 measured it basically as deans of medical schools would
2 measure it. You know, how well did we do the match? And we
3 get the best residents in the country and those kinds of
4 things and that sort of business.

5 I think a lot of times the best doctors are not
6 necessarily some of the folks that are the highest ranked,
7 although we are still looking for that. But I'd like to see
8 how many people actually go out into areas where they really
9 make a difference. We are trying to get some people to
10 study systems to look at, you know, comparative analysis,
11 comparative effectiveness, look at some of the research
12 programs that really we need to help answer the problems
13 that face Medicare and others. And we do not see enough of
14 that kind of research. You know, the type of funding that
15 might come from that kind of study and see house staff go
16 into those kinds of things, you know, in an academic
17 discipline, how many go out and do that, and what type of
18 impact do they make.

19 I have been on programs where we have a local
20 mentor and we have a national mentor with young faculty.
21 For example, they leave from our house staff and join us. I
22 think that is a very good way to go. We did that in

1 patient-center care, a study on patient-centered care. I
2 think we need to do that also in this evidence-based work
3 looking at quality but also looking at the other issues that
4 make our systems function better. Evidence-based policy, if
5 we believe in evidence-based medicine, we ought to be doing
6 evidence-based policy. And I think that would be good to
7 see if we have some -- we don't have to have every house
8 staff come out.

9 Ultimately, you have got to be clinically
10 competent. You have got to be really clinically competent
11 and learn how to think so that you can face the new
12 challenges that come out. I think that is one of the things
13 we are known for, is we didn't just teach you facts. We
14 teach you how to think and how to solve problems. But I
15 would like to see those physicians actually become part of
16 the change leaders that are out there, and many times they
17 just want to go practice medicine and that is the end of it,
18 that is it, and citizenship is not the issue. And that is
19 okay, but I would like to have some who really enter this
20 arena. This is a battlefield where we need their talent.

21 We also now are already mentors to many of the
22 systems. We have had over 30 countries come study our

1 community-oriented primary care, many other health systems
2 who have come to look at it, and I know they go to Denver.
3 We have a system that works, but we invite them all to come.
4 We are working now with the Center for Primary Care in
5 Atlanta, and we are going to doing a COPC symposium this
6 fall and look at -- you know, basically you need more than
7 primary care. I have been in that and really pushed it.
8 But poor people need access to some specialty care. They
9 need access to integrated care within the hospital and back
10 out again. And you need every place basically to be on the
11 same agenda and working toward the same thing, and people do
12 not get to see those systems. We love to mentor folks, but
13 we also love to learn from others. That is an important
14 part.

15 It would be great to have some pilot projects and
16 have a national group of maybe 10 or 12 hospitals like ours
17 who agree to participate in a rapid response research
18 project, for example. Some of those things have been done.
19 AHRQ does some of those. HRSA does some of those. But I
20 think those are the kinds of things where we might be able
21 to look at a national perspective very quickly. IHI does
22 this. How can we rapidly deploy something that would affect

1 policy in two years instead of waiting 10 or 15 or 20 years?
2 I think that would be -- most of us would be glad to do
3 that, I think.

4 DR. MEHLER: We don't actually have our own
5 residency. All of our residents come from the university.
6 So one of the markers that we use that sort of we are doing
7 a good job is that when the university tries to pull them
8 back, the residents revolt and say, "We love being at Denver
9 Health." And so we use that sort of as a marker that, you
10 know, we're giving them a good education there.

11 But I would flip that around a little bit, and I
12 think that in the 1980s and 1990s we gave residents too much
13 independence. So when I trained at Denver Health in the
14 late 1970s and early 1980s, we ran the hospital. We
15 defended Denver at night. And I think we need to take that
16 back, especially because of the work hour issues. I think
17 the attendings have to be involved on a daily basis.

18 When I used to attend on medicine, I had to write
19 a note one in four days, and that was it. It was easy to be
20 an inpatient attending.

21 I think that because residents are students at the
22 end of the day and their training is much more fragmented

1 than it was years ago, I think that we have to impel the
2 attending physicians to take ownership of their service in
3 order to impart the quality to the residents more than we
4 used to because now I think that their care is so fragmented
5 and their training is fragment that if you do not do that, I
6 think you are really apt to have bad medical outcomes. And
7 one of the reasons that we have been on this journey and
8 have been successful is we have done that. We mandate that
9 there is an attending note every day. Regardless if you are
10 a high-priced neurosurgeon or an internist or whatever you
11 are, you have to see the patients every day and write a
12 substantive note in the chart.

13 And so one way that we measure that is we started
14 to do pro-fee billing, which we never did before.
15 Physicians never had to document anything. Now they do.
16 And we follow their earnings that come out of that as a
17 marker of how much are you involved in the patient care. So
18 I think we need to really drill that into all hospitals.

19 In addition to that, as Dr. Anderson said, we have
20 a LEAN Institute at Denver Health where we have a lot of
21 countries come in and sort of learn how we have integrated
22 LEAN into the clinical and into the hospital arena, and that

1 has been good. But we'd love to see Medicare do some
2 demonstration projects with regard to accountable care
3 organizations. We really think that we are poised at Denver
4 Health to do one of these studies because we have the
5 integrated system.

6 As Dr. Anderson was saying, I think, before we
7 started today, if you have a number of private docs that
8 sort of come in three times a year in your hospital, how do
9 you divvy up those dollars from an accountable care
10 organization? But when you have an integrated system with
11 primary care and ER and all the components that we do at
12 Denver Health, I think that we'd be able to demonstrate for
13 you all a way to make this happen and to promote this idea
14 that really if you want to change quality in organizations,
15 you have to have these integrated care delivery systems.

16 DR. CASTELLANOS: First of all, we really
17 appreciate you being here, and the comments were right on
18 line.

19 Glenn asked about policy tools. Karen asked about
20 what other tools can you do, like systems. I happen to be a
21 urologist in a community, and we don't have an academic
22 center. The closest one is 150 miles away. We are on a

1 fee-for-service model. We're not on a salary model. We're
2 totally fragmented. We don't have integration. We're just
3 beginning to get HIT in the hospital and in our community.
4 We don't really have strong leadership. In culture, we
5 compete against each other. We are competing against the
6 system.

7 There is a lot of distrust. My population is 73
8 percent Medicare, and because of what just happened with the
9 cuts on Medicare and the insecurity that we have on whether
10 we are going to get funded or not, it really makes a big
11 difference on who I hire and what I hire, whether I buy HIT,
12 whether I do this, whether I do that. So we have a
13 different community, but we still want to get better. We
14 still want to get where you are.

15 We do practice evidence-based medicine. We do
16 have the incentive to get better. But we don't have the
17 academic model, we don't have the leadership, and we don't
18 have the culture. Where the hell do we go now?

19 DR. ANDERSON: Sometimes not having the academic
20 model may not be, you know, as much of a burden as you
21 think. I love what I live, I suppose, but, you know,
22 sometimes it's very difficult also in an academic model for

1 people to pay attention.

2 There's an old statement that a guy told me years
3 ago when I went into academics, he said, "You have to learn
4 how to be selectively irresponsible to make it and to become
5 tenured," because you can't pay attention to everything.

6 Well, we're asking people to pay attention to
7 everything. We really are. There are ways to create review
8 groups. There are ways -- we're looking at some public
9 hospitals in Texas in a study called Tex-HIT that Ruben
10 Amarasingham did looking at the digital divide between
11 public hospitals, private hospitals, teaching, non-teaching,
12 and rural-urban. And, you know, it was really, really bad
13 if you were in that rural hospital, non-academic affiliated
14 and that sort of thing. You're waiting for that new
15 technology to come.

16 But there are some, you know, maybe portals we're
17 looking at on the Internet where we could actually reach out
18 on the Internet and provide a portal for people to come in.
19 And we met with a granting agency yesterday to try to
20 explain how we could actually, you know, serve as a portal
21 to help using our base, our investment, to have other people
22 get in through an Internet connection. It has not been done

1 anywhere, but we need to study that because there is a huge,
2 huge need out there to standardize.

3 We talked a little bit, Philip, about the waste.
4 Waste is something -- we always talk about fraud and abuse
5 when we're angry with the industry and we want to see
6 change. I've watched it throughout administration after
7 administration. I am far more worried about variation, and
8 variation that cannot be explained, and it just costs a ton
9 of money within communities and also across communities.
10 And we have this example in McAllen, Texas. I think I know
11 what the diagnosis is. They're for-profit, position-owned,
12 equity-owned situations. There are no public, no nonprofit,
13 et cetera, et cetera. And so, you know, it doesn't take
14 rocket science to figure out why utilization levels might be
15 really high.

16 But I think there are ways that we could reach
17 out, and maybe on a regional basis. Texas has seven medical
18 schools. Could we regionalize? One of the things I was
19 going to speak to, we are a regional trauma center, but
20 we're locally funded. We take care of people from a huge,
21 huge geographic area because we are capable of doing that, a
22 burn center, maternal-fetal medicine, neuro intensive care,

1 et cetera, those kinds of things, sophisticated cancer care.
2 How could we work with those folks who are not close to an
3 academic center and be assistive to them without stealing
4 their patients? You know what they are afraid of, is if
5 they ever send them to us, they go into a vortex and they
6 never come back.

7 And so what we have to do is become serving
8 leaders and send those patients back home when they can be
9 cared for back home. And so I think that we need to work
10 those things out on a regional basis, and right now we are
11 living with policies created in the 1950s, county-based
12 finance systems that make no sense at all. We need to at
13 least have regional finance systems, or the Federal
14 Government or someone else saying let's use the resources we
15 already have, the medical school, to become regional
16 centers, and let's reward them for reaching out and taking
17 care of people across their jurisdictions.

18 And I think particularly in things like surge
19 capacity, there is no business model for us to create surge
20 capacity, but we need to for the security of this country,
21 for H1N1, for SARS, et cetera. What could you do to
22 stimulate this through the existing resources and task them

1 with helping others and task them with being mentors to the
2 rest of the system? You know, we can create a virtual
3 network pretty easily without ownership, and the technology
4 is there.

5 DR. MEHLER: I think a couple other ideas, and
6 certainly I do not by any means have all the solutions to
7 that. But I think that providing data to the private folks
8 in the hospital I think is very important. So why does Joe
9 Blow have a readmission rate of 4 percent and yours is 11
10 percent? Why is your blood use twice as much as someone
11 else in the hospital? And figure out systems that could
12 provide credible data in a concurrent and timely manner I
13 think is important across all facets of medical care.

14 In addition to that, if you look at Eric Coleman's
15 paper that was published in the New England Journal about
16 six months ago looking at readmissions in Medicare, it's
17 fascinating when you look at some of the small print in that
18 study, but 50 percent of the patients that got readmitted
19 within a month were actually readmitted for medical reasons,
20 not surgical reasons, in the surgical population. To me, I
21 think that we have to be more integrated within hospitals,
22 and we have to stop these silos, so I am a medicine patient,

1 I can't get the surgeons involved, and vice versa.

2 There was just a study published in the Archives
3 of Internal Medicine this month that looked at ICU outcomes
4 to say for hospitals that don't have a lot of intensivists,
5 how can you achieve great outcomes? And the key there was a
6 multidisciplinary team to effectuate care.

7 And so I think that we have to -- at Denver Health
8 what we have done -- and I have a couple scars on my back
9 from this. We put in mandatory consults. If you have staph
10 aureus bacteremia, you get an ID consult. I don't care how
11 smart you are. I don't care how many of these you have
12 taken care of. Because we published a couple studies on
13 this showing that care, as Dr. Anderson just alluded to, was
14 very varied across providers. You can't have that. There's
15 one way that you take care of staph aureus bacteremia.
16 There's one duration of therapy that you need for them.

17 And so I think that we have to be brave to say
18 that there are certain conditions when you need a specialist
19 involved and you can't be out there on your own. Whether
20 you are in at Denver Health, whether you are in a private
21 hospital, I think you need to have systems of care that
22 ensure that the patients are getting good outcomes and you

1 don't have a cowboy out there who is sort of doing it the
2 way he has done it for 20 years but nobody sort of holds
3 accountability there. And I think the more that we have
4 systems through CPOE that put in guidelines, so when you put
5 in an order for a CTPE, it says have you calculated a Well's
6 score to make sure this person is likely to have a DVT or a
7 PE.

8 As you know, CTPE's are being used way, way too
9 much in the United States right now, creating health issues
10 with lymphoma and other issues, but just waste of care.

11 What we have done is we have embedded rules in
12 CPOE that you have to answer the rules in order to move to
13 the next step, and that's important. If you make it part of
14 the work flow, even in private hospitals or public
15 hospitals, that then drives care if it is evidence-based.

16 MR. BERTKO: First, let me be the next among --
17 it's great to hear success stories from you guys and your
18 leadership teams. The question I have is: If you were
19 sitting on this side of the table, how would you get the
20 attention of the other hospitals around? And I'm guessing
21 that you guys have constant financial pressure from your
22 funding sources. What we find, at least, at Medicare

1 hospitals is that they frequently have pretty good revenue
2 streams from their private payers. And what would you have
3 us do or what would you do to get people in your peer
4 hospitals to act a little more urgently on these quality
5 issues?

6 DR. MEHLER: Well, I think that the key is
7 transparency of data. I think that we have the power within
8 IT now to give good data back to people, and I think we have
9 to have transparency across health care systems. And I
10 think that that is what is holding us back in many places.
11 In many hospitals you have no clue, really, when you drill
12 down as to what's going on.

13 And so if I was sitting on the other side of the
14 table, I would say that if a safety net hospital like
15 Parkland or Denver Health have been able to achieve this
16 phenomenal quality success and this creativity, there's no
17 reason that people that have commercially insured patients
18 can't achieve it.

19 But more importantly, as Dr. Anderson also said,
20 data, you need data, and you need to have transparency in
21 health care so that there is nothing hidden. And regardless
22 of your standing in the community or who you are,

1 everybody's data is out there. And we talk about it at the
2 Med Staff Executive Committee, and if there is an outlier --
3 we have moved too far. We say no blame, no blame in
4 medicine. But we've gone too far. As Wachter and Pronovost
5 have really promoted, no blame is fine, but there's got to
6 be accountability. And the way you get accountability is by
7 having credible objective data that are shared and that you
8 hold people accountable for. That to me is the key.

9 DR. ANDERSON: I'm actually, as a disclosure, on
10 the board of the American Hospital Association, and as I've
11 gone around and looked at a lot of the hospitals and
12 visited, I've got to tell you, most people are very --
13 they're good people of good will who want to see things
14 better. They want to align with their doctors. Sometimes
15 the doctors don't want to. There's not that ability to
16 align as much. There's a lack of trust. But they're
17 basically good people, and I think we could harness a great
18 deal of good will that is existent in the profession and the
19 industry if we actually also try to recognize that we all
20 need to be on a journey to get better daily.

21 There is an Indian proverb that says it's not
22 noble to be better than another man but to be better than

1 yourself yesterday. And if we look at that and we are
2 trying to improve all the time, and we put incentives up
3 there for improvement, some people are going to start at a
4 different place, but you don't want them to say, "I can't
5 get there." You know, "I don't want to jump rope, put the
6 rope on the ground, I'll step over it." No.

7 I mean, we have got to set some standards. We've
8 got to try to move toward the incentives. But I would
9 reward people actually for moving in the right direction and
10 giving doctors an incentive to align with their hospitals
11 toward that direction instead of seeing themselves
12 oftentimes in competition.

13 But, you know, when the business model prevails
14 and the doctors have the day surgery center across the
15 street and they're competing with the hospital, and they
16 give the hospital the really sicker patients, we see stuff
17 like that all the time. It's hard to compare, you know,
18 what's happening in one setting versus another because of
19 financial incentives.

20 I would like to see us be able to neutralize those
21 and to put the patient first, put the outcomes we really
22 want first, and put them out from in front of the people to

1 get them. And there are people who've done it. I mean,
2 everybody has role models, and I won't hold us out as a role
3 model. We still have a long way to go to be where I think
4 we ultimately can be. And so we would help other people go
5 down the road, but we also need to improve. And I think
6 that is the important thing, because none of us have
7 arrived. I don't know any place in the country, no matter -
8 - we'll hear Geisinger mentioned, and you'll hear, you know,
9 Virginia Mason. Everybody writes the stories. They have
10 not arrived either. They are all on a journey. But they're
11 starting at different points in their journey. So I would
12 encourage people to get on the road, if you will, and have
13 incentives for them to do it.

14 You know, there's a lot of people who worry about
15 punitive, they're worried about the stick and they want the
16 carrot all the time. You're going to have to have a mix of
17 both.

18 DR. MILSTEIN: A couple questions. First, I think
19 probably everybody here would agree that with your first
20 prescription, the way to achieve this is through exceptional
21 leadership. But if you think about the words "exceptional
22 leadership," it's not a nationally scalable concept, right,

1 because of the exceptions. I think in most industries the
2 exceptional leaders are the ones that the rest of the
3 industry learns from. That's how it works. In the very
4 competitive industries, everybody else learns very quickly
5 or they're out of business. That's not, you know, in a
6 somewhat less competitive hospital and doctor industry, you
7 know, you don't have that going. And so we then, you know,
8 turn to the problem of, you know, granted, our society needs
9 people like you who can discover, you know, the better,
10 cheaper ways of delivering health, but then we have to --
11 then what do we do for everybody else?

12 I think you've already actually done a terrific
13 job of giving us some ideas on that, and I think the nature
14 of the prior questions really, you know, I think, aligns
15 with what we know about innovation adoption. That is, if
16 you can make them more observable, it's easier for
17 unexceptional people to copy them. And I think things that
18 you're already doing such as, you know, setting up the LEAN
19 institutes and allowing people to sort of come on site and
20 kind of see, hear from peers, you know, who are in the same
21 job that they're in how it's being done and how it really is
22 feasible could really make a difference.

1 But thinking about how you might, you know, speed
2 the rate of spread it seems to me does really on the tools
3 that you mentioned earlier about, you know, you have to
4 think about can you do this by tele-video consults with
5 those that are really, you know, succeeding; how do you do
6 it so it doesn't require people getting on an airplane and
7 flying to Denver or Dallas, which is obviously a barrier for
8 a lot of clinical teams.

9 So my question is: Are there some things that,
10 you know, could be done to aid and abet that would be -- you
11 know, while we're waiting for the technology to put in place
12 to allow any clinician to tune into your best clinical
13 teams, you know, is there something we could do? I'm
14 thinking about in the early era of utilization review,
15 Milliman and Robinson put out a set of so-called, you know,
16 length-of-stay guidelines that had actual -- some suggested
17 inpatient clinical pathways that would get you, based on
18 what the exemplars had done, you know, a shorter length of
19 stay, better -- not so much better outcome, at least a
20 shorter length of stay.

21 For those organizations like yours that have
22 really been working on this for a while and have, I think,

1 very advanced notions as to what the best clinical pathway
2 might be for X, Y, and Z -- maybe you don't have, you know,
3 A through Z, but for many things -- is there an opportunity
4 for that to be kind of bundled into the -- I'll call it the
5 inpatient or in the case of, you know, chronically ill
6 ambulatory care, kind of, you know, version of the M&R
7 guidelines that would essentially make it even more easy,
8 you know, for people who are -- who don't even know about
9 what you're doing to essentially replicate what happened
10 with the M&R guidelines where you have, yes, it's a cookbook
11 and, yes, it would take medical leaders to figure out how to
12 adapt it to institutions and then populations in different
13 circumstances. But I think anything we can -- what are your
14 thoughts on how we get this stuff spread more quickly?
15 Because, you know, exceptional leaders like you are few and
16 far between in the industry.

17 DR. ANDERSON: I've been an educator all my life
18 in the medical school and still see patients and all that,
19 but, you know, sometimes education is not the answer. I
20 hate to say that because you really think that that's all
21 you need to do, and I really want to continue that. But
22 sometimes you have to put hard stops in with explanations.

1 So it's not necessarily cookbook medicine, but a CPOE will
2 tell you what medications you can use and, by the way, this
3 one is extremely expensive and this one is generic now and
4 quite affordable for your patients. And so, you know, what
5 is the difference? You can get the more expensive
6 medication, but you have got to explain yourself. And we
7 put in some hard stops that you can go around, but you have
8 got to explain yourself, and you're subject to peer review.

9 I think sometimes it's that kind of behavioral
10 change, so behavioral interventions may be actually as
11 important as educational interventions, and so a mix of
12 those things. But there are programs available in the CPOE
13 approach to algorithms and that sort of things that help you
14 standardize care and help you force out variations. That's
15 really ready now. Many of the ambulatory settings and that
16 sort of thing, you know, HEDIS recommendations and things.
17 We're measuring more process than outcome. We're going to
18 have to evolve to get outcome. The process in the meantime
19 may be where people need to start.

20 DR. MEHLER: In addition to that, I would just say
21 that the whole science of quality assurance and quality
22 improvement I think is pretty young, and I think it's not

1 well developed quite yet. It would be an interesting that
2 I've thought about a couple times, is that an organization
3 like UpToDate, which really all the residents breathe when
4 they're in the hospital, there's no UpToDate on quality
5 improvement in hospitals. What are the bottom-line things
6 that work that improve quality of care in hospitals? It
7 would be neat to have the leaders of quality in the United
8 States get together and work with UpToDate to put in
9 programs that are updated every quarter that say this is the
10 latest and greatest with regard to improving patient safety
11 across the hospital. So I'd like to see that go in as a way
12 to do it.

13 The other thing is that, as you know, after the
14 studies in the 1990s that proved if you give a patient a
15 beta blocker after a heart attack, you improve their
16 survival. We know that it took 15 years to get docs to
17 prescribe beta blockers. It doesn't make a lot of sense.

18 And one thing we struggle with at Denver Health --
19 and I would really echo what Dr. Anderson said. We're not
20 nirvana. We have a lot of improving at Denver Health.
21 We're doing a good job, but we have room for improvement.
22 And if you don't believe that, you're in trouble. You

1 better get off the boat when you get too cocky about those
2 things.

3 But I think that we all have guidelines. I was
4 just talking to Dr. Anderson's CMO over the last few days.
5 He and I have become buddies. And, you know, one of the big
6 issues, we all have policies and guidelines and care
7 practices, and you go there and there's thousands of these.
8 But what we need is dissemination. We need dissemination
9 committees in hospitals and medical communities to say this
10 is what's out there, now let's figure out a way to get the
11 information to the providers and to the bedside. That's
12 what I think is lacking.

13 So in response to your question, how do you speed
14 it up? We need to spend as much time on policy and
15 guideline development. We have to spend an equal amount or
16 perhaps more time on disseminating that information in an
17 efficient manner.

18 MR. HACKBARTH: Let's just do a time check here,
19 George. We have just about 20 minutes left here. Can I see
20 hands of how many people are in the queue? So we've got six
21 at least. If you will be quite disciplined in your question
22 asking, I'd appreciate it.

1 MR. GEORGE MILLER: Okay. I will be very brief.
2 And I really appreciate both of you being very, very candid
3 about where you are and where you need to be. That is also
4 an admirable trait.

5 I would still like to go back to my first question
6 about disparities of health and how you deal with that and
7 how you feel we, as a policy-making organization, can help
8 deal with that issue nationwide, or if there are things that
9 we can do, or if there's something unique.

10 And I'd also like a response concerning
11 accountable care organizations and the quality metrics that
12 you would recommend we have if we go that step further. I
13 think Dr. Mehler mentioned about accountable care
14 organizations and bundled payments, how we can make sure
15 that all Americans receive the same standard of care, no
16 matter what their ethnic background is or social background
17 or if they're poor or rich. How does that work from a
18 policy standpoint?

19 DR. MEHLER: You know, I think the whole issue of
20 comparative effectiveness, which in the Stimulus bill
21 there's going to be a lot of dollars for, we need those
22 answers right now. As an example, we really don't

1 understand hypertension in the Hispanic population. Those
2 studies have never been done. We understand some things
3 about African American hypertension, a little bit about
4 Caucasian. We know nothing about Hispanic hypertension,
5 really, what kind of pathophysiological basis is it.

6 One thing that could be done is making those
7 studies and sending out RFAs and those kind of things to
8 really promote health disparity research. Certainly, there
9 are some. There are dollars out there right now and I think
10 we've got to get the word out about them. But trying to
11 make that a bit easier to get that funding, I think is an
12 important way to get at ethnic disparities to really answer
13 some of these questions in regard to really how we're going
14 to make things better for the ethnically diverse populations
15 that we take care of.

16 The second question that you had was with regard
17 to -- it slips my mind.

18 MR. GEORGE MILLER: [Off microphone.] About
19 accountable care.

20 DR. MEHLER: I think the metrics have to be really
21 more in outcome than in process, and I think that's one of
22 the big problems right now, the way we incentivize things.

1 So if you get an A1c in a patient, you meet the standard,
2 but that to me is not the issue. It is really what have you
3 achieved with regard to their A1c or their blood pressure,
4 not that you have them on an ACE inhibitor, but what is the
5 hard outcome, and I think that we need more and more metrics
6 that really look at health outcomes rather than just process
7 measures.

8 The other thing that I think we have to be careful
9 of is that people quickly learn how to game those systems.
10 And so if you have a doctor who has dropped a person's sugar
11 from 300 to 150 but the target is 140, he gets nothing, but
12 the person who takes a person at 150 and drops them to 130,
13 they get the carrot, we have to be careful of that. So I
14 think we have to incentivize both outcomes, but we also have
15 to incentivize delta change, and in the vulnerable
16 populations, that's very important. If I take someone who
17 had no health care for the last ten years in my system but I
18 can't achieve blood pressure control after six months and
19 you penalize me, versus someone who has an insured
20 population, I think that's going to create more disparities
21 and more cherry picking, which is not good.

22 DR. ANDERSON: I think that's an important issue,

1 about the cherry picking. I'm on a committee on disparities
2 at the AHA and they're really focused on this issue and one
3 of the big fears of some of the folks in the private sector
4 was that if we really focus too much on these people, we
5 will avoid the population. If we are paying for outcome,
6 one of the bad things about outcome might be, I will just
7 avoid sick people, and that's a big issue.

8 I look at disparities as deferred maintenance on
9 people. It's like slum lords. We have people who have lots
10 of things that have accrued over time. You don't really fix
11 them right away, but you have got to get better and you have
12 got to get better. Sometimes, generationally, you have got
13 to get better. And you have got to then focus.

14 But being Baptist, you will understand this,
15 George, you folks, but I always say, I don't want justice, I
16 want mercy. And when you say, I want to get equal
17 treatment, I would argue with you that equal treatment is
18 not necessarily true. You may want more treatment, and
19 people want equity when in public health it may not be
20 equity. A statistician is a person who will get you drowned
21 crossing a river of average depth of three feet. There are
22 holes in the river that are eight feet deep and what we have

1 to do is go work on those holes and work on the disparity
2 issues.

3 If we're going to really change our numbers as a
4 nation, and part of our issue is because of disparities,
5 this nation doesn't look as good as other nations, and we
6 have the best sick care system in the world -- we have a bad
7 health care system -- and if we focus on disparities, our
8 numbers would come up remarkably.

9 So I think for a while, we need to intentionally
10 go after these issues with some veracity, and so I think for
11 a while, it may not be equity. It may be more than that.

12 DR. KANE: Well, I have two questions, but you
13 don't have to answer both of them. Actually, one is how --
14 you mentioned that the one reason your results on diverse
15 populations was good is that you had a diverse medical
16 staff, and so a question to you maybe is how did you achieve
17 that?

18 And then the second question actually is to Dr.
19 Anderson. If you were to retire sometime in the near
20 future, what would be the characteristics of your successor
21 and how have you ensured that that person will be there when
22 that time comes?

1 So maybe start with the first one about how do you
2 achieve a diversified medical staff. What do you do
3 different, because I know it's really hard to get a
4 diversified faculty, so I'm just wondering how you do a
5 diversified medical staff.

6 DR. MEHLER: Well, I think one of the things that
7 does that is community-oriented primary care. When you have
8 the health care system in the communities, then oftentimes
9 people that grew up in those communities are the ones that
10 come back to your hospital to practice. So we have a number
11 of doctors at Denver Health that grew up in inner-city
12 Denver and they want to come back to their communities. If
13 we didn't have an integrated system, if we didn't have
14 community-oriented primary care, they'd have no reason to
15 come back there.

16 Number two, we try to figure out ways to incent
17 them to understand the sort of sacred mission of what we do
18 at Denver Health. So when I was Chief of Medicine and I was
19 trying to recruit people, I would tell them, this is what I
20 can do for you to study this issue in the culture that you
21 come from. So when I hired those two Russian physicians, I
22 said, we have a captive population of thousands of these

1 patients. I'll give you interpreters. I'll do what we've
2 got to do. And we published off of that population. So
3 when you can tie the academic mission in with the clinical
4 mission, it's a way to get them there, as well.

5 And then the third issue is I think that your
6 reputation sort of drives it. If they in the community and
7 nationally you're known as a Mecca with regard to health
8 care delivery, then people want to come to you and so you
9 try to, therefore, when you have a lot of people that are
10 knocking on your door for jobs, you try to make sure that
11 you're doing a good job in getting an ethnically diverse
12 provider and nursing staff.

13 DR. ANDERSON: Our medical school next door, as
14 Karen will attest, there are not as many women as there
15 ought to be. There are not as many minorities as there
16 ought to be. It's a wonderful medical school, one of the
17 top 15 in the country. But success oftentimes blinds you
18 more than failure.

19 In my COPC, the 150 doctors I have, half are women
20 and half are ethnic minority, and part of the same reason
21 that Philip talked about, people want to come back and serve
22 their community. I have been accused of hiring

1 missionaries, and I will plead guilty, because you can get
2 something done. But I'm hiring doctors who understand that
3 we've got to work with entire patient populations and
4 stewardship is about not just putting everything with one
5 person where you don't know if that's going to help, you
6 know, but that dollar can be used down to take care of other
7 things going on in the community.

8 They like the model. COPC attracts them, because
9 primary care is very difficult to attract people to right
10 now. You've got to have some way to show outcome and my
11 life makes a difference, and I think that's important.

12 Now, as far as my replacement, there are lots of
13 people that would be loving to find that out --

14 [Laughter.]

15 DR. ANDERSON: -- but let me say, I have got three
16 people internally at the very top, and one is the CFO, one
17 is the COO, both have run private hospitals, who came over
18 because they saw something happening at Parkland, and I
19 asked them to because I had helped train them years ago and
20 said, I want you to come back and do this. And then my
21 Chief Medical Officer is a previous Chief Resident who went
22 off someplace else for 20 years and I went and asked him to

1 come back.

2 I have three other outside names of people I have
3 been impressed with that I have on my board, so they will
4 have outside and inside, but they will choose my successor,
5 not me. I'd love to see it be a physician who gets it, who
6 understands that we're taking care of people. That is what
7 this is about. But, you know, it can also be a very good
8 finance person who will have an empowered CMO model. And I
9 think that's really critical.

10 Do you have both components focused on that, and
11 that's important, but not for just when you retire. That's
12 for also if you don't make it to work the next day. I mean,
13 the succession plan is really for if you die, and I've had
14 that happen to me, and that's one reason we've really got a
15 lot of depth in my organization because my number two guy
16 died and I didn't have a succession plan in place for that.
17 So I got to do his job for two years and mine. I didn't
18 like that.

19 But I think it's hard to find replacements for
20 people, because Patty will retire at the same time I do.
21 She had been one of the people I would have gone to steal,
22 you know what I mean? And if I were a board person, because

1 you like to find people who get it. But some of the CMOs
2 that are behind them, I think, are the people who will take
3 our place. Motivation and serving in leadership is what I
4 look for more than I would look for brilliance. Persistence
5 is more important than brilliance.

6 DR. KANE: Great. Thanks.

7 DR. BERENSON: quickly, agreeing that we want to
8 get to integrated care and payment models that support
9 integrated care, are there any immediate things that
10 Medicare could do the way Medicare does business in its
11 current payment models that could happen tomorrow that would
12 make your lives easier, would promote the integrated care
13 that we're talking about, in DRGs, fee schedules, anything
14 like that? Does anything come to mind?

15 DR. MEHLER: You know, I think one thing that
16 ought to be looked at, which may be a conundrum we don't
17 want to talk about, is sort of the doughnut in Medicare D.
18 I mean, I think there's pretty good evidence that when
19 people hit that, their adherence to medical regimens goes
20 off, and because most of the people that are in that have
21 chronic illnesses, they don't suddenly not need their
22 medicines at that point.

1 I really think that those value-based insurance
2 programs where we don't have any copays for things that have
3 been proven in evidence-based to be efficacious, that's the
4 way to go. So, as you know, Pitney-Bowes has really been a
5 leader in that regard, so basically they don't charge for
6 mammograms and they don't charge for pap smears. It makes a
7 lot of sense. The ROI on that is pretty substantial.

8 So I think it's a combination of figuring out that
9 there are things that clearly have been proven to be
10 effective, but in our populations, people have a limited
11 amount of dollars and they're either going to spend it on
12 food or they're going to spend it on health care, and
13 ultimately, we're still going to have to take care of them
14 tomorrow because we're the provider of last resort. So I
15 think there have to be creative ways to think about some of
16 the impediments that in the end will cost us a little money,
17 but I think ultimately will save us money.

18 DR. ANDERSON: I think that we've set the system
19 up in a zero-sum sometimes in policies. And in fact, if
20 five percent costs 50 percent and ten percent costs 90
21 percent -- and you hear these numbers batted around --
22 focusing on those really sick patients and paying for care

1 management, paying for the wrap-around services, paying for
2 the things that we could do as a capitated model if we were
3 in charge for all that.

4 Many of my Medicare patients, as I said, are
5 Medicaid patients, as well, and they're very poor. We, for
6 a while, we don't charge them -- with Medicare, we didn't
7 charge them because they qualified for charity. We still
8 had to go through all of the same policy things to be sure
9 that we weren't trying to entice people to come to us who
10 can't pay. I mean, it was really kind of a crazy thing, you
11 know, that we might be doing something that would entice
12 people to use our services and increase admissions. We
13 don't make money on them.

14 So in a fashion, what could we do to do some
15 demonstration projects on that ten percent that cost so
16 much? Almost anything else we do with the people who don't
17 use very much won't cost hardly anything compared to these
18 folks that we're really not focusing on to maybe do more
19 for, we might do more for, but in an ambulatory setting
20 outside the hospital and their quality of life would
21 improve.

22 And I think palliative care is very important.

1 Somewhere at the end of life, we've got to deal with our --
2 yes, we can do something, but should we do something? We
3 are going to have to have that discussion as a nation,
4 because sometimes we're very meddling and we're
5 mischievous with what we can do and not answer the question
6 should we or not. And I think there are enough patients
7 that don't want us to that we don't have to worry about the
8 ones that want everything done. I mean, that's not the
9 issue ordinarily.

10 So I think we're going to have to be thoughtful
11 about how we deal with things that are marginal value that
12 just don't yield good results, and we think everybody should
13 have access to everything. I don't think we can afford
14 that, but we ought to be scientific about it and evidence-
15 based about it and do no harm if we can't do good.

16 MR. HACKBARTH: Okay. We are down to our last few
17 minutes.

18 DR. CROSSON: I will be brief. I just want to add
19 my praise as a physician for not only the presentations, but
20 the work that you both have done. It's just extraordinary.

21 I want to take one second to see if I can
22 paraphrase a bit what you've said, because the question on

1 the table is what can the Medicare program do, which is
2 admittedly about ten to 15 percent of your revenues,
3 respectively, to help promote quality and efficiency, and
4 what can we learn from the work that you've done, and I
5 think what I heard in here was that the Medicare program
6 could do a lot of things, but they're relatively indirect.
7 They all involve helping shape the environment in which the
8 work that you do takes place.

9 For example, supporting integration, which in
10 different ways for each of your organizations is important.
11 So work we've done, for example, policies that we've
12 discussed about reducing regulatory barriers to physician-
13 hospital integration, promoting bundled payments as an
14 incentive to integration, accountable care organizations,
15 and the like, I think are in that category.

16 And helping to promote incentives, both to your
17 institutions and potentially incentives directly to your
18 providers, that drives things in the right direction -- pay-
19 for-performance, and particularly, I think as was noted,
20 paying for outcomes as opposed to paying for process -- and
21 in so doing also being sensitive to the necessity to risk
22 adjust those systems for the kinds of populations that you

1 all deal with.

2 What I did not hear was direct Medicare help to
3 your institution or other institutions in quality
4 improvement, for example, larger investment in the QIOs.
5 Now, maybe that was just a deafening silence, but I think
6 it's important to have you say, is that what you mean?

7 DR. MEHLER: I'd like to -- so we haven't had a
8 lot of interaction with the QIO in Colorado. They're a good
9 group. I know a number of the doctors that work at CFMC,
10 but I can't tell you directly that they've had a big impact
11 on quality at Denver Health.

12 I think that one thing that we'd love to see
13 Medicare really think about is the core measures that are
14 coming out and them really being evidence-based. They've
15 come under a lot of heat, as you know. There's been
16 unintended consequences because of some of the core
17 measures, specifically the pneumonia ones. And as Dr.
18 Anderson alluded to, that many of the things that really
19 determine how our patients do are not the usual things you'd
20 think about that we measure.

21 There are rumors that the core measures are going
22 to go up in number significantly over the next few years,

1 and as a hospital, we really struggle with that. It takes a
2 lot of resources and it's not clear to me how many of these
3 really impact care.

4 So I would love to see for Medicare going forward
5 that there's perhaps additional deliberation on the core
6 measures that we currently have and ensuring that the new
7 ones that come out are really evidence-based. I think you
8 can effectuate more -- you know, there's this whole concept
9 of improvement fatigue and initiative fatigue. There's just
10 too many things that we have to do right now and I think we
11 just have to be a bit more selective in trying to promulgate
12 the ones that have the most substantive return to really
13 improve care.

14 The QIO issue, maybe some of those dollars could
15 be diverted elsewhere to try to effectuate some of that
16 within the hospital, to effectuate good quality.

17 DR. ANDERSON: You know, I guess instead of
18 looking at the QIO, I've looked at the IOM and some of the
19 studies they've done on outcomes and looking at chronic
20 disease models and which ones we can have big impact on --
21 there are about 20 that cost a fortune -- and how we can
22 actually do care management and those kinds of things.

1 We've looked at the private IHI and the rapid
2 implementation. We've looked at UHC and others who have
3 done comparison so we compare ourselves on that grid with
4 our cohorts, but we've done one or two projects with the QIO
5 in Texas. And we see it a lot of times as looking at the
6 finance side instead of the true quality side as much, I
7 think, or we're trying to deal with the fraud and abuse
8 aspects of things instead of how do I really move this field
9 forward.

10 And so I think we've looked other places more than
11 we've looked at them. Even though they're very good and I
12 don't think anybody doubts their good faith and that sort of
13 thing, they're good people, I don't know if the focus --
14 AHRQ, HRSA, some of the ones that have had demonstration
15 projects, they tend to be more meter movers than I have seen
16 the State's QIOs be. That's my perception. I may be wrong.

17 MR. BUTLER: One quick direct question. We've
18 looked in MedPAC at the relationship between financially-
19 stressed hospitals and the profitability in Medicare and
20 shown that there's something like ten percent of the
21 hospitals that are financially stressed that actually make a
22 0.5 percent margin. So how do each of you do on your

1 Medicare margins?

2 DR. ANDERSON: We lose money on Medicaid, which is
3 a big part of our business, and obviously the self-pay. I
4 think that we're doing pretty well on Medicare. People say
5 they lose money, but when they lose money, they're looking
6 at fully-loaded charges. As we start to build a new
7 hospital, which we're going to build one with 38 percent
8 more capacity, take care of more of the charity load in that
9 community, and you've got new capital costs, because we were
10 debt-free, that profile is going to change. But we were
11 debt-free in an old 1954 building. We were making a margin
12 with Medicare, principally because of the add-ons for
13 medical education and being the largest residency program in
14 Texas.

15 But the fact that there were Medicaid and Medicare
16 patients, you also then had train wrecks, I mean, people
17 that cost a fortune, and the DRG doesn't even begin to touch
18 those folks. So to a degree, we've seen that high-risk
19 population -- that's one reason we try to do the care
20 management we're trying to do, because those folks can
21 really be a huge, huge hit on you. But if you just looked
22 generally across the board, I'd love to have just a routine

1 run-of-the-mill Medicare patient instead of the Medicare-
2 Medicaid crossovers. I would hope I could make money on
3 those, actually.

4 I heard a statement the other day at a board
5 meeting that the tenant had actually said as a corporation,
6 they were trying to figure out how to make it work on
7 Medicare alone because of the payer problems without reform.
8 If reform doesn't come, what are we going to do? And
9 everybody in the room moaned. I mean, everybody moaned
10 except the public hospitals who said, it may be an
11 opportunity.

12 [Laughter.]

13 DR. MEHLER: We do okay on inpatient Medicare. We
14 do very well on Medicare HMO products. Our own Medicare
15 Advantage product, we do very well on. We make actually
16 money on Medicaid, again, in an HMO model. We feel that
17 that's the way to do it. And we have passive enrollment in
18 Colorado, so if you don't sign up for a Medicaid program,
19 you get passively enrolled to Denver Health, and that's been
20 a very significant financial boon for us.

21 On the outpatient arena with Medicare, we sort of
22 break even, perhaps, but we don't make money on our

1 outpatient. But we believe ultimately our outpatient
2 business saves us money because they don't end up in the ER
3 like Dr. Anderson was saying.

4 MR. KUHN: To the point that Arnie asked earlier
5 and Dr. Mehler answered in terms of dissemination, I
6 remember a fact I think I read about a year ago where it
7 said for every dollar spent on patient safety work, maybe
8 less than five cents were on dissemination or bringing that
9 information to the bedside. I hope I'm wrong on that
10 number, but it's disproportionately skewed against the
11 dissemination of the information out there.

12 But the one question I had for both of you, but
13 particularly Dr. Anderson, you raised the question earlier
14 or the issue earlier about social severity or maybe even a
15 poverty index. Can you tell me, have you seen any proxies
16 out there that would make sense that we could look at, and
17 if so, how would you use that or how would you see that
18 effective for institutions like yours or others across the
19 country?

20 DR. ANDERSON: It might be as insensitive as a
21 census tract or a ZIP code. One of the studies we are doing
22 on congestive heart failure readmissions, there was one

1 public housing project, and if that was the one that came
2 up, the chances of them being readmitted were very high.
3 But there are other things. If you have a married couple
4 and you just lost a spouse, for a period of time, we know
5 that they're at higher risk and that sort of thing.

6 But looking at the simple things like income and
7 disease burden, comorbidities, I mean, we looked at that for
8 the health outcome, but I think it's also important for the
9 social severity. I mean, do they have the resources they
10 need to get the care they need, you know, access to social
11 services.

12 We do a lot of our tax dollars, we use them to
13 provide wrap-around services because that keeps you out of
14 the hospital. And so there used to be a guy out in Santa
15 Clara Valley who was a hospital administrator there that
16 came up with the term Social Severity of Illness Index when
17 he was Chair of the National Association of Public
18 Hospitals, and we've all looked at that. But something
19 simple like income, family size, education levels, and
20 poverty area.

21 We have some areas in Dallas, West Dallas and
22 Cadillac Heights, where the people for years were exposed to

1 lead smelters and vermiculite, which is a form of asbestos,
2 and it's in the houses, it's in the attics and everything
3 else, and we looked at cancer rates in those communities.
4 So there's an environmental component, too, of people --
5 particularly poor people, people of color -- who have been
6 exposed to that element. And I can tell you, that makes a
7 huge difference on burden of illness.

8 And so we don't have a good index right now, but
9 that's the thing. We need resources to help us determine
10 what's a simple thing that could be easily measured on
11 admission.

12 The young man that's doing research for us says,
13 let's do it on the day of admission. If we wait until the
14 time they're being discharged, when we're moving them out in
15 3.8 days, it's too late. We haven't gotten things done for
16 them. So we try to identify them day one, and that's the
17 kind of research, I think, that's really important for us to
18 determine.

19 MR. HACKBARTH: Others?

20 Okay, not too bad, a little bit behind schedule.
21 Thank you very much, not just for your contributions to our
22 deliberations, but also for the exemplary model you provide

1 for American health care -- really terrific work that you
2 do.

3 DR. ANDERSON: Thank you.

4 MR. HACKBARTH: Okay, our next session is Services
5 Provided Under the In-Office Ancillary Exception.

6 Ariel, here's what I think we'll do on this.
7 We're about 10 minutes behind schedule, and given that we're
8 not contemplating recommendations in this area I think I'd
9 like to see if we can pare this down just a little bit.
10 What I propose to do is limit the commissioner participation
11 just to clarifying questions for this particular
12 presentation, and that will allow us to get back on schedule
13 and hopefully finish on time today, so whenever you're
14 ready.

15 MR. WINTER: I'll try to pare things back in my
16 presentation as well.

17 MR. HACKBARTH: Okay. Thank you.

18 MR. WINTER: Good afternoon. I'd like to begin by
19 thanking Hannah Miller for her help with this presentation.

20 During this cycle, we've been discussing the in-
21 office ancillary exception to the Stark Law and exploring
22 strategies to address concerns raised by the growth of

1 ancillary services in physician's offices. Our goal is to
2 include a chapter on this topic in the June report, but with
3 no recommendations.

4 In today's session, we'd like to focus on various
5 policy options, some of which you've seen in prior meetings.
6 Depending on your discussion and feedback, we could pursue
7 recommendations for the next cycle of meetings beginning in
8 the fall. I'm going to skip over most of the background
9 material in the interest of time, but it is included in your
10 paper.

11 Over the last several years, there's been an
12 increase in imaging, lab tests and physical therapy provided
13 in physicians' offices. At Peter's request, we examined the
14 share of Part B payments for different specialties that come
15 from ancillary services. We found that ancillaries,
16 particularly diagnostic imaging, accounted for a significant
17 share of Part B revenue in 2008 for several specialties, and
18 there's more information about this in your paper.

19 In a proposed rule, CMS asked for comment on
20 whether certain ancillary services should no longer qualify
21 for the in-office exception such as services not needed at
22 the time of the patient's office visit, to help with

1 diagnosis or treatment, but CMS has not yet followed up with
2 a specific proposal.

3 At our last meeting, we were asked to provide more
4 information about self-referral of radiation therapy and
5 outpatient therapy, which includes both physical and
6 occupational therapy. I'm going to first talk about
7 radiation therapy provided under the in-office exception.
8 This occurs when physicians other than radiation oncologists
9 refer patients for radiation therapy provided in their
10 offices.

11 Medicare paid just over \$100 million to
12 specialties other than radiation oncology for radiation
13 therapy in 2008. This was an 84 percent cumulative increase
14 from 2003, but these specialties' share of total radiation
15 therapy payments stayed relatively small between 2003 and
16 2008 at about 5 percent. This was because there was rapid
17 growth in overall spending on radiation treatments.

18 Outpatient therapy is covered by the in-office
19 exception when a physician orders therapy that is provided
20 by therapists employed by the physician's group. Therapists
21 employed by physicians may provide therapy incident to a
22 physician service or may bill Medicare independently.

1 Therapists who bill independently are called therapists in
2 private practice. The distinction is that incident to
3 services must be supervised by a physician who is in the
4 same office when the services are delivered, whereas
5 therapists who bill independently do not require physician
6 supervision. Many physicians may prefer that a therapist
7 bill Medicare independently because there's no requirement
8 for physician supervision.

9 Now let's take a look at the data on therapy
10 spending. These pie charts show the distribution of
11 physician fee schedule spending for therapy services in 2003
12 on the left and 2008 on the right. Overall, spending grew
13 from \$1.4 billion in 2003 to \$2.2 billion in 2008. The
14 share of therapy services furnished incident to a physician
15 service fell by nearly half from 30 to 16 percent. At the
16 same time, the share of services delivered by physical or
17 occupational therapists in private practice grew from 70 to
18 84 percent.

19 These changes could reflect a policy clarification
20 by CMS in 2003 which said that therapists could be employees
21 of physician practices, but still be considered therapists
22 in private practice. Unfortunately, Medicare claims do not

1 indicate whether therapists in private practice are employed
2 by a physician group or practice separately from a group.
3 So we are unable to estimate how much of the money spent on
4 physical therapy was related to self-referral.

5 Here are a range of options we could consider to
6 address concerns about in-office ancillary services based on
7 your comments from prior meetings and staff work since then.
8 We have separated radiation therapy and outpatient therapy
9 from diagnostic tests based on a concern expressed by
10 several commissioners that self-referral of therapeutic
11 services may have a greater impact on treatment decisions
12 than self-referral of tests. The first column shows
13 potential strategies for radiation therapy and outpatient
14 therapy, and the second column shows potential strategies
15 for imaging and lab tests.

16 I won't go into much detail on the final policy,
17 the payment accuracy option, which is the last one your
18 slide, because there is separate work going on in this area.
19 The reason we included it here is because the rapid growth
20 of ancillary services, along with the use of new
21 technologies, raises questions about equity and accuracy of
22 physician payments.

1 I'll first talk about the set of options related
2 to outpatient therapy and radiation therapy. The first
3 approach would be to exclude these services from in-office
4 exception based on the rationale that physician investment
5 in these services may skew clinical decisions about the
6 treatment of patients. There may be a concern that this
7 change would inconvenience patients by forcing them to
8 receive care in hospitals. However, patients would still be
9 able to receive outpatient therapy from therapists in
10 private practice who are not employed by physician groups.
11 In addition, patients could continue to receive radiation
12 therapy from freestanding radiation oncology practices.

13 This change would not affect providers who
14 primarily serve rural beneficiaries because these providers
15 have a special exception from the self-referral rules.
16 However, this change would limit clinically integrated
17 groups that treat a wide variety of cancers using a range of
18 modalities including radiation therapy. For example, a
19 medical oncologist would no longer be able to refer patients
20 to a radiation oncology who is in the same group, for
21 radiation therapy.

22 Under the second option, radiation therapy and

1 outpatient therapy would be excluded from the in-office
2 exception unless the practices were clinically integrated.
3 What we're trying to do here is balance the risks of higher
4 volume that are related to self-referral with the potential
5 benefits of a clinically integrated practice such as
6 comprehensive and coordinated care. A key issue, of course,
7 would be how to define clinical integration, and there are
8 several ways you could think about this, but one idea would
9 be to require that each physician in the group provide a
10 substantial share of his or her services, such as 75
11 percent, through the group.

12 Currently, groups can contract with or employ
13 specialists on a part-time basis to perform and supervise
14 ancillary services. For example, a group can set up a
15 radiation treatment center and contract part-time with a
16 radiation oncologist to perform and supervise the radiation
17 therapy.

18 It's important to point out that even clinically
19 integrated groups have an incentive to drive up volume under
20 the current fee-for-service payment system. Eventually, the
21 payment system will need to be changed to hold providers
22 accountable for cost and quality.

1 Now I'll move on to talk about imaging and lab
2 tests. Under the first approach under these set of options,
3 diagnostic tests would be excluded from the in-office
4 exception unless they are usually provided on the same day
5 as an office visit. One of the primary justifications for
6 the exception is that it enables physicians to make rapid
7 diagnoses and initiate treatment during a patient's office
8 visit. As we discussed at the last meeting, there's wide
9 variation, and now frequently different types of tests are
10 furnished on the same days as an office visit.

11 An important issue under this option would be
12 defining which diagnostic tests should be covered by the
13 exception. One option would be to set a numeric threshold
14 for how frequently tests should be provided on the same day
15 as an office visit in order to be covered. Another option
16 would be to only cover tests that do not require advanced
17 scheduling. And with either approach, there would be
18 significant implementation challenges.

19 A second option for imaging and lab tests would be
20 to exclude them from the in-office exception unless the
21 practice was clinically integrated. We presented the same
22 option for radiation therapy and physical therapy, and the

1 issues are the same. So I'm going to skip over this and
2 move on to the next slide.

3 The third option would be to reduce payment rates
4 for a task performed by self-referring physicians. Studies
5 by the Commission and other researchers have found that
6 physicians who furnish imaging services in their own offices
7 refer patients for more imaging than other physicians. In
8 addition, research by OIG has found that patients of
9 physicians who owned clinical labs receive 45 percent more
10 lab tests than all Medicare beneficiaries, on average. The
11 objective of this approach is to recapture some of the
12 additional Medicare spending that is associated with self-
13 referral of diagnostic tests while continuing to allow
14 physicians to provide these services in their offices.

15 A couple of policy design options to think about
16 would be whether the policy should apply to all diagnostic
17 tests or a subset. Reducing payments for all tests would be
18 simpler to implement, but it would affect many more
19 providers as well as many more services. Alternatively,
20 this policy could be limited to high-cost imaging services
21 and lab tests, or tests that are not commonly performed on
22 the same day as a visit. Another issue would be how to

1 determine the size of the payment reduction.

2 So, to sum things up, we describe several options
3 to address concerns related to in-office ancillary services.
4 We'd like to get your feedback on which of these strategies,
5 if any, we should consider making recommendations on in the
6 future. Our plan is not to include recommendations on this
7 topic in the June report, but we could consider a
8 recommendation during the next cycle of meetings and
9 reports.

10 MR. HACKBARTH: Okay, thank you, Ariel.

11 We have, let's see, 25 minutes for commissioners.
12 What I'd like to do is let's go through a round one, and
13 then if we have any additional time we'll try to squeeze in
14 a few more substantive comments, but I really do want to
15 finish at 3:45.

16 DR. STUART: This is probably just my naivete, but
17 I'll ask it anyway. It strikes me that somewhere there must
18 be a way to do bundling to handle this. Is this something
19 that makes any sense and have you looked at it?

20 MR. WINTER: It's something on our longer-term
21 agenda, both packaging which refers to increasing the size
22 of the payment for services performed during the same

1 encounter by the same provider, which is frequently done in
2 the outpatient department, as well as bundling which would
3 involve a payment that includes multiple encounters, perhaps
4 by multiple providers.

5 We've not done a lot of really in-depth work this
6 area. There is, of course, the recommendation the
7 Commission made to begin experimenting with bundling for
8 services around admission. But in terms of specifically
9 outpatient services or conditions that tend to be treated
10 more in the outpatient, more outside a hospital, we've not
11 gone very far in that direction, but it is something on our
12 agenda, and we mentioned it briefly in the March report.

13 DR. CASTELLANOS: I guess my clarification is that
14 I think this is a very important subject and to have to
15 limit it because of time constraints I don't think is
16 appropriate, and I don't have any comments.

17 MR. HACKBARTH: Rest assured, Ron, that we will not
18 move ahead on any recommendations until we have the
19 appropriate discussion. So I'm sympathetic with your
20 concern.

21 Others clarifying?

22 MS. KANE: Yes, have you looked at all at the

1 difference in ordering patterns when a physician is employed
2 by a hospital that encourages them to use, you know? I mean
3 I've heard that one of the reasons you employ physicians is
4 to capture their ancillary volume. Then the one question
5 is: Are they also encouraged to order more tests in an
6 employed situation?

7 I guess I'm not sure that this is any worse when
8 the physician owns the equipment than when the physician is
9 employed by an entity that also stands to benefit from
10 tests. Just, have you looked at the ordering pattern
11 differences, if any, between these?

12 MR. WINTER: We have not. It would be a great
13 question to look at.

14 I'm not aware of a way to identify whether
15 physicians are employed by a hospital based on Medicare
16 claims data. There might be other data sets available which
17 identify whether physicians are employed, and we can look
18 into that.

19 One thing I want to point out is that there is an
20 exception in the Stark Law for physicians who are employed,
21 and there is the entity that employs them theoretically is
22 not supposed to be linked, is not supposed to link their

1 compensation to the physician's referrals for diagnostic
2 tests and other ancillary services covered by the Stark Law.
3 So there may be ways to get around that, but that's sort of
4 the technical rule.

5 DR. BERENSON: I'm interested in the integrated
6 group issue, and I understand, as Glenn mentioned last time,
7 it would completely interfere with the whole business model
8 of an integrated group to sort of prevent a self-referral.
9 And at the same time I agree with what you said up there,
10 which is in a fee-for-service world it's not at all clear
11 that we're getting anything other than lots of volume from
12 integration.

13 Do we have an ability to actually look at
14 utilization associated with patients getting care in
15 integrated groups compared to non-integrated groups, maybe
16 through some attribution model? I'd like to know more about
17 what behavior we're seeing currently in thinking about how
18 we would approach this problem. I mean is that something we
19 could do?

20 MR. WINTER: We can think about -- I would want to
21 talk to my colleagues like Christina, who have done work --
22 looking at, with claims data to look at multi-specialty or

1 integrated groups and see if what we could come up with
2 claims data. It would be difficult because we only have a
3 share of their business. We don't have the private payer.

4 DR. BERENSON: That's why it would have to have
5 kind of attribution model that we had some confidence in.
6 I'm not saying it is, but I'm just troubled by sort of this
7 broad exception, and yet I don't have an alternative to it.

8 MR. HACKBARTH: I would say there are integrated
9 groups, and there are integrated groups. If it's a group
10 that is purely fee-for-service and just has everything in
11 one place, you may get a use pattern that is very similar --
12 a high use pattern, that is. On the other hand, if you have
13 a group that is largely capitated, they might have a very
14 different pattern. And it's a continuous variable. The
15 degree of capitation can be anywhere along a wide range. So
16 I'm not sure that it's a meaningful category, integrated
17 group, or not.

18 DR. BERENSON: Well, I was going to suggest that
19 if we had the ability to do it, then we would compare the
20 integrated groups that are predominantly capitated and those
21 that are all or predominantly fee-for-service. If we had
22 the basic methodology, it's something we could do.

1 Obviously, well, if it's capitated, even in fee-
2 for-service Medicare we wouldn't necessarily know how to
3 attribute.

4 MR. HACKBARTH: Okay, any other clarifying
5 questions?

6 MR. BUTLER: So we've discussed before things like
7 flagging the high utilizers if you could and then maybe
8 having starting with preauthorization, particularly for some
9 of the major imaging. Are we dropping that as a strategy or
10 just not on the table today?

11 MR. WINTER: That's sort of up to you all to
12 decide. We didn't bring it forward this time based on we
13 sort of went through the comments we got from the last
14 couple of meetings, and tried to figure out which were the
15 most, which options had the most support among the majority
16 of commissioners. We could certainly work that one back in
17 if that's what you want us to do, for the chapter in the
18 future.

19 MR. BUTLER: I just thought we, especially some
20 insurance colleagues around the table, like John, said this
21 actually works in imaging. So I would like to see it as an
22 option. It's not too hard to impose compared to some of the

1 other things that really are difficult to get around the
2 ownership. This is not a simple thing.

3 MR. WINTER: Just to be clear then, so you're
4 asking us to look at both flagging the high utilizers but
5 then subjecting them to some kind of prior authorization
6 method.

7 MR. BUTLER: I think that, yes. Then the average
8 Joes get off, you know. You're not burdening them with a
9 lot of bureaucracy for now. You're just trying to get the
10 low-hanging fruit, if you will, and putting a process that
11 might work.

12 MR. KUHN: Ariel, you had the one slide up here,
13 and maybe I missed it, but it showed the significant drop of
14 incident two services for therapy and a big gross-up of
15 activity in terms of physical therapy services. What was
16 going on at that time for that big change to occur?

17 MR. WINTER: In 2003, CMS announced a policy
18 clarification which said that therapists could be in prior
19 practice, meaning they don't require physician supervision,
20 but still employed by a physician group. So, until that
21 point, I think it was unclear whether physicians could do
22 that. Or if they wanted to bill for physical therapy, they

1 would have to do it on an incident two basis, which meant
2 they would have to meet all the supervision requirements
3 which are more onerous than when a therapist bills
4 independently in private practice. That could be
5 influencing the shift we're seeing from incident two to
6 therapists in private practice.

7 MR. KUHN: Thank you.

8 MR. WINTER: It's hard to disentangle the factors.

9 DR. CHERNEW: I just want to make sure that I'm
10 right in my assumption that the basic cost analysis would be
11 the same. In other words, we don't think that it's cheaper
12 for the physician necessarily to provide in-house versus
13 refer out. So we don't think there's a meaningful cost
14 difference.

15 This is really just essentially the patient gets a
16 big benefit. It's like lowering a co-pay, if you will.
17 They don't have to travel. So they use it a lot more, and a
18 physician gets a bigger incentive to refer to it because
19 they get more money, but it's not a cost issue.

20 So, if we were to adjust the fees, my point is
21 right now they're paid the same, right. So, if we were
22 going to adjust the fees, if they cost the same, someone is

1 going to be paid more generously than others because we
2 think the cost is the same.

3 MR. WINTER: Right, that's true. We think the
4 costs are the same, but it could be that the self-referring
5 practices because they could have the potential to drive up
6 volume more than a provider that depends on physicians for
7 referrals. So, if they're more efficient, that would lower.
8 That would spread their fixed costs over more services, and
9 that would reduce their cost per service, but we've not been
10 able to look at that analytically.

11 DR. CASTELLANOS: Can you clarify that answer? I
12 thought his question if he refers out, the costs would be
13 the same?

14 MR. WINTER: I thought the question was is the
15 cost the same for a self-referring practice, let's say doing
16 imaging, versus a freestanding center doing imaging? Are
17 the costs the same?

18 My point is if one setting can achieve higher
19 volume than the other, per machine, then they could spread
20 those fixed costs over more services and therefore have
21 lower cost per service.

22 DR. CHERNEW: And you couldn't tell which one was

1 which because the one that's getting referred to could be
2 like a hub. So the physician office might have a smaller
3 set of patients to do the scheduling --

4 DR. CASTELLANOS: How about if it was referred to
5 the hospital?

6 MR. WINTER: Yes, right, that can work both ways.
7 That is the entity that's non-self-referral, that's not
8 self-referring could have higher volume than the self-
9 referring entity, but it could be --

10 DR. CASTELLANOS: The hospital wouldn't have
11 higher costs.

12 DR. BERENSON: Or if not higher costs, we pay them
13 differently, more or less, and that's the point I think. I
14 mean that's what the cardiologists are now complaining
15 about. If we reduce the fees for nuclear imaging tests in
16 the office, then refer everybody to the hospital, and we'll
17 pay five times more is what the allegation is. So the
18 question, I think it's an important issue.

19 What's that?

20 DR. CASTELLANOS: And the co-insurance.

21 DR. BERENSON: And the co-insurance goes up.

22 MR. HACKBARTH: We still have about 15 minutes.

1 Ron, do you want to use some of that?

2 DR. CASTELLANOS: Just, my points are this is a
3 terribly important issue, both from a patient viewpoint, a
4 care continuation and coordination viewpoint, a cost
5 viewpoint not just to the patient, but to the Medicare
6 system. I just think we just need to really look into this.

7 Jay and myself briefly talked about this out in
8 the hall, and I have a lot of concern because I think the
9 system has some merit, but there is just no question that in
10 my opinion that there's abuse also.

11 As Arnie said last time, he said, you know,
12 there's 90 percent of the doctors are doing what they think
13 is appropriate, that they think is right. They're doing the
14 best thing for their patient and best thing for the
15 community. Yet, 10 percent aren't, and you don't want to
16 throw everybody under the bus.

17 MR. HACKBARTH: So where does that leave you in
18 terms of policy response? From that, do you conclude that
19 we ought not do anything at all, or would you lean to any
20 particular option that Ariel laid out, or is there some
21 other option that strikes you as a better choice?

22 DR. CASTELLANOS: I think we need to look at the

1 options, but I think we've already seen one option that does
2 work. It's an option that you've used, and I've heard it
3 discussed previously -- reimbursement on the procedure.
4 Make it appropriate to the procedure. Don't pay, like we
5 have done sometimes, excessively. Make it appropriate.

6 MR. HACKBARTH: Yes. So let's just pursue that
7 for a second.

8 To me, sort of the worst case is that somebody
9 goes out and buys a very expensive piece of equipment, and
10 then once they've got it in place the economics are I ought
11 to use it a lot because that gets me down the cost curve. I
12 spread the fixed costs, and that's where you have sort of
13 the most toxic incentives at work. So, what, if anything,
14 can you do to deter people from maybe making the investment?

15 It seems to me that if you price, set the unit
16 prices at a level that you have to have a substantial volume
17 to achieve, you may at least deter new investments. The
18 ones that are already in place, that's sort of like water
19 over the dam. But if you're really pricing down the cost
20 curve, that may deter people from buying new pieces of
21 equipment.

22 DR. SCANLON: I agree with you, but it's this

1 question of how far down the curve do you go because you
2 have to get to this point where you're getting closer to
3 that incremental cost, so that they're not going to be able
4 to spread that much of their fixed cost -- because if we
5 really believe that there's this potential for abuse, that
6 we can sort of order more of these kinds of tests, as we
7 move somewhat down that curve, the response will be, for the
8 existing owners, well, I can make this back by increasing
9 the volume even further. And then other people can see this
10 and say, well, that's a viable business model too. There's
11 that problem.

12 The other issue is as you're moving down towards
13 trying to get to this incremental cost it's incremental cost
14 at what scale, and what are going to be the implications of
15 that for convenience to patients in terms of access in
16 different areas, because if you get it to the point where
17 you're only able to share, spread a little bit of the fixed
18 costs through any individual service. So, therefore, you
19 have to have really significant volume. You got to have a
20 really large population in order to justify the service.
21 There's where you're going to get into the resistance
22 because you're going to hear from the medium-size and

1 smaller communities, you're shutting us out of the service.

2 DR. CROSSON: Well, I mean I was thinking along
3 the same line. I mean first of all what we have here is a
4 problem that I think we all recognize is real and a whole
5 set of solutions and everyone has them has a significant
6 problem associated with it, either conceptually or in terms
7 of trying to visualize how it would be implemented, and I'm
8 not sure I have a perfect one.

9 But I wondered whether or not we could think about
10 combining the idea that Peter brought back, or that John had
11 discussed initially, and that is to try to focus on those
12 providers, those situations which appear to be problematic
13 based on some statistical analysis. Then, in that
14 situation, you could do different things.

15 One would be to do preauthorization. That happens
16 to be something I don't particularly like because I don't
17 think it's that effective.

18 But another thing you could do in those cases
19 would be in that situation then, once some threshold had
20 been passed, would be to apply marginal pricing. After a
21 while, providers would know, gee, if I get to this point and
22 fall off the cliff, then the economics of using this piece

1 of equipment dramatically changes for me. So I better be
2 sure that I don't do that -- just a thought.

3 DR. BORMAN: I think one of the other pieces that
4 doesn't exactly fit in these very specific options will
5 relate to potentially episodes of care and bundling some of
6 these services -- that, for example, if the point of a visit
7 relates to establishing a new diagnosis of CHF or
8 reassessing it or something, there's so much money that
9 allows you to evaluate that through some bundle of tests.
10 If you want to do it through nuclear plus this lab test,
11 great, or if you want to do it some other way, but there's
12 sort of a limit.

13 And Nancy and I talked a bit about this earlier
14 today, and I think particularly for the four or five kinds
15 of high-volume diagnoses that we could identify some things
16 where perhaps that's an alternative to this because this is
17 fraught with all these risks that we've identified. I think
18 out of all the things we've talked about, what Jay
19 articulated and what was brought up about let's focus on the
20 outliers, I think that's always a good beginning strategy,
21 and I think it's something that perhaps we could do fairly
22 quickly, initially perhaps non-punitively and then ratchet

1 it up.

2 But I think another way to come at this would be
3 from the direction of frequent diagnosis, tests and test-
4 related bundles, that maybe in the end that's where the
5 bigger savings are achieved.

6 And there's more autonomy to local circumstances
7 where, particularly in the smaller community setting, maybe
8 you can work it up by X. You don't have Y available, and so
9 you utilize the resource you have. But you're not either
10 advantaged or disadvantaged, and you're not required to have
11 every kind of equipment in order to get all those returns.

12 DR. MILSTEIN: Yes, I think Ron makes a good point.
13 I think I'm the one who suggested just reduce the payment
14 rates for self-referring.

15 I think Ron's point is a good one. You wouldn't
16 want to penalize providers that were self-referring, but who
17 were doing so in a responsible manner. So the question is:
18 Is there a practical way of defining the term doing so in a
19 responsible manner?

20 I go to two different spots. One is to think
21 about sort of two. You can say, well, it's an algorithm
22 that basically says is the provider self-referring, and then

1 if you are you're in a different bucket than those who
2 aren't.

3 Then the next point in the algorithm might be
4 something, is this provider part of an especially cost-
5 effective, high-quality delivery system? If the answer to
6 that is yes, then they're dropped out of the presumed guilty
7 group.

8 I think about this because I think when we heard
9 the Virginia Mason presentation -- it was three or four
10 years ago -- one of the points they said is as they began to
11 innovate they realized that for low back pain getting the
12 physical therapy, their own physical therapy, involved
13 within two hours is really the way to get much more
14 efficient outcomes.

15 That's why I think having an initial screen of,
16 yes, they self-refer, but we have evidence that they're
17 exceptionally efficient, using the measures that we will
18 inevitably have to come up with as we move to accountable
19 care organizations, et cetera.

20 Then the next thing I would ask because I don't
21 want conscientious good stewards, who happen to be owning
22 their own equipment and self-referring, caught into this

1 penalty net. But say they don't qualify for that, but it
2 seems to be it would be possible to sort of calculate the
3 rate, maybe on some kind of case mix-adjusted basis which
4 they are using, whatever it is that they are self-referring
5 to, relative to the ambient rate in their communities that
6 providers who are using that test, who don't self-refer, who
7 are using external.

8 If there's no delta, which in the case of
9 practices like Ron, I would expect there would be much of a
10 delta, then no penalty. But for those that failed both of
11 the tests, that is their overall care is not exemplary in
12 value, and (b) they indeed are using the ancillary service
13 at a case mix-adjusted rate that is in excess of their peers
14 in the same community, in the same geography, on some kind
15 of a reasonably -- case mix adjustment would get refined
16 over time. But on a case mix adjustment basis, that's where
17 I think an automatic payment reduction would feel better to
18 me than just doing it across the board, which was my
19 inclination last time.

20 MS. KANE: When it's a hospital outpatient visit,
21 they go into a whole other mode of bundled payment for
22 ambulatory service, the APG.

1 MR. HACKBARTH: Not so much bundled.

2 MS. KANE: Some of it's bundled.

3 MR. HACKBARTH: They go into a different payment
4 system.

5 MS. KANE: But doesn't some of that include some
6 bundles of services that naturally occur together, and I
7 guess how different is that from what we're talking about?
8 I don't really have a good feeling for what types, how those
9 things are completely different.

10 I mean in other words, if the same patient with
11 the same problem went to a hospital outpatient department
12 for a bundle of services, they'd get paid on an APG rate for
13 stuff that went with that visit. But when they go to the
14 doctor's office, they get that visit unbundled. I'm just
15 wondering what's the difference in how those are structured.

16 MR. HACKBARTH: Ariel, if you want to address.

17 MR. WINTER: So the APGs have a higher degree of
18 packaging, particularly because of changes made in the last
19 couple of years, than physician fee schedule services. So,
20 as a couple of examples, if you get some kind of surgical
21 procedure or other procedure in the outpatient department,
22 certain imaging procedures that are done at the same time,

1 like image guidance, like if you're doing a biopsy and you
2 need some kind of imaging service that helps guide the
3 needle, that's packaged into the main payment, as well as
4 radial pharmaceuticals. So if you're doing a nuclear
5 medicine study, the radial pharmaceutical that's used,
6 that's packaged into the payment rate in the outpatient
7 side, whereas on the physician fee schedule side those
8 things are still paid separately.

9 So there's a greater degree of packaging on the
10 outpatient side, but it doesn't go so far as to include MRIs
11 and cat scans that are associated with a treatment for a
12 migraine headache or a knee injury, that sort of thing. It
13 doesn't go that far yet. They've expressed some interest in
14 expanding the bundles to include more things, but right now
15 they're sort of including things that are done, that are
16 integral to the main procedure, that are done during the
17 same encounter, same day, that sort of thing.

18 MS. KANE: So, if an outpatient came in and said,
19 I think I've sprained an ankle and needed an x-ray or
20 something, that wouldn't be bundled?

21 MR. WINTER: That's paid separately, currently.
22 The x-ray would be paid separately from the visit.

1 DR. MARK MILLER: [off microphone.]

2 MS. KANE: Yes, that's too bad.

3 DR. DEAN: I guess some of this leaves my head
4 spinning, trying to figure out how we can ever get the
5 prices right. It seems to me that one of the things, one of
6 the troubling things to me in the whole health reform issue
7 is there's been very little attention to the amount of money
8 we're spending on administration of all this system, and
9 these kinds of processes seem to me will only aggravate
10 that.

11 And it seems to me we just have to move toward
12 paying for episodes of care and let the decisions as to what
13 is appropriate be made at a local level based on given a
14 certain package of money, like our previous panel. These
15 guys had a certain amount of money to work with. It was
16 clearly limited, and they figured out a way to do it --
17 obviously, something that's very admirable and inspiring.

18 It seems to me that we need to take that lesson
19 and say, we're spending way too much money on counting
20 beans, and we need to give certain amounts of money. I
21 realize it's not easy and it's a big shift, but instead of
22 getting in these fights about whether that scan was

1 appropriate or inappropriate because on the front line it's
2 hard to make that decision sometimes. So, anyway, whatever.

3 MR. HACKBARTH: Well, I think over the course of
4 the many discussions we've had of this now, I think there's
5 broad agreement that ultimately the best solution is to move
6 to broader bundles of payment, get away from fee-for-
7 service. These issues are a byproduct of fee-for-service.

8 But that in itself is not something that's going
9 to happen overnight. It's got its own set of complexities
10 that we talk about in other conversations. So what we're
11 trying to do here is focus on steps that we might take in
12 the interim before we arrive at that promised land of more
13 bundled payment.

14 I think your point is well taken. While you're
15 working on the interim steps, you need to be very conscious
16 of the amount of resources required and the complexities and
17 the potential inequities. You can get yourself all tied up
18 in knots trying to operationalize halfway solutions. I very
19 much agree with that.

20 DR. CHERNEW: Do we have a sense of how much money
21 is on the table? If we actually knew and we could get it
22 all exactly right, if we were to make one of these changes,

1 how much are we talking about?

2 MR. WINTER: It's very difficult to say. I'll go
3 back to the example I gave about physical therapy, where we
4 don't really know how much of that is driven by or related
5 to physicians employing therapists. And even if we did,
6 there have not been many studies looking at what's the
7 induced demand effect when physicians employ therapists
8 versus referring to them independently.

9 There's a lot more work done in the area of
10 imaging, but there the estimates vary widely depending on
11 the methodology and the types of conditions, the types of
12 imaging modalities and those sorts of things. So it's
13 difficult to come up with a precise estimate.

14 We can try to think about in terms of imaging. We
15 can probably get a better sense of how many dollars are
16 being spent for services that are being delivered in
17 physician's offices. We can come up with some estimate of
18 that and get that to you in the future.

19 DR. CHERNEW: We had a debate, a discussion a
20 while back about the depreciation rules and the number of
21 hours for big types of equipment and stuff and various ways,
22 and we had a recommendation. Am I correct that that

1 recommendation ended up not being implemented or was
2 implemented, then it was repealed?

3 MR. HACKBARTH: It was the hours of use.

4 DR. CHERNEW: Right.

5 MR. HACKBARTH: The assumption that goes into the
6 practice expense calculation, how many hours is the
7 equipment assumed to be in use?

8 DR. CHERNEW: Right.

9 MR. HACKBARTH: Ariel, why don't you say what the
10 status of that is.

11 DR. CHERNEW: You were going to raise that?

12 MR. WINTER: We recommended increasing it, right,
13 to roughly 90 percent of the time, and that was adopted and
14 implemented by CMS beginning this year. It was also in the
15 different health reform bills.

16 DR. CHERNEW: [off microphone]

17 MR. WINTER: I believe that both bills would
18 increase the assumption. I think the Senate bill would have
19 done it more slowly and phased it in and would have done it
20 in a non-budget-neutral way, whereas CMS did it in a budget-
21 neutral way, so the dollars stay within the physician fee
22 schedule.

1 DR. BERENSON: But I think they got to a different
2 place. I don't think they got to 45 hours. I think they
3 got to something less, 75 percent. They got to a lower
4 number.

5 MR. WINTER: The Senate number, the Senate bill.
6 But CMS went to 90 percent. They adopted our
7 recommendation.

8 MR. HACKBARTH: And that is in effect now.

9 MR. WINTER: It's in effect now, yes, for advanced
10 imaging, for MRI and CT and PET.

11 MR. HACKBARTH: I don't think of pricing it more
12 aggressively, moving down the cost curve, as necessarily a
13 punitive thing. I see that as sort of a prudent policy to
14 do, independent of self-referral.

15 We're going to have to bring this to a close for
16 today. Thank you, Ariel, and I appreciate your being a good
17 sport about the shortened time.

18 Next is restructuring medical education funding.

19 [Pause.]

20 Okay. We have allotted two hours for this, and
21 the reason for that is that if we are to have
22 recommendations on GME for the June report, we need to have

1 our final votes, obviously, next month. And so that is our
2 task for today to decide what, if any, recommendations we
3 wish to bring back next month for a final vote.

4 As much time as we've spent on this, as much good
5 work as has been done by Cristina and Craig, this is a
6 difficult subject, and it hasn't been easy to coalesce
7 around recommendations. So we thought it was particularly
8 important, I thought it was particularly important to make
9 sure we had a full opportunity to air the issues.

10 With that preface, let me turn it over to
11 Cristina. Are you going first?

12 MS. BOCCUTI: Yes. Okay, so in this final session
13 this afternoon, Craig and I are going to present a
14 culmination of many of your conversations over the last year
15 and a half on this topic of medical education.

16 We are going to start with a discussion on the
17 need to restructure financing in order to place higher
18 emphasis on educational and workforce objectives. And then
19 we are going to present a set of overarching principles for
20 long-term restructuring. And considering that this set of
21 principles may take a while to implement, we also present
22 three specific recommendations that Medicare can take in the

1 interim. These are steps.

2 Next, please.

3 So, to start, in several ways, our nation's system
4 of medical education and graduate training is excellent: It
5 produces many superbly skilled clinicians while contributing
6 to important advances in medical science.

7 Yet the overall output of our medical education
8 system is not aligned with the fundamental improvements we
9 need in our delivery system to increase value for patients
10 and payers.

11 Delivery system reform cannot be accomplished
12 without simultaneously ensuring that the mix of providers we
13 need have the skills necessary to integrate care across
14 settings, improve quality, and use resources efficiently.

15 Medicare's financing, which marks the single-
16 largest GME payer, has created many of the problems. For
17 example, payments based on hospital admission census and
18 resident numbers are not an effective means for encouraging
19 hospitals to foster ideal educational programs and
20 environments.

21 Medicare spends over \$9 billion with little
22 accountability for educational standards or addressing

1 pipeline concerns. These could range from producing the
2 right mix of professionals, assuring rural access, and
3 increasing the racial, ethnic, and socioeconomic diversity
4 of our doctors and nurses.

5 All this said, we must acknowledge that
6 restructuring medical education financing is, of course, not
7 likely to completely override the incentives embedded in the
8 current fee-for-service system. The signals sent by those
9 systems guide the career choices of both medical students
10 and residents as well as the institutions that provide their
11 training.

12 So on to a set of principles for restructuring
13 medical education financing. The first is to transition to
14 a general revenue financing model. If society benefits from
15 the subsidization of medical education, then the costs
16 should be borne out of general revenue funding rather than
17 the Medicare payroll tax.

18 This broader approach recognizes that the current
19 method is not an effective mechanism for meeting either
20 education or workforce priorities across our country.

21 Pooling expenditures from Medicare, Medicaid, and
22 other public sources offers the opportunity to implement

1 more integrated policies to produce the health care
2 professionals we need for the 21st century.

3 We note three technical requirements that such a
4 transition should take. It should be budget neutral. This
5 transition -- or deficit neutral, excuse me. This
6 transition should not cost the Federal Government any more
7 than it is currently spending on medical education.

8 It should be phased in. Restructuring the funding
9 priorities must be implemented in a way that minimizes the
10 potential for unwanted disruption in medical education and
11 training.

12 And it should assure funding stability across
13 years. To meet educational and workforce goals, mandatory
14 appropriations authorized for multiple years will be
15 important in order to maintain a certain degree of funding
16 stability.

17 The second principle we introduce is to enhance
18 our capability to analyze health care workforce needs,
19 develop coordinated pipeline strategies, and assess their
20 impacts. It has become clear that market-based approaches
21 to workforce policies are not sufficient to ensure that we
22 have the right mix of health professionals in this country.

1 A general revenue financing model for medical
2 education offers the opportunity to study and implement
3 national workforce priorities. Through rigorous, unbiased
4 analysis, we can better understand supply and demand factors
5 across all health professions, inform a strategic plan for
6 pipeline dollars, and conduct longitudinal program
7 evaluation to assess pipeline incentive programs.

8 Multi-stakeholder input could play a role in
9 informing the workforce center's research agenda and
10 analysis.

11 Currently, the HRSA programs in place for
12 addressing workforce priorities are through Title VII, which
13 focuses more on physician training; and Title VIII, which
14 focuses on nurse training; and the National Health Service
15 Corps, which offers scholarship and loan forgiveness
16 programs for primary care providers in underserved areas.

17 Together these programs are budgeted for about
18 \$600 million in 2010. These programs address disparities in
19 patient access, and several are designed to attract students
20 from minority, rural, and low-income communities into health
21 professions.

22 I want to recognize Hannah Miller, who is in the

1 front row back there, who has become a resident expert on
2 these HRSA programs, and we plan to discuss them in more
3 detail in the June report. She can also help today with any
4 questions on these programs that you might have. But for
5 now, I'll just show her colorful chart, which is up here,
6 which represents spending on Title VII. It divides Title
7 VII funding by categories that are listed on the right hand
8 side, including diversity, primary care supply, et cetera.

9 You can see that funding has fluctuated in recent
10 years and that dollars for data collection and analysis have
11 grown to zero. GAO has recommended in the past that greater
12 efforts to measure impacts of these programs be a priority.
13 Investing more in unbiased program evaluation will guide us
14 to fund the programs that are most successful.

15 The third principle is to support accountability
16 for high educational standards. To do this, payment
17 formulas should reflect educational priorities. That is,
18 they should be linked to achievements on set goals.
19 Standards for these goals should be developed and assessed
20 by educational and accrediting bodies, insurers -- that
21 would be employers and health plans -- and patient
22 organizations. Also, payment formulas should recognize the

1 need to support faculty teaching time and faculty
2 development.

3 Teaching sites should also be accountable for the
4 environment that they provide, in terms of both
5 infrastructure and clinical care. It will be important to
6 establish incentives to support delivery system reforms,
7 such as team-based care, coordinated discharge planning, and
8 understanding the relative costs of tests and treatments.
9 The premise here is that residents and nurses who practice
10 in these kinds of environments will learn skills that they
11 need to incorporate into their lifelong practice styles.

12 So now we come to a draft recommendation on this
13 overarching set of three principles. I have working glasses
14 this time. The Congress should restructure medical
15 education financing adopting the following set of
16 principles: one, transition to stable general revenue
17 financing in a phased-in, deficit-neutral manner; two,
18 improve U.S. capabilities to analyze health care workforce
19 needs, develop coordinated pipeline strategies, and assess
20 their impacts; and, three, support teaching sites'
21 accountability for high educational standards.

22 We also have implications here for spending.

1 Given that this is deficit neutral, we have no impacts here
2 on spending on the federal level. And then for provider and
3 beneficiary implications, we say that it would improve
4 financing to address health care's educational and workforce
5 needs for the 21st century.

6 Next we're going to talk about shorter-term steps
7 that Medicare can implement in the interim. These steps
8 would ultimately transfer to general revenue financing.
9 But, for now, Medicare can take the lead by first
10 redirecting its IME overpayments to high-priority areas that
11 you have been discussing in several previous meetings.

12 MedPAC staff work led by Craig here has repeatedly
13 found significant overpayments to hospitals for IME. For
14 2008, this totaled about \$3.5 billion. These dollars could
15 be deployed to the following five areas: pipeline goals,
16 direct GME costs, supervision in offices and outpatient
17 clinics, hospital quality incentive payment program, and
18 Medicare solvency.

19 So, in a bit of a tag-team fashion, Craig and I
20 are going to review each of these five items on the next
21 five slides, the first one being on pipeline issues we
22 discussed through Principle 2, so I'm not going to go too

1 much into the objective. But I do want to note that it's
2 important for Medicare to lead the way in this area because
3 Medicare's current financing has really no pipeline analysis
4 component to it.

5 Subsidizing residents comes way too late to affect
6 a person's career choice, and it overlooks other important
7 health professions, like nurses and dentists.

8 MR. LISK: A second approach to redirecting IME
9 funds is to use them to increase direct GME payments to
10 support educational activities and faculty expertise.
11 Redirecting some of Medicare's overpayments for IME to
12 qualify for DGME would endorse the importance of teaching
13 and recognize increases in direct GME costs that have
14 occurred.

15 Remember, Medicare's direct GME payment rates were
16 set based on hospital-specific rates from over a quarter
17 century ago when the practice models for residency training
18 were different and the emphasis on competency-based
19 educational experience had not yet evolved.

20 Redirecting some IME funds to direct GME support
21 would allow these payments to recognize increased costs due
22 to more intensive accreditation requirements, particularly

1 with regard to the core competencies from ACGME, recognizing
2 the importance of supporting supervisory costs during the
3 training process, and faculty development needs for the
4 faculty, in addition to increases in resident compensation
5 that have occurred since these rates were set, particularly
6 due to rises in benefit costs, for instance. Some of these
7 funds could also be directed to providing direct support for
8 clinical graduate medical education.

9 Now, there are a number of ways that these direct
10 GME funds could be reallocated. We could just bump up the
11 current per resident payment amounts. We could rebase the
12 per resident payment amounts. We have not gotten into a
13 discussion of that yet, but there are a number of different
14 ways to consider how that could be done. And if we do that,
15 that would also mean there would be some redistribution of
16 how these funds would be distributed across teaching
17 hospitals because it would be distributed in a different
18 manner.

19 MS. BOCCUTI: The third source for redirected IME
20 funds would be for Medicare to make payments to office-based
21 settings and outpatient clinics that supervise residents and
22 other health professionals.

1 As you have discussed, acute-care experience is
2 essential for exposing students to a variety of serious
3 illnesses, but equally important is adequate experience with
4 ambulatory care, particularly for diagnosis and treatment of
5 chronic illnesses.

6 Although physicians in community-based practices
7 may enjoy mentoring residents and garner some prestige as
8 "adjunct faculty," the productivity losses -- and thus the
9 revenue losses -- that they face when supervising students,
10 may deter them from this important activity.

11 So modest payments for community-based supervision
12 could help offset the associated costs and may foster better
13 experiences for residents in well-functioning offices and
14 outpatient clinics. And better residency experiences may
15 not only draw more physicians to community practice, but
16 also train new physicians to practice in a high-quality
17 environment.

18 MR. LISK: A fourth use of IME savings could go to
19 funding a quality incentive payment program for hospitals.
20 The Commission has recommended in the past that a quality
21 incentive payment program be developed for hospitals. Such
22 a program would provide a strong incentive for hospitals to

1 improve quality.

2 The Commission has previously recommended that
3 Medicare fund a quality incentive payment program for
4 hospitals through a combination of reductions in the base
5 rates for PPS hospitals and from savings from a lower IME
6 adjustment. The Commission, however, did not include the
7 IME portion of the recommendation in this year's March
8 report commending the Commission's broader discussion of GME
9 financing.

10 In addition to the sustainability problems for
11 Medicare trust funds, the country is experiencing soaring
12 deficits. Teaching hospitals with relatively high margins
13 have benefitted from an overly generous IME payment formula
14 for over a quarter century. Reducing Medicare's liability
15 for a portion of these overpayments could be a small but
16 reasonable means for increasing the solvency of the Medicare
17 trust fund.

18 MS. BOCCUTI: So here is the language for draft
19 recommendation two summarizing these last slides. It reads:
20 The Congress should deploy IME overpayments towards high-
21 priority needs. These are: invest in workforce analysis,
22 pipeline strategies and program evaluation; increase DGME

1 payments to support educational activities and faculty
2 expertise; make payments to support supervision of residents
3 and nurse practitioners and physician assistants in offices
4 and outpatient clinics; fund a hospital quality incentive
5 payment program; and improve Medicare solvency.

6 Spending implications. For this, savings would be
7 equal to the unspent share of the IME overpayment for
8 provider and beneficiary implications. First we note that
9 it would reduce hospital payments to some teaching
10 hospitals. It would improve pipeline analysis and program
11 implementation, enhance medical education activities,
12 improve hospital quality, increase community-based training
13 experiences, and increase Medicare solvency for
14 beneficiaries and providers.

15 MR. LISK: Okay. I'll transition to another set
16 of recommendation topics, and this one is on increasing
17 transparency.

18 As we should know by now, Medicare provides
19 financial support to hospitals in two ways: one, through
20 the direct GME payments, and the other is through indirect
21 medical education payments, both of which go to hospitals.

22 Then hospitals provide financial support to the

1 residency programs. Sometimes this may be the medical
2 school, too, but through the hospital. And they may pay the
3 residents for stipends and benefits, supervising faculty,
4 and program administrative expenses. Support for these
5 expenses will come in part from Medicare, but also Medicaid
6 and private payers potentially as well, to the extent --
7 through private payer revenues.

8 Residency programs, however, do not necessarily
9 know how much support Medicare -- or Medicaid, for that
10 instance -- provides to the hospital, and they may not feel
11 as though they are getting their fair share of support from
12 Medicare.

13 So how could Medicare foster greater transparency
14 and help in this regard to IME and GME funding? CMS could
15 produce an annual report on indirect and direct GME payments
16 that individual hospitals and other entities that are
17 eligible for these payments could receive. Such a report
18 could be easily produced from Medicare cost reports and, in
19 fact, CMS already creates a file that includes some of this
20 information, but it is not necessarily in a user-friendly
21 format or easy to find on their website. But that
22 information is actually reported.

1 The New York Council on Graduate Medical Education
2 also has a proposal on transparency that goes several steps
3 further, which I describe in your mailing materials, and if
4 you want, I can describe that more, if you want, in
5 questioning.

6 So to help increase transparency, here is draft
7 recommendation three, and it reads: The Secretary should
8 annually publish a report that shows total Medicare DGME and
9 IME payments received by each hospital. This report should
10 be publicly accessible and clearly identify each hospital,
11 the teaching payments received, and the number of residents
12 and other health professions that Medicare supports.

13 The spending implications for this are none. It
14 is already basically almost done within the current
15 administration budget. We'd just be improving it. And what
16 it would do for provider-beneficiary implications, it would
17 provide greater understanding about Medicare's payments for
18 graduate medical education and make them more publicly
19 transparent.

20 Moving on, we want to next talk about reducing
21 barriers to residents' educational experiences in community
22 settings. Current rules and regulations create

1 disincentives for training in non-hospital settings. Time
2 spent in didactic activities outside the hospital may not
3 always be counted for Medicare payment purposes, for
4 instance. In addition, rules governing requirements of
5 hospitals to pay for all or substantial all training costs
6 in non-hospital settings may discourage many training
7 opportunities in many ambulatory settings.

8 There is also a paperwork burden placed upon
9 programs in hospitals for tracking residents' hours in all
10 the different sites that they attend to keep up with CMS'
11 rules on this.

12 So those are some of the constraints on there.
13 But even if we relieved these restraints, there are other
14 financial disincentives for hospitals' experience, and those
15 will continue. For one, residents provide a valuable
16 service to hospitals, and they'd like to keep that if they
17 can. In addition, paying non-residents if they want to take
18 them out may end up being more expensive for the hospital.
19 The other type of replacement staff may be more expensive.

20 Given the statutory and regulatory concerns that
21 may provide barriers to training in many potential
22 ambulatory settings, the chairman offers the following draft

1 recommendation for your consideration, and it reads as
2 follows: The Congress should require the Secretary to count
3 full-time residents as eligible for full DGME and IME
4 payments. Residents' clinical, didactic, and other
5 education-related time should count toward full-time
6 equivalency regardless of the setting where the resident
7 trains.

8 The spending implications for this is it would be
9 a minimal increase. And the provider and beneficiary
10 implications, it will help support community-based education
11 and training and also reduce paperwork burden. This is
12 essentially a recommendation that is also part of some of
13 the health care reform bills, too.

14 MS. BOCCUTTI: Okay. This is the slide. It is a
15 summary slide, and it provides a summary of what we were
16 talking about and the four recommendations up there.

17 The first was composed of a set of principles for
18 restructuring medical education financing, namely, that it
19 transition to a general revenue model, enhance pipeline
20 analysis and strategies, and support accountability for
21 educational standards.

22 But in the interim, under number two, Medicare

1 could redirect its IME overpayments to the five high-
2 priority areas we discussed. I won't read them.

3 Then for three, increase IME -- let's see. I
4 can't -- maybe you should read them.

5 MR. LISK: Three, increase IME and DGME
6 transparency, payment transparency. And then four is modify
7 the statutory and regulatory non-hospital provisions to
8 encourage ambulatory training.

9 MS. BOCCUTI: So we'll just keep this slide --
10 this slide I think will be a good one to keep up on the
11 screen. I think it will help people refer to what numbers
12 we're talking about.

13 MR. HACKBARTH: Good. Let me just offer a couple
14 additional comments. First of all, on this list under
15 number 2, what I tried to do here was capture a list of
16 ideas that have come up over the course of our discussion.
17 These are the ways that we might apply the so-called IME
18 extra differently to achieve different policy goals. I'm
19 not sure that we would want to do all of these things, so
20 don't infer from this list that this is a proposal that we
21 divide up the \$3.5 billion across all these purposes.

22 So one of my objectives for today is to see which,

1 if any, items on this list had the most interest and support
2 among Commissioners. So that's something that I'll be
3 looking for.

4 The other thing that occurs to me that might be a
5 helpful reminder or clarifying for the Commissioners would
6 be for you, Craig, to just briefly describe the process by
7 which the DGME money is distributed, in particular the per
8 resident amount, because we have proposals to shift money
9 from IME to DGME, but that DGME may be a little bit murky to
10 people, so if you could do that.

11 MR. LISK: I would be happy to. So direct GME
12 payments were based on 1984 costs from a hospital, and it
13 was calculated based on what they spent in 1984 inflated on
14 a per resident basis. So each hospital has a per resident
15 amount for each resident. So let's say it's \$100,000 -- and
16 it's actually close to an average of \$100,000 today in terms
17 of what the per resident amount is.

18 Now, there is a little bit higher amount for some
19 residents who are primary care residents versus other
20 residents.

21 In terms of Medicare payment, Medicare's payment
22 is the per resident amount times the number of residents --

1 I'll actually say the weighted number of residents time
2 Medicare patient share, which is determined based on the
3 inpatient days to total patient days. That's how Medicare's
4 share is done. It's based on inpatient share.

5 The weighting factor, this weighting factor counts
6 -- residents who are subspecialty or who pass their initial
7 board eligibility, it's half an FTE. So they're counted at
8 0.5 versus other residents are counted as 1. So we do have
9 a differential for subspecialty residents here. So you make
10 that formula in terms of what the weighting factors are.

11 There is a cap, though. We have the cap on
12 residents, so hospitals that are over the cap, you know, are
13 up to their cap.

14 The other important factor on the per resident
15 amount to understand is back with the BBA and MMA
16 legislation, there were changes to the per resident amounts
17 for hospitals that had low per resident amounts, and they
18 were brought up to an amount that's 85 percent of a
19 geographically adjusted national average rate. So the low
20 end was brought up. People who were at the high end had
21 their rates capped -- the rate of increase, the CPI rate
22 capped, so they would not be more. So if they're over 140

1 percent of the national average, their rates would not
2 increase until they got to 140 percent of the national
3 average.

4 So you have basically that -- here the basics are
5 the per resident amount times the weighted count of
6 residents, which may be capped, times the Medicare patient
7 share gives you the total direct GME payments, which total
8 about \$3 billion in total today.

9 MR. HACKBARTH: So there are a couple points in
10 particular that I wanted to make sure that people
11 understood. One is that the idea behind DGME was, well,
12 this is how we're going to pay for the stipends and faculty
13 salaries and the direct expenses of the training programs.
14 But because the amounts are fixed per resident amounts based
15 on a 1984 base year, then with the series of adjustments
16 that Craig has described, how much an institution spends
17 today on those things doesn't influence their payment. It's
18 sort of like a fixed, prospectively determined amount based
19 on historical considerations. And I just wanted to make
20 sure that that was clear to people.

21 Then the second thing that I wanted to make sure
22 was understood was it's not a uniform amount. There's

1 substantial variation from the lowest per resident amount to
2 the highest. Again, it's rooted in what was spent in this
3 base year.

4 DR. CROSSON: I would just say the last point was
5 the point I was going to make, because I wasn't quite sure
6 in how Craig described it that that came across, that, in
7 fact, when the baselines -- if I understand it right, when
8 the baselines were set, they were set by institutions, not
9 an across-the-board number that was then adjusted.

10 MR. LISK: That's correct.

11 MR. HACKBARTH: And Mark just reminded me to
12 emphasize one other point. It was never intended to cover
13 the full cost. It was all always linked to Medicare's share
14 based on the admissions ratio.

15 Okay. So let's do round one clarifying questions,
16 and we'll do a different pattern this time. We'll start
17 with Bill and go down this way and around.

18 DR. SCANLON: To continue on this DGME line, do we
19 have a sense of what share the current payments are of what
20 would be the total Medicare share? In other words --

21 MR. LISK: Could you repeat that again? I'm not
22 sure which share you're talking about.

1 DR. SCANLON: If we were to fully fund one of
2 these resident -- a residency slot, what would that cost be
3 today versus what we pay? And let's inflate the Medicare
4 share up to 100 percent. Does that make sense? Because if
5 Medicare is paying 40 percent, then -- what's 40 percent of
6 the cost of a resident slot today?

7 MR. LISK: Right now, in terms of -- this is
8 unaudited data, but between \$130,000 and \$140,000, is what
9 we would say off of the cost reports, on average, in terms
10 of the cost of what's reported.

11 DR. SCANLON: Okay. And then what would be the
12 share that is Medicare on average? And what is the payment
13 amount on average?

14 MR. LISK: Now, that's another good question
15 because how Medicare's share is calculated, that gives you a
16 different number, because Medicare's share over what
17 resident services provide. So Medicare's share in terms of
18 how the direct GME calculation is made is on inpatient
19 share. Inpatient share is higher than what it is for the
20 entire hospital, so that produces a bigger number. So,
21 actually, if you look at Medicare's share for teaching
22 hospitals in terms of Medicare's share of the cost and the

1 resident's cost in those units, if you allocate it that way,
2 you're talking between 25 and 30 percent. If you talk about
3 it the other way, you're talking probably between 35 and 40
4 percent if you talk about it based on inpatient share.

5 So if you talk about the total resident costs in
6 one way, you can get different numbers here, depending upon
7 how you look at it. And this is getting confusing. I'm
8 sorry.

9 MR. BUTLER: I'll try to clarify from one person's
10 perspective, and then you can tell me it's so, because I was
11 involved -- I remember those base years. So in a very
12 maybe, hopefully, clear, practical sense, we took the cost
13 report, and you recorded all your direct costs of both the
14 faculty as well as the residents' salaries and benefits as
15 well as overhead that literally gets stepped down and
16 allocated to the intern-resident cost center on the Medicare
17 cost report. You divided by the number of residents, and
18 that became your cost per resident, which had wide variation
19 around the country, and still does today.

20 We have continued to report that every year on our
21 cost report and continued to allocate those costs, and it
22 bears no relationship to the payment, as was said, which has

1 been updated by the urban CPI, which, for example, this last
2 year in a lot of metropolitan areas was actually negative.
3 You use a different CPI update. Anyway, my understanding is
4 if you compare -- this is at the heart of the issue -- the
5 payment received today versus what the costs are showing on
6 the cost report, the \$3 billion becomes something like \$4.3
7 billion. So there's about a \$1.3 billion difference between
8 the costs that are being reported today and Medicare's share
9 of those costs versus the \$3 billion. And that -- and let
10 me finish, and I'll let you respond to this. That's one gap
11 in the shortfall. The other is the ones that are over the
12 cap. So there are about, what, 6,000 or so positions over
13 the cap that have -- that would be in addition to this
14 amount.

15 Now, the \$1.3 billion that I have alleged, that I
16 think is the AAMC's number, you can -- I mean, it's not a --
17 it's a number that can be verified, so it's not something
18 that can politically be thrown out, but that's roughly the
19 rationale in many ways why you would take some of the IME
20 money and say these things have escalated in cost above the
21 urban CPI, some for very good reasons because of the
22 infrastructure accreditation, and some for maybe unknown

1 reasons, but the costs have increased more rapidly than the
2 payment.

3 I hope that helps.

4 MR. LISK: And actually, what I would want to
5 qualify, there are kind of two numbers. The 4.3 is based on
6 calculating Medicare's share as it is done in the current
7 direct GME payment formula based on the hospital. If you
8 looked at it based on what share residents are in the
9 departments where they serve, that number I estimate would
10 be \$3.6 billion. So it would be -- so you have a range here
11 in terms of what you might think of Medicare's share.

12 MR. BUTLER: And if you threw in ones over the
13 cap, you'd get another \$600 million --

14 MR. LISK: And that would be a different number.
15 That's --

16 MR. BUTLER: But, anyway, there's a difference
17 between -- that is an opportunity to more appropriately
18 align IME and DGME.

19 MR. HACKBARTH: Okay. Let's continue down the row
20 here with clarifying questions.

21 MS. HANSEN: Right. This is a different topic,
22 but what is also covered in GME, and I think I've spoken

1 with you, Craig and Cristina, about the question about the
2 nursing money that right now is part of the GME. I believe
3 the amount is about \$100 million, ballpark or so?

4 MS. BOCCUTI: I think it's a little bit more than
5 that, but it's between one and three hundred --

6 MS. HANSEN: But ballpark.

7 MS. BOCCUTI: Yeah.

8 MS. HANSEN: I guess the question, as we're going
9 through this modernization process of looking at GME, given
10 the fact that these are funds that go directly to hospitals
11 rather than educational institutions, which is where
12 professional nursing is being prepared, have there been some
13 discussions -- and I know, of course, this is so sensitive
14 just because there is a funding flow already. But relative
15 to upgrading the professionalism and the kinds of things
16 we're doing, any discussion or thoughts about that?

17 MS. BOCCUTI: Well, some of the things that we
18 included in this presentation take into account perhaps some
19 of the supervision payments, including supervising for
20 nursing and physician assistants and residents, because we
21 certainly have learned that nursing has much more
22 application outside the hospital, so they may better benefit

1 from supervision help and payments in the community setting.
2 So that is one way where we've brought that in.

3 Another would be from the pipeline issues, because
4 I think that there are issues about integrating what the
5 workforce needs are when you look across all the health
6 professions, and so that would be another consideration
7 there.

8 And then another one would be when we talked about
9 the educational environment and teaching hospitals, I think
10 that here is where team models could also be rewarded in an
11 educational component, so a teaching hospital and residency
12 programs that made sure that there was communication between
13 nursing staff and physicians and residents and that in a
14 professional way where even nurse practitioners could be
15 teaching residents, you know, what they're doing. And in
16 many regards, there is learning that can happen there.

17 So I think that there are many avenues to enhance
18 the role of nursing in medical education. But I don't think
19 that there's a specific one recommendation that we've
20 discussed here that only applies to nursing and other
21 professions. But we've tried to bring that in in many of
22 these.

1 MS. HANSEN: I appreciate the options, and I
2 wasn't asking really as much the question about nursing's
3 role to medical residency education really. It was really
4 the fact that right now under Medicare and under GME there's
5 specific funding that is going directly to hospitals,
6 bypassing really the intent of the educational system. So,
7 again, it's whether or not we're preparing nurses in an
8 academic manner rather than an apprenticeship manner.

9 MS. BOCCUTI: Yes, and that's why I think that
10 outpatient setting -- and I think that's what you're saying
11 -- is a better environment for that. And what's going to
12 those hospitals you are talking about, it's a limited number
13 of hospitals that are doing it, and it's for diploma
14 programs, and that's sort of a vestige of an earlier model.

15 MS. HANSEN: And then to that point, the last
16 thing I would say is if it's to be deployed differently, you
17 know, there is a movement of even getting residencies for
18 nursing. So if it was deployed definitely and using the
19 similar graduate medical education model, you know, there is
20 a movement for a graduate nurse education because oftentimes
21 people -- hospitals themselves are finding that people
22 graduating from schools are not prepared clinically, and as

1 a result, there's a turnover oftentimes easily of 20 to 25
2 percent in that first year.

3 So another thought of if we're going to
4 efficiently use it for effective results, another concept.

5 MR. HACKBARTH: Clarifying questions.

6 DR. CHERNEW: I would like you to clarify what's
7 meant by general revenue financing model. I didn't
8 understand the description on page 1.

9 MS. BOCCUTI: Well, let's turn to page 1.

10 DR. CHERNEW: My specific question is: Is that
11 just whether the money is raised from general taxes, like
12 income taxes, or through the Medicare payroll tax? Or does
13 that have something to do with the way the money is paid out
14 as a part of the DRG fee schedule?

15 MS. BOCCUTI: More the former.

16 MR. HACKBARTH: And we'll come back and discuss
17 this in more detail, but the short answer is it's the
18 former. It's how the money is raised, whether it is through
19 the payroll tax or through the progressive income tax.
20 That's the short answer. But I know for a fact we will
21 discuss this more.

22 DR. DEAN: I was curious, you didn't address the

1 issue of the cap at all in this. Why was that?

2 MS. BOCCUTTI: Well, if you think about the
3 workforce issue that did come up, the pipeline issues, I
4 think that that may be an opportunity to look at that. But
5 we weren't taking that on specifically. But, Glenn, you
6 want to come in here.

7 MR. HACKBARTH: Yes, let me take a crack at that
8 since it came from me. It seems to me that to address the
9 cap, what we need to do is have a coherent assessment of
10 what our workforce needs are, both the aggregate numbers and
11 how they should be divided by specialty and the like and
12 alternative non-physician clinicians, et cetera. And so it
13 seemed to me that was part of a long-term effort as opposed
14 to a short-term decision. That was my thinking on it.

15 Other clarifying questions?

16 DR. BORMAN: Could we just clarify a little bit
17 about what we mean about make payments for office and clinic
18 supervision? Is that increasing payment for the primary
19 care clinic exception? Is that some new payment stream?
20 Just help me understand what we might imply by making
21 payments for office and clinic supervision.

22 MS. BOCCUTTI: I hadn't thought about it being

1 related to the supervision requirements in the billing, like
2 what you just said, but more related to whether it be a
3 billable code for it or an add-on or an amount. I think
4 sort of the technicalities of operationalizing this we
5 haven't gotten to, but in some sense boosting payments to
6 the outpatient clinic or to the physician office when they
7 are actively supervising nurses and residents. So it
8 wouldn't just be, you know, all the time, but for those
9 kinds of activities.

10 MR. LISK: Recognizing the inefficiencies that may
11 be associated with participating in the activity.

12 MS. BOCCUTI: You could bring up ways that you
13 might think it would work well, and we can talk about that.
14 But we haven't gone -- with many of these, we haven't gone
15 down the steps of exactly how it could be implemented.

16 DR. BORMAN: But the intention, if I hear you
17 correctly, was largely directed at places where there's not
18 currently something going toward that. So, for example, if
19 a resident went to an office of other than a faculty member
20 for some specific exposure or curricular reason, and that
21 physician wasn't billing as a teaching physician or getting
22 something in some other way from the residency program or

1 the hospital, which presumably wouldn't give him anything
2 either, that this then would be another mechanism to pay
3 those physicians.

4 MS. BOCCUTI: That's right.

5 DR. BORMAN: That's sort of what you were
6 thinking.

7 MS. BOCCUTI: Exactly.

8 DR. MARK MILLER: One thing on this to keep in
9 mind, of course, if we do go down this road, we have to be
10 conscious of the potential for increase in volume for
11 billing for these things and think about some way of kind of
12 building a bit of a house around it.

13 DR. CASTELLANOS: Just a continuation on Mike's
14 question about general revenue. My question is stability.
15 How stable is stable? And is it better or less stable than
16 what we have now?

17 MR. HACKBARTH: And it's an important question,
18 and we'll come back to that once we go through round one.

19 DR. MILSTEIN: I have three very narrow questions.

20 First, do we ever -- you know, we've actually made
21 some great progress in the last, you know, few years on
22 trying to think about Congress' idea of, you know, pay for

1 efficient delivery. Have we ever done that, that is,
2 basically said, well, let's take the subset of residency
3 programs that get an A-plus on their ACGME rating, and then
4 actually ask what does it cost if the most efficient
5 producer of -- if the teaching hospital is the most
6 efficient producer of A ratings. So we begin to get a
7 picture as to what IME ought to be if medical education is
8 being -- if residents are being efficiently used in places
9 that are getting great scores from ACGME. Have we ever
10 attempted anything like that? Because I certainly -- my
11 intuition is that we have scores from ACGME, we have a basis
12 for -- ACGME has scores, and, you know, we have bases for
13 doing cost studies. Have we ever pursued that, thought
14 about that, so we could begin to sort of think about getting
15 this onto the same platform, you know, that we've had other
16 --

17 MR. HACKBARTH: Well, a critical premise there is
18 graduated assessment programs by ACGME, and, you know, Karen
19 knows way more about that than I do, and Craig and Cristina
20 may also want to comment on it.

21 My impression has been that that's maybe an
22 objective, but we don't have that infrastructure now.

1 Karen, do you want to address that?

2 DR. BORMAN: Yes, just briefly. The short answer
3 I think would be that, yes, there are some things that could
4 start toward a score. I think the plan is for it to get
5 better and better through the Milestones Project, which
6 Glenn is familiar with, but that there are some things now.
7 For example, in each specialty there's a potentially longest
8 cycle between accreditation visits, and so a program that
9 gets the longest or near to longest, that's a reflection of
10 a judgment that that program has commitments and processes
11 and outcomes that suggest they don't need as much
12 monitoring.

13 So there are a few things like that. It suffers
14 the vagaries of they differ from specialty to specialty
15 because there's different residency review committees. But
16 there might be some things that would be a starter set on
17 it, yes.

18 DR. MILSTEIN: That's good enough for me.

19 MR. HACKBARTH: So, Arnie, the way I thought about
20 this -- and it may not be the right way -- was that our goal
21 of having more rigorous graduated assessment of how well
22 training programs do in producing the physicians we need is

1 a goal that people have repeatedly referred to in our
2 conversation. I'm not sure we're quite there yet. So I had
3 it on the longer-term part of the agenda. So the summary
4 here, the third bullet, restructure our financing to support
5 accountability for educational standards, and what I was
6 thinking there was in the future be able to link payment to
7 performance. But I'm not sure that's a short-term step.

8 DR. MILSTEIN: Thank you. A second very narrow
9 question. This quality -- I guess this idea of taking some
10 of the money and moving it into quality, we're referring --
11 that would be just for teaching hospitals. Is that right?
12 Oh, the whole thing, okay.

13 MR. HACKBARTH: So that particular bullet is a
14 basically a reiteration of what we've recommended for three
15 or four years now about how to take 1 percent of the IME and
16 put it into pay for performance.

17 DR. MILSTEIN: Then I think that leads to my third
18 question, and I'm a little puzzled by this, because I think
19 one of the examples in the quality-based payments said,
20 well, let's start linking these quality-based payments to
21 the content of what's being taught, team-based care, you
22 know, et cetera. I guess what you're saying is that would

1 apply to teaching hospitals, but to the non-teaching
2 hospital redirection of this into quality incentives that
3 wouldn't be relevant because there'd be nobody -- nobody
4 would be being taught.

5 But my question is more for you, Glenn, and that
6 is, this is somewhat of -- this notion of linking it to
7 educational content is a deviation from what I thought you'd
8 said earlier, which I had grown to -- I'd migrated toward,
9 which was this idea of, you know, look, what constitutes --
10 you know, great quality is going to change very quickly. So
11 rather than, you know, link the quality payments to teaching
12 hospitals based on certain curricular content, but you were
13 saying instead let's begin to move it towards teaching
14 hospitals that score fantastically on -- like Denver, you
15 know, on quality, resource use, you know, the works. Why
16 the change, or is it just an interim idea?

17 MR. HACKBARTH: Well, actually what I am trying to
18 do is create a discussion here about how to do that. As
19 I've listened to the discussion and I've had some follow-up
20 conversations with individuals, I've heard sort of two
21 schools of thought about how to increase accountability for
22 performance.

1 One school, which I will characterize as the Arnie
2 Milstein School, is sort of if we can get people trained in
3 settings that are high-value settings, presumably that will
4 influence the skills that they're taught, the culture that
5 they're imbued with when they go out into practice, and we
6 want to reward training in those high-performance
7 environment, the Denver Healths, et cetera.

8 And, you know, one shorthand label for that is,
9 you know, sort of think of teaching ACOs, we'll pay the
10 extra only if the teaching is done in a certain type of
11 high-performance setting.

12 Peter -- and jump in, Peter, if I'm not
13 representing your views correctly -- is a little concerned
14 that maybe that's too restrictive, that there are high-
15 quality teaching venues that may not want to be accountable
16 care organizations, not able to be accountable care
17 organizations because, for example, like MD Anderson,
18 they're very specialized. And so to say, oh, you're not
19 eligible to get these performance dollars because you are,
20 you know, a specialized institution as opposed to a more
21 general purpose, that wouldn't be right.

22 And so Peter said, you know, let's see if we can

1 link our performance incentives to a rigorous assessment of
2 how well they're carrying out the training mission, and
3 perhaps ACGME can provide us the infrastructure to do that
4 through graduated assessment.

5 Is that a fair characterization?

6 MR. BUTLER: Yeah. But I could see there might be
7 some hybrid in the end. It's not black and white. But I
8 favor more the latter. So if you look at Denver Health, for
9 example, one thing that they take capitate -- you can kind
10 of tell it's maybe the -- but if they didn't do LEAN
11 training for any of their residents, they shouldn't
12 automatically -- you know, it has to be part of the training
13 program itself, not just an environment that is progressive
14 in the delivery system; whereas, say Ron -- and he can't
15 defend himself. I suspect his residents are being used in
16 more of the traditional way in his system than maybe in -- I
17 mean, it would be totally unfair, but I could see how that
18 can happen. And so I would want to make sure the
19 "curriculum," the program itself, would have attributes
20 that, you know, earned them extra points.

21 MR. HACKBARTH: [off microphone] Okay. We're
22 still on clarifying questions.

1 MR. GEORGE MILLER: You may have covered this, but
2 my clarifying question that hasn't been asked is: Why the
3 movement away from the payments from the general funds from
4 what we currently have? Are you going to explain that later
5 when we --

6 MR. HACKBARTH: [off microphone] George? Why --

7 MR. GEORGE MILLER: Why the movement to the
8 general funds for funding?

9 MR. HACKBARTH: [off microphone] Why propose
10 that?

11 MR. GEORGE MILLER: Yes.

12 MR. HACKBARTH: [off microphone] Okay --

13 THE COURT REPORTER: Your microphone, sir.

14 MR. HACKBARTH: I'm sorry. There are a couple
15 issues here, and I know Bill wants to go into this as well.
16 In fact, before we do that, why don't we let Nancy ask her
17 clarifying question. Then we'll go to Bill, and we'll leap
18 into this topic, I'm sure.

19 DR. KANE: Thanks. On Slide 11, you mentioned
20 that we can put GME and IME towards workforce analysis and
21 pipeline strategies, so that's not something Medicare has
22 done historically, but others have. And I guess I'm

1 wondering, did you have some -- and also this notion that
2 career choices -- I guess I'm trying to connect up what
3 vehicle does Medicare use to change its role with health
4 care workforce. There are parties that do that now, that do
5 think about the workforce and that do think about career
6 choices. So where would Medicare fit them? Would they just
7 start funding these places or --

8 MS. BOCCUTI: Right. Some of these dollars with
9 some of the savings could offset expenses that potentially
10 other agencies incur from doing this work. So they could
11 boost their resources for doing these services, or the
12 dollars could come directly from other revenue sources and -
13 - go ahead, Mark.

14 DR. MARK MILLER: I think one way to think about
15 it is if you were just thinking of it in a unified budget,
16 deficit-neutral way, you add money -- and I'm just going to
17 say, because I know this has some sensitivity. You add
18 money to Title VII and VIII programs, assuming they're
19 functioning well and all of that, because I know that issue
20 has been raised, and you offset it with a reduction in IME.
21 Okay. That's why it says "with IME savings." That's kind
22 of the thought there.

1 DR. KANE: Yeah, I caught that because Medicare is
2 not [off microphone] -- Medicare wouldn't be playing a role
3 other than paying for somebody else to do this job.

4 DR. MARK MILLER: Well, playing a unified budget
5 role by lowering its expenditures and creating the room for
6 some other expenditure to occur. Now, it's currently two
7 different pots of money, just to keep that in mind, and I
8 think when we get into the discussion that's going to be
9 triggered by Bill's comment on, you know, Medicare's role
10 and Medicare dollars, you know, you can raise the questions
11 of whether Medicare dollars should directly go to this. But
12 in this thought, this wasn't the statement that you made.
13 Is this Medicare dollar traveling to a different program?
14 Here it's being -- this is the interim one. This is just
15 the thought of it would serve more as an offset in order to
16 increase more of those activities.

17 DR. KANE: So do we have a sense then that those
18 programs that might receive this money are able to change
19 the way the workforce pipeline is? Have they had a history
20 or how successful are they at achieving anything like this?

21 MS. BOCCUTI: Right. There is an issue here. GAO
22 has studied this. We've been looking at it. Hannah has

1 been doing a lot of work on the articles. It's hard to
2 point to very rigorous research on all of the Title VII,
3 Title VIII National Health Service Corps work. The National
4 Health Service Corps has been around the longest and does
5 have more data on how many people they've produced. Like 80
6 percent stay longer than their service requires. You know,
7 I think up to 50 percent of the people who participated stay
8 at least five years past -- or, you know, I don't know these
9 numbers directly, but they do keep some statistics on
10 National Health Service Corps, and that goal is very clear,
11 you know, to get primary care providers in underserved areas
12 so it's easier to track.

13 But the goals for some of the other programs are
14 more difficult to track. They change from year to year
15 because the programs change, because sometimes the programs
16 have to be new each time. There's also lack of funding for
17 analyzing these programs. And I think we've tried to stress
18 how important that's going to be. If you want to invest in
19 pipeline concerns and issues, then you need to also invest
20 in where you're getting the biggest bang for the buck and
21 which programs are successful and which ones are not.

22 So it's very important, if you're going to put

1 money in, to see whether that money is working. And I
2 completely hear your concern, and I have been hearing it
3 before, that we don't know if they work and we're not
4 comfortable endorsing something when we don't know how
5 successful it is.

6 So we think that it's absolutely essential that we
7 have program evaluation as a component of this kind of
8 spending.

9 DR. MARK MILLER: And just so you think about the
10 overall construct of the recommendations, this is clearly
11 one where you could say because -- I've got two concerns.
12 One if IME is reduced but the Congress doesn't choose to
13 raise that funding, that's an issue. And, number two, if
14 they do choose to raise that funding, but we're not sure
15 those programs are functioning, this is also discussed more
16 in the principles. And you could, as Commissioners, make a
17 decision that this is the kind of thing that really needs to
18 be handled more in where we're headed as opposed to the
19 interim, and that's one of the things I think you have to
20 think through on these interim steps.

21 MR. BUTLER: One more quick clarifying. I don't
22 know if there's a substantive reason, but we keep calling

1 this, including the chapter heading, Medical Education
2 Financing when it is graduate medical education financing.
3 There is no money in Medicare for medical education, as it's
4 known. Outside of this room, it gets probably -- you know,
5 you say, well, all medical education is financed. That's
6 not true. So I think that distinction is important.

7 MR. HACKBARTH: Just one last thought on this
8 issue of the mix of people being produced. I don't think it
9 can be overemphasized at least when I say I don't think
10 we're getting the mix of specialties, for example, that we
11 need, that is not an indictment of the institutions doing
12 the training. In fact, I think Medicare bears a large share
13 of responsibility for that, and probably the most important
14 influence Medicare has on it is how we pay for services.
15 And we shape the preferences of clinicians in training and
16 doctors or students in medical school and how they think
17 about their futures in medicine. And so I just want to be
18 clear that it's not a criticism of the institutions.
19 Medicare bears lots of responsibility for what's coming out
20 of the pipeline. And so we're not assigning blame. We're
21 trying to say is there a way that we can redeploy the
22 resources to produce a mix that is more in keeping with

1 society's needs.

2 So if we are done with clarifying questions, let's
3 go to round two, and Bill is first.

4 DR. SCANLON: Okay. Since the question of the
5 financing has come up, let me give you my take on this. If
6 you look at the summary slide and you take the second two
7 bullets in one and the whole rest of that slide, to me,
8 those are all about the issue of how do we invest in human
9 capital that is going to improve the Medicare program for
10 the future. Embedded in there are issues of what is it that
11 we want in the way of human capital, sort of how are we
12 going to sort of best accomplish that, how do we introduce
13 accountability to make sure that we are accomplishing it.
14 And a part of that is sort of greater latitude in terms of
15 what we are doing now. And so I think those are all sort of
16 very positive steps in terms of how we sort of make an
17 investment that we think is going to have benefits to the
18 Medicare program and to Medicare beneficiaries for the
19 future.

20 Bullet number one -- the first bullet under number
21 one is different. It's about financing. It's kind of where
22 the money comes from and this notion of that we should

1 switch to general revenues can have sort of multiple
2 motives. One could be that we are trying to save the Part A
3 Trust Fund, but there's not enough money here to save the
4 Part A Trust Fund, so I think we can take that sort of off
5 the table.

6 The second one could be that what we're thinking
7 about is the incidence of the taxes that are being used to
8 support this activity. Part A is funded out of a payroll
9 tax and general revenues are funded from different kinds of
10 taxes. Thinking about it in those terms, though, I think is
11 -- first of all, it's not the normal purview of the
12 Commission, and secondly, to think about it in such a narrow
13 focus is not the way one ordinarily would think about sort
14 of tax incidence analysis because the issue in terms of tax
15 incidence is what do I as an individual pay sort of in all
16 forms of taxes and what do I get as an individual sort of in
17 all forms of benefits. This is so isolated in terms of that
18 that it is problematic to sort of think we would make a
19 decision on the basis of that.

20 On top of that, a complicating factor is that the
21 payroll tax here for Medicare is different than the payroll
22 tax for Social Security. It has an unlimited base in terms

1 of earned income. It's also being discussed now to think
2 about should we add unearned income to the base? Should we
3 vary the rate? I mean, it would become a very different tax
4 and so the whole sort of analysis would change.

5 The other thing, I think, to take into account
6 here is the other implication of switching to general
7 revenues which changes how this is dealt with sort of in the
8 Congress. It puts it into the budgetary and appropriation
9 process, and even if we -- in our paper, we have cited sort
10 of the Children's Health Insurance Program as an example of
11 something where there has been, I would call it, relatively
12 stable funding. We had an initial sort of ten-year
13 allotment or appropriation of funding, but when the ten
14 years were up, we saw that it wasn't sort of necessarily
15 easy to renew it, that when you go to renew it, you have to
16 think about what are going to be the pay-fors, and the pay-
17 fors can become a source of controversy. They can affect
18 sort of whether or not you have disruptions in the
19 continuation or whatever you have a change in level in the
20 continuations. Those are not necessarily good things when
21 you're thinking about making an investment for the long
22 term.

1 When you're trying to build capital, and this is
2 in some respects -- you know, we talk all the time about
3 States having balanced budget requirements. Their capital
4 budgets are often separate from that because there's a
5 recognition that capital budgets are something that you're
6 trying to build for the future and you want stability there.
7 And so there's this question of thinking about how do we
8 have sort of a stable sort of funding source for what is
9 essentially a capital investment for the Medicare program.

10 So I actually think we shouldn't be sort of
11 focused on this as one of our recommendations. We should be
12 focused more on the question of how do we invest in the
13 human capital that's going to improve Medicare, and what are
14 going to -- there's a whole series of things we'd have to
15 consider here. What's the target? How do we ensure that
16 the target is being sort of met? What's the best mechanisms
17 for doing sort of both of those kinds of things? Those are
18 big challenges for us and those would be big changes to what
19 we currently are doing now and sort of in a potentially
20 positive direction.

21 MR. HACKBARTH: What I'm going to propose here is
22 that we proceed by issue as opposed to just sort of going

1 around. So what I'd like to do is focus on the issue of
2 general revenue financing for a second.

3 Before I turn to you, Bob, let me just react to
4 what Bill has said. Bill at the outset said that there are
5 different reasons why you might say general revenue
6 financing versus payroll tax, and I agree with his list.
7 All three were in my head. In Bill's list was save the
8 trust fund. I don't disagree with his statement on that,
9 however.

10 Second, the difference between financing social
11 good using a payroll tax as opposed to progressive income
12 tax. You know, I plead guilty to having made that point
13 multiple times. But I accept Bill's point that that's
14 really not something normally within our province, our
15 expertise. Fair enough.

16 The one that is very much Medicare policy-related
17 is this. I've been struggling with how we use Medicare-
18 based financing and get to our goal of moving away from the
19 Federal Government contributing to GME by add-ons to service
20 payments. Instead, get to an alternative model where the
21 Federal Government pools all of its resources for financing
22 GME at a place and then deploys them based on a rational

1 model for planning our future workforce needs.

2 So I was sort of stuck on taking dollars from the
3 HI Trust Fund to support activities that might be housed in
4 PHS to develop a coherent workforce policy, and that was
5 part of the reason that I was thinking it probably needs to
6 come out of the Medicare funding stream. So of the three,
7 that's the one that really seemed most important in my head.

8 DR. SCANLON: Okay. As I said, there is an
9 alternative, which is the Congress creates the latitude for
10 the Medicare funding stream to do some of the things that
11 have been in the Public Health Service. But what we would
12 probably say is do it with the assurance that you have
13 accountability --

14 MR. HACKBARTH: Yes.

15 DR. SCANLON: -- for those dollars and that they
16 are not on some kind of automatic pilot where they're not
17 going to be stopped at some future point if they're not
18 being used appropriately.

19 MR. HACKBARTH: Yes, and Bob may wish to address
20 this in just a minute. If we can do that -- one of my
21 concerns about taking it out of Medicare is the stability
22 issue and assuring stability in financing. But we had

1 talked about sort of the CHIP model of the mandatory
2 appropriation, but I recognize that is an imperfect
3 solution.

4 Let me get Bob and then Mike.

5 DR. BERENSON: Yes. I do want to follow up on
6 that, because I was going to make a similar point about the
7 sort of theoretical niceness of using progressive taxes to
8 fund the social good, but the reality of what happens in our
9 budgetary process right now, which is to freeze
10 discretionary spending and have no ability to do anything,
11 really, with mandatory spending.

12 I found some data that was in a Macy Foundation
13 report looking at Title VII, which we've talked about as one
14 of the important pipeline programs, and it's currently
15 funded at between \$200 and \$300 million a year. It got a
16 one-time boost from ARRA. Apparently, in 1970s dollars,
17 when it was originally funded, it would be funded now at
18 \$2.5 billion. It is basically being funded at about ten
19 percent of what the original funding was. Now, it could be
20 that somebody did an evaluation. My hunch is that that
21 didn't happen, that it has just been subject to squeezing
22 over the years.

1 So I'm reluctant to go down the road in which we
2 would suggest to the Congress that they would support the
3 pipeline aspects of what we are proposing by dedicating some
4 of the IME funding over there. That wouldn't happen, in my
5 view, and I think we then want to look at ways in which we
6 can potentially target Medicare dollars for those programs
7 with accountability, with evaluation. And again, the model
8 that I think might be instructive is the apportionment to
9 QIOs, which comes out of the trust fund. It's a specific
10 apportionment for specific services. There's a scope of
11 work. There's controversy over whether that's achieving its
12 purpose. But I could imagine something comparable to
13 support programs in the pipeline. So that was my point.

14 MR. HACKBARTH: Okay. So comments on this issue
15 of general revenue financing? I have Mike, Mitra, Peter,
16 and Herb.

17 DR. CHERNEW: So my original source of confusion
18 was whether it's funded by a payroll tax through Medicare or
19 general revenues is completely independent, as near as I can
20 tell, as to whether or not it's paid by an add-on to the fee
21 schedules. And it strikes me that the basic problem that
22 we're worried about is we don't think -- and I agree with

1 this -- it doesn't seem to be a very effective way to
2 finance education as an add-on to the fee schedule, because
3 there's a whole series of distortions that occur when you
4 manipulate the fee schedules for something that is not what
5 you really want to pay for.

6 And that seems to me to be what the recommendation
7 should focus on, removing the add-on payment and not how
8 it's raised. You could even conceivably, for example, say,
9 let's lower the payroll tax for the Medicare Trust Funds and
10 have a payroll tax for the medical education part, if you
11 wanted. That strikes me as a little crazy.

12 But in any case, I think there's a lot of ways to
13 deal with the stability and the financing issues and the
14 autonomy of who makes these decisions that are different
15 than the basic problem, which I think is the crux of the
16 discussion we've been having, which is we want to move away
17 from a fee schedule payment system to paying for something
18 about education.

19 MS. BEHROOZI: Yes. I think my comment is kind of
20 related. This is a historical anomaly, kind of, that
21 Medicare is the major player in financing graduate medical
22 education because it's the only thing we've got close to

1 national health care policy or coverage or whatever. But
2 it's not necessarily coherent that Medicare is looking at
3 what Medicare beneficiaries need and that's what should
4 inform how to enhance workforce analysis and pipeline
5 strategies.

6 There's a whole medical profession out there
7 that's not all geared toward servicing Medicare
8 beneficiaries, and hospitals that depend on this money to
9 support part of the training for physicians or as part of
10 their general revenue stream or whatever it becomes, you
11 know, I don't know that they're thinking so much about how
12 am I educating these doctors to treat Medicare
13 beneficiaries.

14 I think whether it's payroll tax or general
15 revenue, it should be stable, and so I guess just regular
16 old general old revenue. I get that it's not going to be a
17 stable source, either, for the education or for the
18 hospitals who have come to depend on it as general revenue,
19 but I think, to me, as Mike was saying, detaching it from
20 the status of being an add-on to payments.

21 Similarly, I think that it's sort of incoherent to
22 have Medicare doing its thing and we do our examinations of

1 the physician workforce and all of that stuff, and then
2 there are other sources of funding that we're not really
3 talking to and coordinating with, and just an all-payer kind
4 of strategy, the New York approach.

5 So I think you end up thinking about funding
6 issues, but not so much first, but rather maybe as a
7 consequence of trying to be more coherent about it.

8 MR. BUTLER: So just to distinguish one more time,
9 the -- we keep talking about add-on payments. DGME is not
10 an add-on payment, depending on volume, and is a lump-sum
11 payment we get based on the percentage of Medicare business
12 in the hospital. So the more you do, it doesn't mean you
13 get paid more. It is a fixed amount. IME is the one that's
14 the add-on.

15 Now, I think my perspective on the general
16 revenues concept was that if I go back to last summer's
17 retreat, we kind of went around the room on a base chapter
18 that was pretty good and we kind of said, what do we want to
19 do, and I think accountability was a theme, primary care was
20 a theme, ambulatory-based training was a theme. Those are
21 three themes I can remember, and I think we even had this on
22 there but it kind of got lukewarm support for kind of -- we

1 kind of looked at all payer and think it is a good idea, but
2 pretty difficult to do.

3 So I think now that it's suddenly kind of right at
4 the beginning, it's overarching, is saying, have we really
5 thought this thing through? There are a lot of logistics
6 with it, including does it have both DGME and IME payments
7 in there? I'm not clear. And then it says pooling the
8 money from Medicaid and other payers. Is that what we mean?
9 So I don't know if we have really a lot of answers to a
10 pretty big principle if we roll it out as our overarching
11 one. So I'm not real excited about this as a lead
12 principle.

13 DR. CROSSON: Cristina or Craig, do you want to
14 clarify the intent?

15 MS. BOCCUTI: I think -- thinking at the intent of
16 the general revenue, as Glenn had talked with us, was more
17 about the opportunities that are involved when you can
18 coordinate all the public dollars. So that would be
19 Medicaid, Medicare. There's more, even the HRSA dollars and
20 VA, DOD may be separate. But the idea was that if, yes, if
21 that were pooled, you'd have a better ability to think
22 across all health professions, across all learning

1 environments, and have a more rational approach to answer
2 the needs, the societal needs for the graduate medical
3 education. So it was considering all the dollars, if that's
4 the intent you're asking about.

5 DR. CROSSON: Right. So --

6 MR. BUTLER: Very complicated.

7 DR. CROSSON: In terms of IME and DGME, this
8 recommendation, which is a long-term recommendation, as I
9 understand it, is to move all the money out of --

10 MS. BOCCUTI: All of the dollars.

11 DR. CROSSON: -- the responsibility of the
12 Medicare trust to general revenues. The short-term
13 recommendations, which come later, which talk about moving
14 the IME payment, is just limited to IME.

15 MR. BUTLER: But IME dollars are patient care
16 dollars. They're not education -- they're a consequence of
17 having an educational presence, perhaps, or correlated with,
18 but they're not education. This is where it gets
19 complicated, and beyond where I think we're at right now --

20 DR. KANE: The direct GME, part of that is that
21 you're paying for residents to do a lot of work in the
22 hospital. So it's not just education. I mean, I think

1 that's part of what -- well, I mean, it's not just education
2 that you're doing DGME. At least, that's not how it's used,
3 so --

4 DR. CROSSON: We have Herb next, and Bruce, then
5 Ron.

6 MR. KUHN: Thanks. I want to pick up on a bit of
7 a theme that Bill was talking about earlier, and that's the
8 issue of stability here. He used the example of the
9 Children's Medical Education Program and the ten-year
10 reauthorization. But if you think about the need for
11 stability here, you can get up to eight years in terms of
12 training for a student in medical school or in their
13 training program. And so again, I think, this augers for
14 the need for real stability. So I would have difficulty
15 thinking to move this out of the trust fund over into
16 general appropriations.

17 Beyond that, just think about what that sends a
18 signal, is it is a bit of a mandate, and to a degree an
19 unfunded mandate, from an authorizing committee to an
20 appropriations committee in Congress, and that sets up a
21 dynamic that could, be problematic, as well, in terms of the
22 stability that we're after here. So that would be my

1 concerns there.

2 DR. STUART: In listening to my colleagues, it
3 seems that there's pretty clear almost unanimity that that
4 first bullet be dropped, and it strikes me that that does
5 not affect the next two bullets. So my recommendation would
6 be -- now, this is awkward with Glenn not here -- that
7 unless there's somebody that is really strongly in favor of
8 that first bullet, that we really should probably strike it
9 from the recommendation.

10 MR. HACKBARTH: I apologize for that. My son was
11 repeatedly calling me, and he's 19 years old.

12 [Laughter.]

13 MR. HACKBARTH: The last thing a 19-year-old boy
14 ever does is repeatedly call a parent unless there's real
15 trouble, and so I just wanted to make sure what was going
16 on.

17 DR. CASTELLANOS: [Off microphone.] Do you want
18 us to help with the donations?

19 MR. HACKBARTH: Right. Right. That's all right.

20 [Laughter.]

21 MR. HACKBARTH: And I apologize, Mitra, for
22 getting up while you were talking, but it doesn't happen

1 often and so I just needed to check it out. You can relate
2 to that.

3 So, go ahead. Why don't you describe what I
4 missed.

5 [Laughter.]

6 MR. HACKBARTH: Was it good?

7 DR. CROSSON: I'll be very summationous [phonetic].
8 Mitra talked about the fact that we need to move eventually
9 to an all-payer approach, I think to summarize that. Herb
10 expressed the fact that he sees a problem with this
11 recommendation, at least the first bullet point, with the
12 lack of stability and particularly that it would create an
13 unfunded mandate to the appropriators. And Bruce was just
14 commenting as you came in that he thinks he has not heard
15 much support for the first bullet of the recommendation and
16 recommended that we consider dropping it, but that we should
17 wait for you to come back, and then you came back.

18 MR. HACKBARTH: Okay. And so what I'd suggest, I
19 think we've had enough on this particular one and what I'd
20 like to do is move on to additional issues.

21 Bill having gone first, let's go to Peter and see
22 what he finds for us.

1 MR. BUTLER: Do you want me -- I can, in two or
2 three minutes, just cover all of them. Or do you want to
3 just do one at --

4 MR. HACKBARTH: I think it's better to do them one
5 at a time. Then we can have sort of people chime in and
6 organize the discussion that way.

7 MR. BUTLER: Okay. Well, then I will preface it
8 with I don't like -- we have got kind of three categories we
9 have in the paper. One was principles. Then we had
10 interim, and then we had this transparency. I would rather
11 just have, let's have five recommendations, whatever they
12 are. There's some time differences between some of them,
13 maybe, and we can put that in there. But it would be
14 cleaner, because I can't in my mind -- is timing the only
15 difference, principle versus --

16 MR. HACKBARTH: Yes, long-term, short-term,
17 basically.

18 MR. BUTLER: So that wasn't clear to me. Okay.
19 So I am -- of course, it's good to study pipeline. How can
20 you -- I can't imagine there's a huge amount of money and
21 it's something we should understand as we inform caps and
22 things like that. So the logistics of using this money for

1 it, even if we do and can do it, it's not -- this isn't
2 going to be a billion dollars to study pipeline, but we
3 should understand it better than we do, so I can -- Bob was
4 going --

5 DR. BERENSON: I didn't think it was to study
6 pipeline. It was to support the pipeline.

7 MR. BUTLER: Well --

8 MR. HACKBARTH: Yes. Let me just leap in and then
9 Cristina and Craig can help also. Bob is correct. So the
10 basic ideas here --

11 MR. BUTLER: Okay. So the second one down below
12 is the study which could result in pipeline strategies --

13 MR. HACKBARTH: So the basic idea is to say, as
14 opposed to the current system where we put money into
15 graduate medical education without regard to what's coming
16 out the other end of the pipeline, we need to change from
17 that and put out the Federal money in accordance with a
18 strategy for producing the workforce that we need.

19 And the problem, or a problem that we've got is
20 that we're not entirely confident that the existing programs
21 that exist for influencing the pipeline are exactly the ones
22 that we're going to need long-term. There are some

1 questions about their effectiveness and the like.

2 So what we're trying to do is make two points. We
3 need to redeploy the resources to support a rational long-
4 term workforce strategy, and as we do so, we need to
5 carefully evaluate whether those interventions are working
6 as intended. Is that a fair summary, Cristina?

7 MS. BOCCUTI: I think to clear up confusion about
8 the second bullet under number one and the first bullet
9 under number two, they're the same, and everything that
10 Glenn just said applies to both of them. The reason they're
11 repeated is because once there was a construct of being an
12 overall principle, and if you had general revenue financing,
13 you could do these pipeline and workforce priorities and the
14 analysis that goes with them in the realm of the overall
15 financing.

16 But to the extent that that wasn't going to happen
17 tomorrow, Medicare could do some things, too, or with the
18 IME savings, some things could be done, too, all for the
19 exact same objective. So they're repetitive on purpose and
20 they are the same. It's just where the dollars would come
21 from.

22 MR. HACKBARTH: [Off microphone.] Is that

1 helping?

2 MR. BUTLER: Just a little bit. So I think I'll
3 pass.

4 MR. HACKBARTH: Okay. So I'm not sure that we --

5 DR. KANE: [Off microphone.] The second bullet?
6 Bullet number one or number two?

7 MR. HACKBARTH: Yes. I think the real focus here
8 that Peter is raising is on the first bullet of number two.
9 So we're talking about in the short term -- this is not long
10 term, now -- pretty quickly saying we're going to take a
11 piece of the resources currently devoted to IME and start
12 reorienting them to support a pipeline strategy.

13 MR. BUTLER: So I wouldn't want to -- now that
14 I've relinquished my time -- I wouldn't want to do that
15 without studying the thing first and then say, but there is
16 a potential recommendation that would come out of it, right?
17 I guess.

18 DR. MARK MILLER: I think if you're talking about
19 number two and there is a general consensus that people are
20 not sure what effect -- which of those pipeline programs are
21 currently effective -- that's an assumption if you reach
22 that conclusion -- then I think the natural place you have

1 to get to is then you wouldn't do that right away.

2 MS. BOCCUTI: [Off microphone.]

3 DR. MARK MILLER: Say that again?

4 MS. BOCCUTI: What you're saying you wouldn't do
5 is put the money right into a pipeline program --

6 DR. MARK MILLER: That's right, and --

7 MS. BOCCUTI: -- but that money originally could
8 go towards the analysis component of how they're doing now
9 and funding research to determine it.

10 DR. MARK MILLER: Okay. And I think if the
11 conversation -- what I am going to say is this. If the
12 conversation has shifted off the kind of Medicare general
13 revenue, then I think the principle that the Commission has
14 to keep in mind as you go through this is what is it -- how
15 far are you going to extend the definition of Medicare
16 funding, you know, from services to -- and I think that's
17 what you have to keep in the back of your mind for this
18 portion of the conversation, because now we're saying that
19 Medicare dollars that were for service -- and remember this
20 morning's conversation of beneficiary protections and how
21 much we pay providers and all the rest of it. And now we're
22 taking the Medicare dollar and saying we're actually going

1 to go further in defining what it's used for. That's what
2 the decision we've made by moving off of the general revenue
3 point. So keep that in mind as you go through it and talk
4 about this.

5 DR. CROSSON: Let me just make one point, because
6 I think what we decided, sort of, was to drop the first
7 bullet --

8 DR. MARK MILLER: Dropping the general revenue --

9 DR. CROSSON: Right, but not to drop the general
10 principle, right?

11 DR. MARK MILLER: Here is what I think is --

12 DR. CROSSON: That there should be a restructuring
13 of overall financing --

14 DR. MARK MILLER: So here is --

15 DR. CROSSON: -- then Mitra made the case, I
16 think, for --

17 DR. MARK MILLER: I've got it. So here's where I
18 think this conversation stands. You're saying, I want to
19 continue using Medicare dollars, and Bill, I fully
20 understand Medicare is a trust fund and those are all
21 accounting, you know, apparatus that can be easily
22 dissembled. But for the moment, just let me go with I want

1 to use -- what you were saying is I want to use mandatory
2 Medicare dollars to accomplish the principles or the
3 objectives that we're going to talk through here.

4 So in a sense, just to give you one narrow
5 illustration of this, what you're saying is a Medicare
6 dollar could now be used for, say, a pipeline program, or
7 even further, to study whether a pipeline program is
8 effective. And that may be a fine point to come to, but I
9 think it's just now the framework has shifted. You're using
10 that dollar which was for IME or to pay the provider or
11 whatever the case may be. That dollar will now be, if you
12 think of what portions it's used for, some portion of that
13 dollar would now go to studying Title VII and VIII, and I
14 think you should be clear the precedent that you're starting
15 to walk out here.

16 I'm not telling you not to do it, but I think the
17 conversation shifts fundamentally when you say, okay, it's
18 not a general revenue proposition. It's a Medicare
19 proposition. Now you're talking about how are you going to
20 use Medicare dollars. So I think you should keep that in
21 mind as you go through and talk through the rest of your
22 conversation.

1 MR. HACKBARTH: I have Mike and then Mitra, and
2 let me see hands on this particular point is what I'm
3 looking for. Karen, Ron, and George.

4 DR. CHERNEW: What I'm confused about in this
5 discussion about moving away is I have lost track in number
6 two, bullet point one, for example, who is making the
7 decisions about how to do the workforce analysis and
8 pipeline strategies. So as we move away from using IME
9 dollars, tying them to service deliveries, and instead put
10 them in some other -- I don't know what, that is my question
11 -- there has to be some other organization -- it may be CMS,
12 it could be out of CMS, I don't know -- but my question is,
13 for that one, I don't know who's doing it.

14 And similarly, when it gets down to three under
15 two, it says, make payments for office and clinic
16 supervision, is that bullet point meant to increase the fee-
17 for-service component that one would use that would be
18 medical education going in those other settings, which I
19 would have to probably oppose, or is there this other entity
20 from bullet one that is now making maybe lump-sum payments?

21 And my only comment on that is, I think the right
22 conceptual thing is to try and figure out where there's the

1 marginal and the fixed cost component because you don't want
2 to run everything through the payment system so that the
3 payment becomes really profitable for something that, for
4 example, might be a fixed cost to an institution. Then you
5 would want to pay it in a fixed cost way. But that requires
6 some other institution to do bullet point one. I think also
7 to do bullet point two, to do bullet point three, to do
8 bullet point four, and I guess the last bullet point you
9 could do just by paying less. But all the ones under two
10 require one other organization that I don't fully grasp.

11 DR. MARK MILLER: [Off microphone.] Okay. The
12 way I would parse through those five bullets are as follows.
13 The last one, you're absolutely right. You pay out less
14 IME, you've got some savings, some solvency.

15 The fourth one is the one that we've talked about
16 many times here and we put it on hold during the update
17 process and said, I'm going to reduce IME by, let's just
18 say, a point, and that dollar is now going to become
19 available to all hospitals if their quality performance is
20 high. So that's that one. You remember during the update
21 process we said, put it on hold because we're going to talk
22 about GMEs. So, so forth, no entity --

1 DR. CHERNEW: [Off microphone.] -- fee-for-
2 service.

3 DR. MARK MILLER: That's right. There's no super
4 entity that says, I'm going to shift the dollar around.

5 The next one up, you could characterize as saying
6 -- okay, and again, I think this is within a Medicare type
7 of operation. You wouldn't need a super --

8 DR. CHERNEW: [Off microphone.]

9 DR. MARK MILLER: So anyway, the third one from
10 the bottom, it says, okay, I'm going to make some adjustment
11 to the fee schedule in order to reimburse the physician
12 who's doing, say, didactic training outside of the hospital
13 and it would be offset with a reduction in IME.

14 DR. CHERNEW: But you could do that not through
15 the fee schedule.

16 DR. MARK MILLER: That's correct, but that was the
17 thought there and I would leave it to you guys to answer to
18 that.

19 The next one up, I think, is also potentially an
20 inside Medicare type of arrangement, where you say -- I'm
21 just going to take one of the possible options. The DGME
22 base amount has now been increased and I'm offsetting that

1 increase by lowering IME. No super entity there. I think
2 when you get to that first one, it starts to get a little
3 bit hairier, which is why it was discussed as a matter of
4 principle, because at principle it was, change the funding
5 source. You probably would change who is making those
6 allocation decisions if you were in a really different
7 environment. And that's what number one was all about.

8 But here, I admit, on number two, the first
9 bullet, kind of awkward.

10 MR. HACKBARTH: Yes, and I agree with that, Mark.
11 So what I'd like to do, as opposed to spend a lot of time
12 and say, yes, that's an important question, if the
13 resources, if Medicare resources are going to be redeployed
14 for bullet point one under number two, that raises some
15 questions about, you know, who is allocating the dollars for
16 what purpose, so that's flagged and we'll go back to it.

17 At the risk of being overly redundant, I do want
18 to emphasize that I don't think we necessarily want to do
19 all five of the bullets under number two, and so at some
20 point in the not-too-distant future, I'm going to want to
21 get input from people on which of those five people think
22 are particularly important.

1 So on my list now I have Mitra, Karen, Ron, and
2 George and Nancy. Mitra?

3 MS. BEHROOZI: Mark, the way you've laid it out is
4 incredibly helpful because I think it jumps out that that
5 first one is distinguishable because all the rest of those
6 things, besides not paying, really fit within MedPAC's
7 jurisdiction, and I think that's something we have kind of
8 struggled with as we have delved into the very juicy,
9 interesting area of GME and IME -- or graduate medical
10 education, forget the financing part even, and how to create
11 the workforce of the future that will care for Medicare
12 beneficiaries and all that. And we always get a point where
13 it's, like, but we're just MedPAC. Who are we to be making
14 recommendations about what the curriculum should involve and
15 all of that?

16 So I do feel like talking about all of those
17 things has really pushed us to the point of saying it's got
18 to be a bigger thing. There have got to be more payers
19 involved and coordinated and all of that. So I think that
20 really means that what we do in the interim should be
21 limited to what our direct payment-related kind of items.

22 MR. HACKBARTH: Karen?

1 DR. BORMAN: Yes. I'm increasingly troubled by
2 this what might be construed under number one and I share
3 Peter's concern about the term medical education. I think,
4 if I hear everyone correctly, we're really talking about
5 health professional education in its broadest sense is
6 really where collectively the group is talking about going.

7 I might make the suggestion that bullet number
8 three under number one move down to number two and we
9 perhaps back off on number one to say something to the --
10 that the topic here or the principle here is committing to
11 getting to some sort of definition of what the workforce to
12 meet the needs of the program are and the education that
13 underlies all of that. Just keep the principle focused on
14 that. Get out of the weeds with it. Move number three, or,
15 like I say, bullet three into the second thing. Get rid of
16 the top two bullets and just sort of move forward.

17 DR. CASTELLANOS: I guess I want to go back to
18 round one just for clarification. I've heard so many things
19 today that I'm not really sure where we are. Just for
20 clarification, we're going to take off restructuring the
21 medical education financing at this time? Or is that part
22 of -- I heard so many things about that, I'm not sure where

1 we stand, not with two, but number one, just restructuring
2 the overall medical education financing.

3 MR. HACKBARTH: Well, that's what Karen just
4 proposed, is basically take out that first item except for
5 the third bullet and move the third bullet into the second
6 part.

7 DR. CASTELLANOS: Okay.

8 DR. BORMAN: Just to clarify, if we want to say
9 it's a principle that this is a complex area, we need to
10 reassess it in the context of overall health professional
11 education financing for the appropriate workforce, great.
12 Let's not go past that.

13 MR. HACKBARTH: Yes. And so, Ron, maybe a bit
14 more responsive is based on the initial discussion about
15 Bill's point on general revenue financing, we'll take that
16 out.

17 DR. CASTELLANOS: Okay.

18 MR. HACKBARTH: Okay. And so that one is out. We
19 can say that pretty definitively. And I'll think through
20 Karen's point about the restructuring. It sounds right to
21 me, I just want to think about it some more. Does that
22 help? Is that responsive to you?

1 DR. CASTELLANOS: I think it helps. I just need
2 to think about it. Thank you.

3 MR. HACKBARTH: Okay. I see some other quizzical
4 looks.

5 MR. GEORGE MILLER: I may now not have a question
6 because Karen really hit what I wanted to say, but in two,
7 since you suggested that all of those are not -- we would
8 choose one or two of all of those options, are we going to
9 have some type of number -- maybe number is not the correct
10 thing -- I guess analysis of if you do A, or if you do one
11 versus two versus three or four, what's the number? And I
12 keep using "number." I think you follow what I'm saying.
13 What's the financial impact, or what would be the impact,
14 because they're different.

15 MR. HACKBARTH: They are different.

16 MR. GEORGE MILLER: Yes.

17 MR. HACKBARTH: So in that category, number two,
18 the IME extra is about \$3.5 billion, I think Craig said in
19 his presentation. So we're saying conceivably you could
20 take up to \$3.5 billion to redeploy for different purposes,
21 and this is a list of sample purposes.

22 MR. GEORGE MILLER: You would have to have a

1 number --

2 MR. HACKBARTH: For each one.

3 MR. GEORGE MILLER: -- for each one of them to

4 know --

5 MR. HACKBARTH: Well, you know, I'm not sure that,
6 in fact, we need to get to the point where we'd say it would
7 be 3.5 total and 1.65 would be for this purpose and 1.0
8 would be for that purpose. I think that's probably a level
9 of granularity --

10 MR. GEORGE MILLER: Yes.

11 MR. HACKBARTH: -- beyond where we need to go.

12 And I would urge us to think more in terms of a concept or
13 recommendation to the Congress --

14 MR. GEORGE MILLER: Which is the higher priority
15 of those?

16 MR. HACKBARTH: Yes.

17 MR. GEORGE MILLER: Okay.

18 MR. HACKBARTH: We think the priority areas among
19 these are -- I think that's an ambitious enough task for us.
20 Does that help?

21 MR. GEORGE MILLER: I think. But if I were to ask
22 our panelists, if they were given this choice, they may both

1 differently make different decisions on this based on their
2 needs. So we are trying to make a decision for the entire
3 country? I'm just struggling with this, I guess. I'll
4 think about it more.

5 MR. HACKBARTH: Well, let's come back. I want the
6 next round to be about priorities among these items. So
7 we'll come back to that in a minute. Nancy?

8 DR. KANE: Okay. Well, I don't know if I'm on
9 topic or not, because I'm a little lost to what exact topic
10 we are on, but I'm stuck a little bit on one, still, and so
11 here's where I'm trying to go. A couple things have always
12 bothered me about the way we pay for graduate medical
13 education through Medicare. One is that a big chunk of it
14 is going in DGME, which is resident salaries. A lot of what
15 they do is service, not education. And in some ways -- and
16 then a lot of other hospitals who don't have those residents
17 are hiring people hospitalists or whatever, to charge for
18 those same services.

19 And to me, we should really rethink DGME and
20 perhaps say, oh, if a resident is doing a patient service,
21 let's pay them a fee as though they were a hospitalist or
22 something. We can move all the DGME that's there that we

1 say is for education, because it's actually for service to
2 Medicare patients, and just say, now let's look at what
3 programs do we want to train the kind of residents we need
4 to take care of the Medicare population.

5 That would do a couple things. Then the dollars
6 would go out on program rather than service, but it would do
7 a couple things, one of which, which has always bothered me,
8 is that if you don't have a lot of Medicare patients, even
9 though you're training residents, you don't get any Medicare
10 dollars. I've visited quite a few safety net hospitals this
11 past year who are actively looking around to find some
12 Medicare patients so they can get some DGME and IME in
13 there.

14 So to me, we do need to reform, I don't know
15 whether it's one or two -- I think it's one, a restructure.
16 Rather than worrying about where the revenue is coming from,
17 I would think we ought to think about is DGME appropriate to
18 be paid out the way it is when right now it's being paid out
19 as salary support for service to Medicare patients. And
20 instead, let's just -- maybe we should say, let's start
21 paying fee-for-service for that the way we do when a
22 hospital doesn't have residents and then take all that money

1 and say, okay, we want to put that towards gerontology
2 training or redesigning in family practice or training
3 nursing home directors or -- so I just couldn't find in all
4 those bullets where I was, if that helps some.

5 MR. HACKBARTH: A couple points in reaction. One,
6 about the Medicare link, this has been one of our repeated
7 themes. If this is how the Federal Government is going to
8 contribute to graduate medical education, having this link
9 to Medicare service delivery gets in the way. And so that's
10 what a bunch of these things were about, was disconnecting
11 the flow of dollars for graduate medical education from
12 service delivery.

13 Having said that, you know, part of what, in fact,
14 was proposed here was shift some IME dollars to DGME. Now,
15 DGME is not based as a percentage add-on to service, but the
16 Medicare share is an instrumental part of the formula.

17 DR. KANE: [Off microphone.] You have to have
18 Medicare.

19 MR. HACKBARTH: Yes. And so, again, let's flag
20 that, as opposed to trying to resolve it. I hear what
21 you're saying. That is an important distortion in the
22 system.

1 specialties that aren't as lucrative to the sponsoring
2 institutions and the number of those might be fewer in the
3 absence of subsidies for the residents' salaries. And so
4 we've got a continuum here of economic circumstances.

5 Ideally, what you'd want to do is dig into what
6 the economics are of different types of specialty programs
7 and vary the Federal subsidy depending on whether they're
8 self-sustaining or not. That's an appealing concept. I
9 don't know how readily operationalized it is. I know for
10 certain that it's beyond the scope of anything that we can
11 do in the reasonably near future.

12 So we could make the observation that the
13 economics vary and a principle ought to be that we ought to,
14 over time, strive to vary the subsidy based on the
15 underlying economics of different types of programs. But I
16 think that sort of would be a longer-term objective as
17 opposed to something that can be done relatively quickly.

18 This second list that's in the interim list -- and
19 forgive me if I'm being tedious here -- the idea there was
20 to try to come up with some things that could be done
21 relatively quickly, not long-term but relatively quickly.
22 So it may be that we want to say that we would support some

1 shift from IME to DGME in the short-term, but in the long-
2 term, what you want to do is gear the subsidy for DGME to
3 the economics of the different types of training programs.

4 DR. KANE: Not just that, but to the programs that
5 don't have Medicare beneficiaries but do have an important
6 training function.

7 MR. HACKBARTH: Yes.

8 DR. KANE: And even IME could be shifted that way.

9 MR. HACKBARTH: Yes. So I think I understand what
10 you're saying and let's think some more about how we might
11 address that.

12 Did I miss anybody else on the list?

13 DR. MILSTEIN: [Off microphone.] Is this round
14 two or round three?

15 MR. HACKBARTH: This is round two, but we are
16 getting very close to the last round, which is why I want to
17 focus on this list of five items. Again, this is sort of a
18 catch-all list of things that have been mentioned in the
19 course of our conversation. In fact, I'll even venture to
20 add a sixth item, which would be --

21 MR. GEORGE MILLER: [Off microphone.]

22 MR. HACKBARTH: Let's not make the accounting any

1 more complicated than it needs to be.

2 So another potential item for this lower list
3 under item two would be to put part of the extra IME back
4 into the base rates for hospitals, which would, in effect,
5 redistribute it to non-teaching institutions as opposed to
6 sending it to the Treasury and taking it out of the system.

7 So this is a list of ideas that have been raised
8 in our conversation. I don't think it would be coherent and
9 best for us to say, oh, do a little bit of all these things.
10 And so what I want to get in this round, a sense of who
11 thinks particular items are important, and I would ask
12 somebody to lead off, and then I am going to gear off of
13 their statements. Peter?

14 MR. BUTLER: Okay. So I agree first with Karen's
15 summary of what to do with number one, so I think we're
16 beyond that.

17 So on number two, the ones that hit home are we
18 overpay, clearly, for IME and it is directly tied to volume
19 to service. We underpay for DGME. How much, we can
20 calculate. And that if we shift money to DGME, I think
21 there are several benefits, including you could look at the
22 true costs -- you could reduce variation on what you're

1 actually paying out and get -- I think Arnie or somebody
2 said, if you looked at the variation, you could eventually
3 both get your arms around what is an efficient -- you know,
4 what would the cost be, and you could also use it in a
5 pipeline sense over time and you could leverage the dollars
6 better in DGME and including addressing Nancy's issue, as
7 well. You could eventually have formulas that weren't just
8 driven by your Medicare share, and I think that's better
9 done by taking the overpayment in IME and putting it in DGME
10 as a principle, I think an important contribution that we
11 could make.

12 I do feel strongly that a portion, sooner rather
13 than later, should go for the accountability piece, because
14 our real leveraging is the long-term behaviors of these
15 physicians that are out in practice. And if we just say,
16 well, that's not going to happen anytime soon, I'd rather
17 kind of force us to kind of put it out there and as soon as
18 possible use that as carrot to kind of earn up to X-number
19 of dollars as a really important principle, because I think
20 it can be an important catalyst in what we do.

21 MR. HACKBARTH: I think, too, this actually -- I'm
22 going to constrain your list.

1 MR. BUTLER: Those are my two favorite.

2 MR. HACKBARTH: Okay.

3 MS. BOCCUTI: [Off microphone.] When you say
4 accountability, is it all that we've talked about, both
5 accountability for meeting standards for education and the
6 environment?

7 MR. BUTLER: Well, I favor more of the latter than
8 the former, but I confess there might be some kind of
9 blending of the two.

10 MS. BOCCUTI: Okay. Thank you.

11 MR. HACKBARTH: As you know, Peter, I agree in
12 terms of the accountability. This is a point that you've
13 raised and Arnie has raised and others. I think that that's
14 a critical long-term direction.

15 The question that I've raised is how quickly that
16 can be accomplished, whether we have the infrastructure for
17 that assessment of training program performance. That's a
18 relative detail right now.

19 So Peter has identified his high priorities. I'd
20 like to get other Commissioners to react to those, beginning
21 with Karen and Bruce and Arnie.

22 DR. BORMAN: I'm going to support Peter's two

1 priority items, just for perhaps some slightly different
2 reasons. One is that I am increasingly concerned about the
3 6,000 over-the-cap residents. And while we may all agree
4 that perhaps they may be maldistributed, although I'm not
5 sure we know enough about it to say that, they are, to some
6 degree, getting funded out of this pool of money that we're
7 now talking about moving around. I don't think any of us in
8 this room are prepared to have 6,000 fewer graduates next
9 academic year. I don't think our system is quite ready for
10 that. So that's one concern I have.

11 A second concern I have is I want to talk a little
12 bit about the issue that Nancy brought up about service.
13 There is no doubt that there is some service going on. The
14 line between service and experiential education at times is
15 extraordinarily blurry and may relate to the incremental
16 value of learning. So the 25th time you do something, maybe
17 you learn a little less taking care of that particular
18 patient than you did on the difference between number eight
19 and number 15, but we don't exactly know how to say that, to
20 measure that. We don't know what that is. I also think
21 there's a lot of complexities to this.

22 For example, related to internal medicine, and

1 Glenn probably knows some things about this and certainly
2 Bob, internal medicine has caps on resident workload so that
3 lots of programs that -- or places that have internal
4 medicine programs, for example, my own, regularly pay for
5 coverage for the patients that aren't there similar to the
6 situation that you described, Nancy, of a hospital that has
7 no residents. So granted, there is still a difference
8 there. It's not as big as it used to be. I just want to be
9 very careful about thinking we really understand the service
10 to education ratio and use it as a clear maneuvering point
11 here.

12 So I think the Medicare solvency piece, I think,
13 is minuscule, although I love the principle that sooner or
14 later we have got to start to pay down on some things.

15 The office and clinic supervision, I found to be
16 rather nebulous, and I also don't hear too many providers
17 out there clamoring back that they aren't going to have
18 residents because they're not getting paid and they don't
19 want to buy into the GC modifier and all the other
20 compliance pieces that go along with being a teaching
21 physician. So I would take that one off the table, too.

22 So again, I think we're primarily left with

1 accountability, increased DGME, the enhanced workforce
2 analysis, and some pipeline strategies. I just don't know.
3 I guess I wouldn't oppose that being in there, but I
4 personally have some concern about funding individuals who
5 don't provide 24/7 coverage which physicians and residents
6 do. And so I'm not sure that it's exactly the same to fund
7 others, thinking we're doing something similar with those
8 dollars that originally went to that. But the top two, I'm
9 for.

10 DR. STUART: I generally support Peter's
11 recommendations, as well. We haven't talked about that fund
12 Hospital Quality Incentive Payment Program. That was a big
13 piece when we got into this in the past, and the idea was
14 that the IME overpayment wasn't really paying for education.
15 And so the idea that somehow, something that wasn't paying
16 for education is going to be then funneled back just for
17 education, to me doesn't make much sense.

18 So I like to look at that fourth bullet point
19 under the -- well, the bullet point, the Hospital Quality
20 Incentive Payment Program is kind of a freebie that you get
21 when you cut IME to its true cost, but also recognizing the
22 fact that these IME overpayments currently go to medical

1 centers, and I would be -- that are involved in teaching,
2 and I would be hesitant to say, okay, well, let's take this
3 money that you had this year and next year we'll put it into
4 the rates, which was one -- the base rate, which was one
5 thing that Glenn suggested, because that would just take
6 away that money and they'd have to fill that hole somehow.
7 And even though maybe they were overpaid, it's not that that
8 money isn't doing any good. Whereas funding Hospital
9 Quality Incentive Payment Programs at least gives them a
10 chance to keep it, or at least to compete for it.

11 So I'd like to keep that piece there. I think
12 they make payments for office and clinic supervision,
13 probably funds under -- that that would go through the
14 current educational programs themselves. You indicate that
15 this doesn't work very well. Maybe that's part of where you
16 put a little bit on money on support accountability and
17 educational standards. I'm not sure that it matters which
18 of the bullet points you put that under, but that's my
19 thought.

20 DR. CASTELLANOS: Yes. I'm still struggling with
21 a lot of the conversation, but I'm still struggling with the
22 stability of the financing.

1 DR. MILSTEIN: I'll start with Peter's basis. If
2 we're overpaying, we're overpaying. If we're overpaying, I
3 think we should take it back to the Treasury. That's what I
4 think. And so I'd like to see, rather than increased DGME
5 payments, it would be more like right-sized DGME payments.
6 I take your point, Glenn, that that might take some analysis
7 to figure out what is a -- of the programs that get whatever
8 is the maximum high rating, an outside contractor could help
9 us and the Congress figure out what is the most efficient
10 provider of a high-quality graduate medical education
11 program, and that's the amount I would like to pay.

12 I think your point about making it specific to the
13 type of resident being trained is a really good one. But
14 it's a reiteration of a point I made earlier, is that if we
15 -- basically, I don't mean we, but the Medicare program
16 can't move more quickly in relation to problems that have
17 been obvious and around for a long time, then we're never
18 going to -- we'll always be way too slow. We need to have
19 more of a -- I know that this is not easy to do in a
20 political environment, but more of a rapid cycle in a
21 mentality for fixing these problems.

22 And so I would say right-sized DGME payments based

1 on an analysis that a contractor could probably do for us in
2 six months to what an efficient high-quality program
3 requires.

4 And then on the fourth, I support, but I do think,
5 actually, I back Pete's idea, is only temporarily tie it to
6 particular educational content. Otherwise, gear it to the
7 value that that teaching hospital is providing using the
8 same value definition that we've now introduced into the
9 Medicare update program. It's the total use of resources,
10 quality, and actual production cost.

11 I don't know whether -- it's funny. I'm a little
12 -- so anyway, that's my recommendation. It's a variant of
13 Pete's.

14 MR. GEORGE MILLER: I support Peter's
15 recommendations. I'm not sure -- I support them. I'll save
16 some time.

17 DR. KANE: Well, I support the whole idea of
18 right-sizing the DGME and also workforce analysis in some
19 way. But I wanted to put in a pitch for paying community-
20 based supervision, and actually, I would change that to
21 saying community-based, not office and clinic. I mean, I
22 was on the board of a physician group that did a lot of

1 pretty innovative stuff with frail elders and we were
2 constantly in demand to sort of train people and we really
3 didn't have time and we couldn't afford it. And I think
4 that's too bad. We are losing opportunities out there to
5 expose residents and medical students to -- and, you know,
6 nurse practitioners, as well, I might add. We actually
7 stopped taking nurse practitioner students because we
8 couldn't afford the time it took to oversee them.

9 So if we're really thinking about, you know,
10 training physicians to take care of geriatric patients, I
11 think we have to consider making payments for community-
12 based supervision, and that includes house calls, nursing
13 home, office, and clinic. So I still want to keep that one
14 on.

15 The last two, I prefer to -- if we're talking
16 about just IME, I prefer to redeploy it to improve the
17 educational output of the program and not put it in the
18 quality incentives, which I think in kind of a different
19 way.

20 And Medicare solvency, there's too many things it
21 needs besides this to solve the Medicare solvency.

22 DR. BERENSON: I think this is where I'm at right

1 now, sort of where Arnie is, perhaps with a modification. I
2 mean, I see the potential of redistributing the IME dollars
3 into DGME as a carrot, as an important carrot to get the
4 accountability that we want. So I might do something like
5 have a phase-out of the IME over an extended period of time,
6 and if, in fact, the teaching hospitals and we and whomever
7 else needs to be at the table can figure that out, we can
8 transfer that money. I wouldn't just do it without getting
9 something for it.

10 I still think in the long run, the best --
11 enhanced workforce analysis and pipeline strategies are
12 going to be done by somebody and the question is whether we
13 want to have any influence on it. In particular, from what
14 I've seen about work to support Title VII, National Health
15 Service Corps, those kinds of activities, they're sort of
16 oblivious to the particular needs of Medicare beneficiaries
17 and the Medicare program. I'd like to be able to play a
18 little bit in that arena if there was a way of using what
19 would be a tiny bit of Medicare money to be able to
20 influence that process. I think that would be a valuable
21 thing. But I understand there's this sort of precedent of
22 are we going to just start picking at Medicare money to

1 support somebody's good idea.

2 So I'm not sure ultimately where I come out, but I
3 do think in the long run, we want to be producing -- we have
4 to get at before graduate medical education. We have to get
5 into medical education and there might be a way of making a
6 small investment in that area.

7 DR. CROSSON: I think I'm in the Kane camp because
8 my number one is the support for broadening the payment to
9 other sites of care, community-based sites of care,
10 outpatient care. This is not a new issue. We have talked
11 about it before. We have had this recommendation now to
12 request regulatory changes in that arena. I think that
13 correlates -- is likely to correlate with a better output.
14 That would be my first one.

15 The second one is, in concert with that, is the
16 support for accountability in general, because I think,
17 again, we've talked of that. We're not sure exactly how to
18 do that, but that would be my second one.

19 And then two-and-a-half would be --

20 MR. HACKBARTH: You're over budget.

21 DR. CROSSON: -- would be the IME to DGME. I have
22 some question as to whether that's more than just doing it

1 for appearance sake, maybe a good appearance, but still not
2 really changing the amount of money available except for the
3 reallocation phenomenon. But I would support that as two-
4 and-a-half.

5 MR. HACKBARTH: Others on this side? Bill?

6 DR. SCANLON: I guess until Arnie mentioned right-
7 sizing, I was feeling very uncomfortable. I don't feel like
8 I know enough to decide sort of what to do at this point and
9 that actually -- I mean, it doesn't mean that it's going to
10 take us forever to know enough. I mean, I think that if you
11 redistribute money immediately, you create new
12 constituencies that are going to be there to try to preserve
13 that new status quo and I think that's potentially a problem
14 that we'd like to avoid.

15 So I would say a very short-term but intensive
16 investment in trying to understand more of the economics of
17 training, and I'll go along with Nancy. Let's keep the
18 money in training, this investment in human capital that we
19 want to have, but let's figure out where to put it. Some of
20 it may be community. Some of it may be DGME. But right
21 now, I couldn't tell you how to do the allocation.

22 MS. HANSEN: Yes. I would echo the whole training

1 process in the community-based environments based on similar
2 experience that Nancy has had with our PACE programs. That
3 would be my number one.

4 And I think this concept of accountability,
5 however we're going to build that in. There is just lots of
6 interpretation onto that. But it would be probably
7 components of that that I would probably want to lift up a
8 little bit more, but I'll leave it at that in terms of going
9 to Jay's one and two.

10 DR. CHERNEW: So I also believe in getting the
11 payments right, and also I think, though, it's a question of
12 getting them of the right form. So I think we have to be
13 very careful. So it's not just, for example -- so my number
14 one would have been make payments for office and clinic
15 supervision, like was just said by Nancy and Jennie and some
16 others. But that doesn't mean that I think we should bump
17 up the fees for those particular services and I think we
18 need to think clearly how that money works, because there
19 are incentives associated with whether we distort the fees
20 or otherwise send money there and I think that's a big issue
21 there. That's my number one.

22 My number two, and I think I'm going to be in the

1 minority here, is extend Medicare solvency. Now let me just
2 say, I don't think we should use any money to extend
3 Medicare solvency, but I don't think we should spend it
4 somewhere else just because we don't want to extend Medicare
5 solvency. I think when we spend money, we should spend
6 money that gets us some return. And if there's not another
7 place to do that, and I think there probably is, but unless
8 I'm convinced there's another place to do it, then we
9 shouldn't spend the money, and that's where it would put me
10 in the last bullet point.

11 DR. DEAN: Well, I would echo what Mike just said.
12 I guess I was struck in looking at the -- obviously, no
13 great surprise -- I think we need to support office and
14 clinic education. But it seems to me that that is
15 qualitatively different than the other issues, because to
16 really support that requires a much more basic change in the
17 whole formula. Then you have to get the residents there,
18 and that's been a big problem, getting released from
19 inpatient commitments, and there's a whole lot of other
20 barriers.

21 So I certainly think once we can get them into an
22 ambulatory setting, which I think we all agree is where we

1 need to shift the focus of the training, we've got to
2 support them. But it seemed to me that this was a much
3 bigger issue. These others were all places to use a little
4 extra money if we had it. So that's grossly oversimplified.

5 MR. HACKBARTH: Yes. Well, remember, Tom, that
6 it's basically a two-pronged approach. Number four is about
7 taking out some of the existing barriers to residents
8 leaving the hospital for training, and then the third bullet
9 under number two is to say let's also make it more
10 attractive for the people who would provide that training,
11 that supervision on the ambulatory side. So it's doing --

12 DR. DEAN: Okay. And maybe I didn't completely
13 have that all in context.

14 MR. HACKBARTH: Yes. Now, having said that, I
15 think Cristina was absolutely right to emphasize earlier
16 that even if there were no regulatory barriers, there are
17 still pretty strong incentives for hospitals to want to keep
18 their residents working there as opposed to having them out.

19 DR. DEAN: To me, that's a much bigger barrier
20 than the lack of payment for the time, although what Nancy
21 says is certainly true.

22 DR. CROSSON: Yes, but that could be dealt with in

1 this approach to what we were calling support for
2 accountability.

3 MR. HACKBARTH: Yes, right, and that's a good
4 point. One of the things that makes this such a confounding
5 topic to talk about is the interrelatedness among so many
6 different pieces.

7 So just to pick up on Jay's point, you could
8 imagine three different pieces working in conjunction with
9 one another. One is that the standards on what constitutes
10 appropriate training increasingly emphasized that to be
11 accredited, you have to get your residents into high-quality
12 ambulatory environments. And then you want to take away
13 some of the existing barriers that make it difficult for
14 hospitals to do that and how the hours are counted and the
15 documentation and all that. And then you also want to make
16 it a reasonable economic proposition for the ambulatory
17 sites that would provide the training. And so you want
18 those three pieces to work in combination with one another
19 if you're going to shift the locus of training.

20 I appreciate everybody's willingness to sort of
21 plow through this. It is very difficult and what I ask is
22 just a little time to sort of digest today's conversation

1 and try to figure out a recommended course for us.

2 I thought it was important to put up draft
3 recommendations to try to focus the conversation, but
4 clearly, we've got a significant ways to go here. And
5 Cristina and Craig, as always, thank you for your excellent
6 work on this.

7 So it is already 6:00 and what I want to do is
8 have our public comment period. I suspect we've got some
9 people out there. I would ask people to be sensitive to the
10 hour. It's been a long day for us, and maybe for you, as
11 well. So please keep your comments to no more than two
12 minutes. Begin by identifying yourself and your
13 organization.

14 I would remind everybody that this is not your
15 only, or even your best, opportunity to provide input to the
16 Commission. I urge people to use the website as a place to
17 present comments. We also read our mail. And last, and
18 most important, talk to the staff.

19 So when the red light comes back on, your two
20 minutes is up and we'll move to the next speaker.

21 MS. BONE: I was going to say good afternoon, but
22 I'll say good evening.

1 My name is Traci Bone and I'm here on behalf of
2 the College of American Pathologists, CAP. The CAP
3 represents 17,000 physicians who provide diagnosis and
4 interpretation for physicians on cancer and other related
5 diseases.

6 First of all, the CAP would like to thank MedPAC
7 for its attention to the issue of the in-office ancillary
8 services and its effect on increased self-referral of
9 designated health services. We are encouraged that MedPAC
10 will continue to study the impact of self-referral on
11 utilization of physician services in Medicare, particularly
12 pathology services.

13 The CAP supports the option to exclude certain
14 services from the IOAS exception. However, we would
15 encourage MedPAC to focus this exclusion on the time that
16 the patient is in the office, not whether or not the lab
17 tests or other service that can be provided on the same day.

18 Also, CAP has a bit of a concern that there's been
19 no distinction between clinical laboratory services and
20 anatomic pathology services. Anatomic pathology services,
21 as you may know, are very different from the routine
22 clinical lab tests that were initially contemplated from

1 Congress when they provided the in-office ancillary services
2 exception.

3 Finally, anatomic pathology services afford no
4 added convenience or quality of care to the patient because
5 these tests are too complex and time-consuming to be
6 performed and analyzed while the patient visits. Therefore,
7 the time-based rationale for the IOAS exception should not
8 apply to the anatomic pathology service.

9 We look forward to working with MedPAC on
10 addressing these important issues.

11 Thank you.

12 DR. CZEISLER: Chairman Hackbarth, Vice President
13 Crosson, and members of the Commission, my name is Charles
14 Czeisler, Professor of Medicine and Director of the Division
15 of Sleep Medicine, Harvard Medical School, and a member of
16 the Sleep Disorders Research Advisory Board of the National
17 Center for Sleep Disorders Research at the NHLBI.

18 I have flown from Boston today to strongly urge
19 the Medicare Payment Advisory Commission to address the
20 issue of resident physician work hours as you contemplate
21 restructuring overall graduate medical education financing.

22 In 2008, a blue ribbon Congressionally mandated

1 IOM Committee concluded that scheduling resident physicians
2 to work for more than 16 consecutive hours without sleep is
3 hazardous to hospital patients, many of whom are Medicare
4 beneficiaries, and hazardous to the resident physicians
5 themselves. Yet the ACGMA has failed to implement the 2008
6 IOM recommendations to limit resident physician work hours
7 and is currently sanctioning academic medical centers to
8 schedule resident physicians to work 30 hours shifts twice a
9 week.

10 Sleep loss impairs brain function, concentration,
11 coordination, and increases the risk of error. After 24
12 hours without sleep, performance impairment is comparable to
13 being legally drunk, clinical performance drops to the 7th
14 percentile of its rested performance, and memory
15 consolidation -- which occurs during sleep -- is, of course,
16 impaired.

17 As with alcohol, those affected by sleep loss
18 often do not recognize the impairment. One out of five
19 interns have admitted to us that they have made a fatigue-
20 related mistake that has injured patients. One out of 20
21 admits to making a fatigue-related mistake that has resulted
22 in the death of a patient. These errors are costly just

1 with those numbers of admitted errors, costing more than \$20
2 million a year.

3 Medicare has standing to implement safer resident
4 work hours. It pays \$10 billion a year to support IME and
5 DGME. The Medicare program has the authority to require
6 implementation of the 2008 IOM recommendations to limit
7 resident physician work hours as a condition for Medicare
8 participation in hospitals.

9 I certainly thing that no increase in the cap of
10 the number of residents supported by Medicare should be
11 approved or recommended until the 2008 IOM recommendations
12 on resident physician work hours are implemented.

13 Furthermore, Medicare beneficiaries -- three out
14 of four whom say that they would want a different physician
15 if they knew that the physician has been working for 24
16 hours and was going to care for them -- they should have the
17 right to know whether or not a physician has been working
18 for more than 24 hours without sleep before caring for them.

19 Thank you.

20 DR. MOHLER: I'm Jim Mohler. I was here today
21 testifying at the House Committee on Oversight and
22 Government Reform and thought I'd stop over here as well.

1 I am a urologist, the Chair of the Department of
2 Urology at Roswell Park and the Chair of the NCCN Prostate
3 Cancer Treatment Guideline Panel.

4 I just wanted to support the staff recommendation
5 to exempt radiation therapy from the in-office ancillary
6 services exception. We spent a lot of time talking today
7 about how treatment and early detection for prostate cancer
8 suffers when you over-diagnose and over-treat prostate
9 cancer. The radiation therapy exception is contributing to
10 this by removing freestanding radiation therapy centers from
11 the CON process at the state level and then making it
12 financially very attractive at the Federal level, and is
13 resulting in over-diagnosis and over-treatment of men with
14 prostate cancer.

15 Thank you.

16 MR. KETCH: My name is Todd Ketch. I'm with the
17 American Health Quality Association. We're the organization
18 that represents the national network of community-based
19 quality improvement organizations that not only work with
20 the Medicare program but Medicaid and other private payers
21 and government entities.

22 I wanted to just say a couple of things about the

1 discussion today about the quality improvement organizations
2 as it relates to the discussion of hospitals. It's
3 important, I believe, for the Commission to fully understand
4 that quality improvement organizations are not funded or
5 tasked to work with every hospital in a state. So they have
6 a very limited scope in terms of their ability to get out
7 and work hand-in-hand with hospitals. So it represents a
8 very small subset of the facilities in the state.

9 These exemplary organizations you had here today
10 have great results but may not necessarily have been -- and
11 I doubt were -- among the target set of hospitals that the
12 QIOs were working with in either of those states because
13 much of what they're doing is focused on those that are in
14 the greatest need from a quality standpoint. And so these
15 organizations are doing a great job and certainly we want to
16 learn from them, but may not have been in the group that
17 they targeted to work with. So I just point that out first.

18 For the Commission, just a couple of things that I
19 would recommend is to take a look at how we can strengthen
20 this really critical national quality improvement
21 infrastructure that we've built. Part of that is making
22 sure that the dollars that go to the program actually reach

1 the organizations that can do the work on the ground, these
2 QIOs in every state.

3 A significant portion of those funds right now are
4 diverted to national infrastructure development, which is
5 critically important, has all the measures, all of the other
6 things that go into that. We don't actually know where all
7 of that funding goes, but that's the way it's labeled in the
8 funding description for the scope of work. But it
9 represents a pretty significant portion of the funding for
10 the program.

11 So if we can find another way to fund those
12 activities, those national activities, that's going to help
13 to have more of those funds go toward the community-based
14 quality improvement efforts on the ground.

15 I'll stop there. Thank you.

16 MS. FISHER: Hi, I'm Karen with the AAMC, and I
17 hopefully will be brief.

18 I first applaud you for your endurance in dealing
19 with these issues, but specifically at the end of the day.

20 I'd like to recognize Craig and Cristina, too,
21 because in order to get your hands even somewhat around
22 these issues and the myriad issues that you've dealt with

1 through the past year-and-a-half that range from general
2 revenue financing and Title VII down to technical issues
3 relating to how you count resident time in ambulatory sites.
4 So it's a lot to take in.

5 I just want to focus in, though, on the
6 disappointment we have that there hasn't been more
7 discussion about the Medicare resident caps issue and the
8 6,000 residents that are not receiving any Medicare funding
9 by teaching hospitals. As the comments pointed out, this
10 may involve some long-term analysis and long-term thinking.
11 But I think most people would agree that 6,000 -- we're
12 going to need at least 6,000 additional physicians. And
13 this educational safety net that is developing is getting
14 frayed by teaching hospitals taking on these
15 responsibilities without receiving any support at all.

16 And so I would like to hope that maybe between
17 March and April you might reconsider your thinking about
18 adjusting the Medicare cap issue.

19 Thank you.

20 MR. HACKBARTH: Okay, we are adjourned until 8:30
21 tomorrow morning.

22 [Whereupon, at 6:12 p.m., the meeting was

1 recessed, to reconvene at 8:30 a.m. on Friday, March 5,
2 2010.]

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

The Horizon Ballroom
Ronald Reagan Building
International Trade Center
1300 Pennsylvania Avenue, N.W.
Washington, D.C.

Friday, March 5, 2010
8:30 a.m.

COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, J.D., Chair
FRANCIS J. CROSSON, M.D., Vice Chair
MITRA BEHROOZI, J.D.
ROBERT A. BERENSON, M.D.
JOHN M. BERTKO, F.S.A., M.A.A.A.
KAREN R. BORMAN, M.D.
PETER W. BUTLER, M.H.S.A.
RONALD D. CASTELLANOS, M.D.
MICHAEL CHERNEW, Ph.D.
THOMAS M. DEAN, M.D.
JENNIE CHIN HANSEN, R.N., M.S.N., F.A.A.N
NANCY M. KANE, D.B.A.
HERB B. KUHN
GEORGE N. MILLER, JR., M.H.S.A.
ARNOLD MILSTEIN, M.D., M.P.H.
WILLIAM J. SCANLON, Ph.D.
BRUCE STUART, Ph.D.

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1 P R O C E E D I N G S

2 MR. HACKBARTH: Okay, so first up this morning we
3 have two guests [inaudible] [Technical difficulties].

4 MS. RAY: Good morning. This morning we're going
5 to focus on giving Medicare flexibility to be a more
6 innovative, value-based payer with two presentations.
7 First, I'm going to look at the potential of three policies
8 to improve the efficiency of the program. In the next
9 session, John will discuss enhancing Medicare's research and
10 demonstration capacity.

11 The pace of delivery system reform and improved
12 efficiency in Medicare is slow, at best. The Commission has
13 made the argument for delivery reform but the statute has
14 not kept up. Medicare law affects the program's ability to
15 adopt innovative strategies. In some instances, the
16 statutory language does not clearly lay out Medicare's
17 authority. In other instances, Medicare cannot implement
18 these strategies because it does not have statutory
19 authority. Some policy experts have recently noted that
20 Medicare needs more flexibility in carrying out its mission.

21 This session focuses on giving Medicare
22 flexibility to implement three strategies: reference

1 pricing, performance risk strategies, and coverage with
2 evidence development. We have selected these three policies
3 because their application could improve price accuracy and
4 the efficiency of the Medicare program and decrease
5 knowledge gaps.

6 Under reference pricing, also called least costly
7 alternative, a single payment rate is set for clinically
8 similar services. Medicare has implemented this policy most
9 recently for durable medical equipment and also for some
10 drugs but two recent court decisions have affected its
11 future use.

12 Performance-based risk strategies link payment of
13 a service to beneficiary outcomes through risk-sharing with
14 product developers and providers. The basis of risk is the
15 quality of the performance of the product or service and is
16 measured by agreed upon outcomes. A change in law is
17 necessary to implement this strategy.

18 Under coverage with evidence development, Medicare
19 links payment to a requirement for prospective data
20 collection for potentially beneficial services that lack
21 clear evidence showing their clinical effectiveness among
22 beneficiaries. This strategy provides an approach that

1 permits payers to move beyond the yes/no coverage decisions
2 but the lack of clear legal foundation to implement this
3 strategy has affected its use.

4 I want to remind you, that we have recently
5 discussed these issues, the first two issues most recently
6 in last year's June report and we discussed coverage with
7 evidence development at the last November meeting.

8 We have brought two experts to discuss these three
9 strategies, Peter Neumann and Sean Tunis. Peter is director
10 of the Center for Evaluation of Value and Risk in Health, at
11 the Tufts Medical Center. Sean is founder and director of
12 the Center for Medical Technology Policy, an independent
13 nonprofit research group. Prior to founding the Center in
14 2006, he was the director of the Office of Clinical
15 Standards and Quality and Chief Medical Officer at CMS.

16 After Peter and Sean conclude their presentations,
17 we look forward to Commission discussion on the pros and
18 cons of increasing Medicare's flexibility to adopt these
19 policies and ways to include safeguards to ensure
20 accountability. We expect to include a discussion of these
21 policies in the June report. This would be an informational
22 chapter composed of this material and John's material on

1 enhancing Medicare's research and demonstration capacity.

2 Our goal today and at the April meeting is to
3 capture you comments.

4 DR. NEUMANN: Thank you, Nancy, and members of the
5 Commission. My name is Peter Neumann from Tufts Medical
6 Center in Boston and I'd like to acknowledge my colleague,
7 James Chambers, who's here with me today, and Lisa Meckley
8 of Tufts Medical Center, who contributed to our report.

9 Health policy makers have advanced different ideas
10 for value-based coverage and payment policies. These
11 policies attempt to link payment to evidence of achieved
12 outcomes and guide incentives to target resources towards
13 patients most likely to receive appreciable benefits.

14 Rather than paying for services delivered
15 regardless of results, the new approaches seek to reward
16 performance. In theory, these arrangements can help better
17 align systemwide incentives, reduce waste --

18 MR. HACKBARTH: We are having a microphone
19 problem.

20 DR. NEUMANN: Okay. Is that better?

21 MR. HACKBARTH: Yes. Go ahead.

22 DR. NEUMANN: In theory, these arrangements can

1 better align systemwide incentives, reduce waste, and
2 improve the overall value of the health system. These
3 experiences could hold important lessons for Medicare.

4 Our specific objectives in our work from MedPAC
5 were to describe various value-based policies for drugs,
6 devices, other medical services adopted by payers in the
7 U.S. other than Medicare and abroad, discuss the issues and
8 challenges that U.S. and international payers have faced in
9 adopting such approaches, and discuss implications for
10 Medicare.

11 Here, we focus on three types of value-based
12 policies, outcomes of performance-based arrangements or
13 agreements, sometimes called risk-sharing agreements, value-
14 based insurance design, and reference-based pricing
15 strategies.

16 Under outcomes of performance-based agreements,
17 coverage or payment for a product or service is dependent
18 upon the collection of additional population-level evidence.
19 We are tied by formula to a measure of clinical outcome in a
20 real-world environment. An arrangement involves risk
21 sharing, because both parties, typically the company and the
22 payer, support the financial consequences of reducing

1 uncertainty.

2 Value-based insurance design refers to the idea of
3 tailoring benefit design to encourage high-value services
4 and discourage low-value care. For example, drugs with
5 favorable evidence of value or cost effectiveness would
6 receive preferential formulary status in terms of reduced
7 cost sharing for patients.

8 Reference pricing refers to an arrangement in
9 which health insurers pay a maximum allowable amount for
10 drugs in a therapeutic class, and typically, patients pay
11 the difference if they want higher-priced drugs in the same
12 class.

13 In conjunction with MedPAC staff, we identified
14 case studies of policies implemented for a range of
15 technologies and services, though most of the cases focus on
16 pharmaceuticals. Ultimately, we selected several cases:
17 Beta-interferon for multiple sclerosis, MS; bortezomib,
18 Velcade for multiple myeloma; the Oncotype Dx test
19 implemented with United Health Care; sitagliptin, Januvia,
20 an arrangement with Cigna; and risedronates odium, Actonel,
21 an arrangement with Health Alliance.

22 We also looked at various value-based insurance

1 design and reference pricing arrangements. Our analysis is
2 based on reviews of the literature reviews with senior
3 officials working in different sectors of the health care
4 system.

5 So let me go through the case studies in turn.

6 First, the beta-interferons for multiple
7 sclerosis. This was an agreement in the U.K., and it's an
8 example of a performance-based arrangement. Because of
9 uncertainty about the drug's long-term benefits and concern
10 about poor value, an agreement was established permitting
11 prescribing of the new MS treatments conditional on
12 development of a ten-year longitudinal cohort study in which
13 the therapy's efficacy was monitored. The manufacturers
14 discounted their products on condition that the prices would
15 be adjusted based on study results. If any products failed
16 to show benefits consistent with projections, the National
17 Health Service in the U.K. would lower the price. A planned
18 interim analysis in 2009 did not support the conclusion that
19 the treatments offered good value.

20 Velcade multiple myeloma, also a case in the U.K.,
21 a protease inhibitor indicated for the treatment of multiple
22 myeloma, is the subject of an ongoing outcomes-based payment

1 initiative. This arrangement involves adjustments to
2 reimbursement after four months by the product manufacturer
3 to the National Health Service conditional on the drug's
4 effectiveness. If the drug does not shrink tumors by a
5 certain amount, the NHS receives a refund. Two years
6 following initiation, the arrangement seems to be viewed
7 favorably by all parties.

8 Third, Oncotype Dx and United Health Care.
9 Oncotype Dx is a molecular diagnostic test to predict the
10 risk of breast cancer recurrence in patients with early-
11 stage breast cancer. The test generates a recurrent score
12 and thus helps target adjuvant chemotherapy to those at
13 highest risk. Because of Oncotype's high cost -- over
14 \$3,600 -- and concerns about inappropriate use, United
15 Health Care restricted coverage through a pre-authorization
16 process that linked reimbursement to clinical criteria for
17 testing. The contract specifies that if chemotherapy does
18 not follow the test recommendation, United can renegotiate
19 rates for Oncotype Dx. In the agreement's first year, 15
20 percent of patients were treated contrary to the Oncotype Dx
21 results. In the second year, the rate decreased to six
22 percent.

1 Diabetes medication and Cigna. In 2009, Merck and
2 Cigna entered into an agreement involving sitagliptin,
3 Januvia, sitagliptin plus metformin, Janumet. This
4 agreement links rebates for the drugs to overall control of
5 hemoglobin A1c levels and adherence to therapy. Under the
6 agreement, Merck increases Cigna's discount for the drugs if
7 there is an increase in the patients -- in the percentage of
8 their diabetes patients reaching A1c goals -- under eight
9 percent -- regardless of which oral diabetes medications the
10 patients are taking.

11 Merck also increases the discount if the
12 percentage of patients adherent to the drugs increases. In
13 a sense, the better the drug works, the less it costs the
14 payer. For Cigna, improved compliance rates would lower A1c
15 levels, thus gaining them larger rebates and better managed
16 care with fewer complications. The manufacturer gains by
17 increasing drug utilization and perhaps market share for its
18 products.

19 Risedronates sodium, Actonel, the bisphosphonate drug
20 for osteoporosis, was the subject of a value-based agreement
21 between Health Alliance, an insurer in Illinois and Iowa,
22 and pharmaceutical companies who manufacture and market the

1 product. Under the arrangement, the manufacturers help pay
2 for the cost of treating fractures for patients who suffer a
3 fracture despite taking this drug. Health Alliance receives
4 a rebate for each non-vertebral fracture suffered by its
5 members. Notably, Health Alliance only receives
6 reimbursement for fractures suffered by patients who have
7 demonstrated adequate medication compliance. Thus, the
8 agreement encourages higher compliance rates and in theory
9 leads to improved medical outcomes. An analysis revealed
10 the company's rebate to the insurer was lower than the
11 maximum allowed in the agreement.

12 Policy makers have experimented with various
13 value-based insurance design approaches in recent years.
14 Some employers have waived copays for certain medications,
15 for example. Programs have reduced drug copayments for
16 patients with diabetes, asthma, high blood pressure, in an
17 attempt to prevent high-cost complications.

18 Some programs have claimed the arrangements have
19 improved health and saved money, though rigorous evaluations
20 have generally been lacking. Some new evidence suggests
21 some savings might be possible, at least from a societal
22 perspective.

1 Finally, reference pricing. Under these
2 arrangements, health plans pay the same amount for different
3 drugs or other products judged to have identical or similar
4 therapeutic effects. Health authorities around the world
5 have used the strategy. Canada, Germany, Netherlands have
6 policies. The government sets the maximum allowable rate
7 for drugs in a therapeutic class and patients choosing the
8 more expensive drug generally must pay the difference
9 between that price and the reference price.

10 Medicare has implemented this policy most
11 frequently as a least-costly alternative option, though
12 there are questions about Medicare's statutory authority in
13 this area.

14 So finally, let me just turn to some key
15 challenges and lessons learned. Reference-based pricing
16 models have gained a foothold in some countries. The
17 strategy may lead to reduced spending, though questions
18 remain about which products should be considered
19 interchangeable, and on that basis be assigned the same
20 price, as well as concerns about impacts on health and
21 innovation.

22 Value-based insurance design options have shown

1 some promise, but experience and rigorous evaluations are
2 generally limited. Moreover, the options to date have
3 tended to focus on waiving copayments for high-value
4 services rather than imposing them for low-value services.

5 Performance-based and risk-sharing agreements have
6 attracted interest from many quarters. Their conceptual
7 appeal is understandable. However, to date, they have had
8 only limited testing. This may reflect the fact that they
9 remain in an early adoption phase and experimentation is
10 ongoing. The paucity of examples may also reflect the fact
11 that to the extent they exist, agreements are not in the
12 public domain. A third possibility is that it has proven
13 difficult to find good candidates and difficult to find
14 willing negotiating partners given the complexities
15 involved.

16 A key challenge pertains to implementation costs.
17 Developing data protocols, negotiating arrangements,
18 assessing the performance of products, and designing
19 procedures to adjudicate disputes can be costly and time
20 consuming.

21 Ultimately, success will depend on how payers and
22 manufactures view the risks and rewards. For success,

1 several factors seem needed: High intervention costs,
2 substantial uncertainty about efficacy, concerns about
3 inappropriate use, and willing negotiating partners.
4 Ideally, the outcomes should be objective, clearly defined,
5 reproducible, and difficult to manipulate. They must be
6 valid measures of the desired treatment effect and should
7 not be confounded by patient characteristics or other
8 therapies.

9 Successful implementation will require high-
10 quality information systems, databases, and operational and
11 analytic expertise. Current systems typically do not
12 capture the level of detail required.

13 Value-based policies would appear to present some
14 unique opportunities for Medicare, given its leverage in the
15 marketplace and consequence of non-coverage to product
16 manufacturers and service providers. However, it also
17 presents some unique challenges. To the best of our
18 knowledge, Medicare has not implemented such a policy and a
19 change in Medicare law would likely be needed.

20 Thank you very much.

21 MR. HACKBARTH: Sean Tunis?

22 DR. TUNIS: Well, thanks, Glenn and Mark and

1 Nancy, for inviting me to speak to folks today. I heard
2 from all three of you that you don't care much what I say as
3 long as I do it in ten minutes, so I will try to honor that.

4 [Laughter.]

5 DR. TUNIS: So I am going to give a quick overview
6 of Medicare's experience with coverage with evidence
7 development. A number of folks in the room have
8 participated heavily in developing this program, including
9 one of the MedPAC members, Herb Kuhn.

10 So what I'll do is give a quick definition of CED,
11 what the purpose of the policy is, talk about the
12 relationship to comparative effectiveness research, which I
13 think in some ways is the most important thing about it,
14 which is it's a potentially very important tool for
15 promoting and supporting comparative effectiveness research
16 particularly relevant to Medicare. I'll list some of the
17 case studies that we examined to then extract some lessons
18 learned about what has worked and what not worked so well
19 and potentially how to fix CED in the Medicare program,
20 focusing on the statutory authority, priority setting, how
21 topics are selected for it, and also funding for it.

22 So first of all, the definition of coverage with

1 evidence development is kind of self-evident, but it's
2 Medicare reimbursement that is contingent on participation
3 of a patient in a clinical study, either a clinical trial or
4 a registry. In other words, the service is not paid for
5 unless the individual is enrolled in a systematic data
6 gathering exercise. So that's all CED is.

7 In terms of the reason for it, the main reason for
8 it is that there are not too many ways to reconcile the
9 tension between a desire for good evidence about
10 effectiveness and rapid adoption of new technology. By
11 definition, when technologies are new, the evidence of their
12 effectiveness and their comparative effectiveness is
13 limited, but there's also a lot of pressure to adopt those
14 technologies rapidly.

15 And one of the few ways you can actually reconcile
16 those two recurring tensions is figure out ways to study
17 things after they're being reimbursed, because if you impose
18 too high a threshold for coverage or reimbursement, you may
19 impose tremendous difficulties on actually generating the
20 evidence that you want. So this is a sort of the quid pro
21 quo of we'll pay for something in the context of getting the
22 evidence we need to make a more informed decision later.

1 And as I pointed out there, traditionally, when
2 evidence is limited, payers are in a pretty poor position to
3 restrict access to technology, so while payers, including
4 Medicare, talk a good game about evidence-based coverage
5 policy, when there is public and clinical demand for a
6 technology, the absence of good evidence of its
7 effectiveness is not a very robust basis to deny
8 reimbursement. Look at things like proton beam therapy or
9 vertebralplasty or many things for which it's just not
10 reasonable or plausible for a payer to actually say no, and
11 so you end up saying yes, holding your nose, and living
12 without any good evidence.

13 The approach here is to say, well, we might as
14 well at least say yes and also have the potential to get
15 some reasonable information to inform future decisions.

16 A key thing, I think, that is often missed about
17 the importance and power of coverage with evidence
18 development is it allows for Medicare's views on study
19 design to be incorporated into the trial. So oftentimes
20 you'll see studies that don't enroll Medicare patients or
21 they measure outcomes that aren't particularly relevant to
22 Medicare. With CED, because Medicare is approving the study

1 protocol before they approve a reimbursement, then they have
2 a say in actually how the study is designed, and this is the
3 key relationship.

4 Why CED is considered a tool for comparative
5 effectiveness research is that comparative effectiveness
6 research is really distinguished by the fact that it is
7 studies designed to inform decision making. That's what
8 distinguishes comparative effectiveness research from any
9 other form of clinical research, and I'm going to illustrate
10 that with my molecular basis of uncertainty, which is
11 probably one of the few times that this Commission is going
12 to be exposed to molecular biology, but I thought you'd
13 appreciate it.

14 [Laughter.]

15 DR. TUNIS: So this is actually an explanation.
16 You'll understand CER after I go through this slide quickly.
17 So what you have here is you've got your decision makers
18 inside the cell and you've got your research enterprise out
19 here in the extracellular milieu. All of you will remember
20 this from your education somewhere.

21 So most research is driven by intellectual
22 curiosity that's published as evidence and then that is

1 forced into -- towards the decision maker inside the cell
2 via KT1 or KT2. Those stand for knowledge transfer 1 and
3 knowledge transfer 2, but they're just meant to sound
4 scientific.

5 So the notion here is that you have this
6 translation problem where there's published evidence that
7 needs to get to the decision makers and a good amount of
8 that is -- unfortunately, the decision makers are coated
9 with those little low-affinity receptors for evidence, so
10 that's one problem --

11 [Laughter.]

12 DR. TUNIS: But the real issue is that most health
13 technology assessments identify major gaps in evidence. The
14 questions that you really want to know haven't been
15 answered, and the problem is that there's poor communication
16 from those gaps in evidence out to the research enterprise.
17 You have a defective transport here. So you don't get the
18 most important questions from the decision-maker perspective
19 acted upon by the research enterprise, and all comparative
20 effectiveness research really is is targeted therapy for the
21 defective transport so that the evidence needs of the
22 decision makers are acted upon by the research enterprise,

1 because if you have poor transport at KT3, it leads to
2 accumulation of ignorance inside the cell, which is toxic.

3 [Laughter.]

4 DR. TUNIS: So CED is really one mechanism by
5 which the information needs of decision makers are
6 communicated to the research enterprise, right, because if
7 researchers aren't going to get their services funded unless
8 they design a study that's meaningful to Medicare, then --
9 so by definition, CED is a tool for comparative
10 effectiveness research.

11 So, hopefully, you will be convinced that CED is
12 something that's important to figure out how to do well-

13 MR. HACKBARTH: What it makes me wonder, Sean, is
14 how much accumulated ignorance is necessary to kill the
15 cell.

16 [Laughter.]

17 DR. TUNIS: Yes. Well, that would need to be
18 looked at in further research that should be funded.

19 [Laughter.]

20 MR. HACKBARTH: I fear we're close to the
21 boundary.

22 DR. TUNIS: Yes. We could look into that for you.

1 [Laughter.]

2 DR. TUNIS: So the case studies that we looked at
3 to sort of identify what's worked and what's not worked, a
4 number. Lung volume reduction surgery, that was actually
5 done in the mid-1990s before real CED. PET for dementia,
6 off-label use of colorectal cancer drugs, use of FDG-PET in
7 oncology diagnosis, several others, and one of the recent
8 ones, genetic testing for warfarin. So this is just a list
9 of examples of CED that we reviewed, and so here's the kind
10 of lessons learned.

11 I'd say, and there are a number of folks from CMS
12 here who may want to comment later, but I would say that CED
13 remains a promising idea for which the implementation,
14 though done with great valor, has been relatively
15 unsuccessful for the most part, not uniformly unsuccessful.
16 I think there are some examples -- the National Oncologic
17 PET Registry, the ICD Registry--there's a few things that
18 have really gone forward, but probably fallen well short of
19 their real promise in terms of generating useful information
20 for decision making.

21 And I would say the key problem is the statutory
22 authority for coverage of evidence development is

1 controversial, which is probably a euphemism, but it's
2 simply not sufficiently robust to allow the agency to use
3 the policy when and how it needs to be used. And there's a
4 good reason for that. Originally, CED was based on
5 1862(a)(1)(A), which is the reasonable and necessary
6 coverage authority for Medicare. And when that was written
7 in 1965, no one was imagining the idea of coverage
8 contingent on participation in clinical research, so it's
9 simply not -- it's not really conceptualized in the statute.

10 Currently, they're using 1862(a)(1)(E) as the
11 statutory authority for CED, and that is an AHRQ authority
12 which introduces a lot of collaborative complications and
13 some timing issues. But fundamentally, what this leads to
14 is that because the statutory authority is controversial and
15 non-specific, not very robust, the agency has to be pretty
16 conservative and minimalist in how they approach this and
17 it's just not going to work if it's approached in a -- you
18 know, without sort of going at it full steam.

19 Sort of related to that, the priority setting
20 issue is CED has always been applied to technologies in a
21 reactive way when someone comes in and requests a coverage
22 decision. Therefore, each project is sort of created de

1 novo. It's a huge amount of staff time. It's very labor
2 intensive. It's very kind of idiosyncratic, and so there's
3 no kind of well-defined model by which it can be pursued.
4 And the topics that are selected aren't necessarily the
5 technologies for which you would most think that it would be
6 appropriate to apply CED, because they have to come over the
7 transom.

8 So some approach of horizon scanning, a careful
9 priority setting process to intelligently select topics that
10 would be good candidates for CED, i.e., technologies that
11 have a high likelihood of disseminating without evidence,
12 for which it would be a better idea to reimburse with the
13 idea of getting evidence, is probably essential for this to
14 work.

15 And then one other point here just to say is, you
16 know, because these CED research protocols have to be
17 developed in the time frame and the context of a coverage
18 decision which is highly politicized with great financial
19 stakes, it's not the best context to have a nuanced
20 scientific discussion about what's the appropriate research
21 protocol, and so a huge problem with most of the CED studies
22 to date is that there are compromises on the science as a

1 result of the politics and the time constraints, as opposed
2 to let's do the right study to really answer this question.

3 And then a final limitation, funding for research
4 costs. There's been several CED efforts where they've come
5 up with a study that would answer an important question
6 about PET scanners, implantable defibrillators, and it's
7 taken years to find the money to pay the costs of the
8 research, even though Medicare is willing to pay the costs
9 of the services. And in one case, for example, PET scanning
10 for Alzheimer's disease, where Medicare agreed to pay for
11 PET for suspected dementia in the context of a trial, it's,
12 I don't know, six years later and there's one center
13 enrolling patients and there's been several grant proposals
14 to the NIH for funding of that study that have been turned
15 down.

16 So if CED is going to work, you're going to have
17 to come up with some solution of dedicated funds to support
18 the research costs for doing these studies. If Medicare
19 thinks there's a technology for which you need a CED study,
20 there ought to be resources to pay the research costs for
21 the study without having to go through a competitive
22 scientific review process like any other NIH grant proposal.

1 So Medicare's experience with CED to date has
2 fallen short of the original policy objectives, despite, I
3 think, tremendous effort. My view is that the shortcomings
4 of CED are not intrinsic to the CED concept, and in fact, I
5 continue to believe that CED is not only possible, it's
6 inevitable because, as I said at the beginning, there's a
7 few other ideas that actually reconcile demand for access to
8 technology with the need for evidence. The experience to
9 date has highlighted ways that it could be improved.

10 There is growing interest among private payers in
11 CED. We're doing a bunch of work with private payers on
12 potentially implementing a CED approach, and CED that would
13 align and coordinate Medicare with private payers around the
14 same technologies would be incredibly powerful if we could
15 figure out how to do it.

16 And so those are my comments. Thanks very much.

17 MR. HACKBARTH: Thank you. So we will, as usual,
18 proceed with two rounds of questions and comments, the first
19 round being strictly clarifying questions, and we'll start
20 over on this side. Any clarifying questions? Tom?

21 DR. DEAN: Thank you. Those are very interesting.
22 The CED process, is it more than just a registry? I guess I

1 wasn't clear about that. I mean, it would seem that as far
2 as the costs are concerned, this would be relatively
3 inexpensive compared to a lot of research, but maybe I'm
4 offbase on that.

5 DR. TUNIS: So several of the CED initiatives have
6 been registries, like implantable defibrillators. There's
7 now, I think, somewhere between 300,000 and 400,000 patients
8 enrolled in an ICD registry. And it is relatively low-cost
9 and very limited data.

10 The original sort of CED before CED, the National
11 Emphysema Treatment Trial of this lung surgery for emphysema
12 was an 1,800-patient randomized trial. It took seven years,
13 \$50 million. But there are certain questions about, like
14 that one particularly, the effectiveness of the surgery that
15 actually require randomization. So while randomization
16 imposes a lot more sort of technical and financial barriers,
17 in some cases, it's probably the only way to actually
18 accurately and legitimately answer questions about a certain
19 technology, where for other things, registries are perfectly
20 fine.

21 DR. DEAN: Okay.

22 MS. BEHROOZI: I had a question about the

1 performance-based agreements, and I wondered if the
2 participants had looked at overall savings to the payer, for
3 example, with respect to the Actonel, if they had done
4 tiered copayments or excluded Actonel from their formulary
5 as opposed to the rebates or payments that they got in
6 relation to fractures. I mean, clearly, there's a health
7 outcomes benefit, no question, but I just wonder if they did
8 dollar savings in any of those cases.

9 DR. NEUMANN: Right. Certainly, the hope is that
10 it will generate savings. I think, to date, we just haven't
11 had rigorous studies. Some evaluations are ongoing, I think
12 in that case, as well, but we just don't have peer-reviewed
13 rigorous design studies that would allow us to say anything
14 more, at least not yet.

15 MR. KUHN: Sean, good morning. It's good to see
16 you. Great presentation. Two questions, just clarifying.
17 One is the number of CEDs that have been launched by CMS
18 thus far, if I remember right, it's about a dozen, and only
19 one has come to maybe conclusion and that's PET for
20 oncology. Is that correct? Do I have my numbers right on
21 that?

22 DR. TUNIS: Yes. I think a dozen might be on the

1 high end, but that's the right range. It's between eight
2 and 12 -- ten. So the PET registry probably has the most
3 mature published results. There are -- there's been a lot
4 of information generated and abstracts and I think some
5 papers from the ICD registry. But for the most part, I
6 think the general view is that there hasn't been a lot of
7 published evidence that would rise to the usual level of
8 decision making requirements of Medicare or any other payer.

9 MR. KUHN: And the second question is you did talk
10 about the difficulty between (a)(1)(A) and (a)(1)(E), and
11 those are difficult statutes to help make this work, but
12 also to add to the complication of this, this is also tied
13 to the NCD process, as well, if I remember correctly, which
14 further complicates it and makes it difficult to process.
15 Is that correct?

16 DR. TUNIS: Yes, I think for several reasons. One
17 is just, as I said, sort of the political dynamics of the
18 NCD process aren't a great setting to discuss kind of
19 scientific issues and the best knowledge generation
20 strategy, so how to do the best research. It also imposes
21 kind of time constraints, because the NCD process is very
22 fixed in terms of how long is allowed, you know, nine months

1 without a MEDCAC meeting, 12 months with it. You may or may
2 not be able to work things out in that period of time. So I
3 think, yes, a number of ways in which being tied to the NCE
4 process is problematic.

5 Of course, when it was started, that was really
6 the -- the reasonable and necessary authority was the
7 mechanism by which you can actually link the requirement of
8 reimbursement to data collection.

9 MR. KUHN: Right.

10 DR. TUNIS: So I suppose you could invent another
11 authority to make that linkage, but, of course, that's the
12 key thing, which is we don't pay unless the person is in a
13 study.

14 MR. KUHN: Thanks.

15 DR. SCANLON: A quick question about the
16 performance-based agreements, the Januvia example. Did I
17 hear right that if the drug performed better, that the
18 discount increased, which seems counterintuitive because
19 shouldn't the manufacturer want a reward?

20 DR. NEUMANN: Right. So that's my understanding.
21 It does sound a bit counterintuitive, that the better the
22 drug works, the better the discount. So in a sense, the

1 plan has an incentive to make sure that the patients are
2 adherent to the drug. And, in fact, they had a diabetes
3 disease management program in place already and this is sort
4 of an incentive to get them to adhere to that even more
5 strictly.

6 DR. CROSSON: I just want to compliment you both
7 on very clear presentations. Sean, I just had one
8 suggestion for the diagram. You left out in the
9 extracellular milieu the killer T cells that circulate and
10 disrupt the entire process. Without suggesting what those
11 might be, I just thought maybe you might want to add those.

12 [Laughter.]

13 DR. CROSSON: I actually have a question for
14 Peter. With respect to the performance-based agreements,
15 you listed three sorts of performance, actually,
16 effectiveness, appropriateness, and then adherence. The
17 appropriateness one struck my fancy a little bit, and the
18 question is, you talked about it with respect to the
19 diagnostic test Oncotype Dx. So in terms of determining the
20 appropriateness for that, was that based on information that
21 was contained within data already collected by Medicare, or
22 did it require extra data collection?

1 DR. NEUMANN: Right. So it was contingent on data
2 that had already been collected, but it was not Medicare
3 data. But there had been considerable data that showed the
4 test essentially gives a recurrent score and categorizes
5 people into high, medium, or low recurrence and therefore
6 adjutant chemotherapy is targeted based on that recurrent
7 score. But certainly the arrangement sort of needed that
8 pre-data collection effort to have preceded it.

9 DR. BERENSON: For Sean, I'm interested in sort of
10 the operational logistics of registry data collection. I
11 mean, two that you've mentioned, PET and ICDs, I think
12 you've probably got a relatively limited universe of people
13 who need to be reporting. Are there some kinds of
14 technologies, I assume, where it would be all hospitals or a
15 whole subset of doctors for which the issues around
16 reliability and completeness of reporting would just be a
17 real problem? And, in fact, in the current registries, is
18 there an issue of incomplete or invalid reporting to the
19 registry?

20 DR. TUNIS: Well, my sense is that the implantable
21 defibrillator registry is least problematic because it was
22 shifted over to the American College of Cardiology's

1 National Cardiovascular Data Registry, which is run by Duke
2 University, and they have all kinds of very well-developed
3 data quality and data collection strategies.

4 I think for the PET registry, it's been much more
5 problematic, in part because the actual -- you know, you
6 have the ordering physician and then you have the PET
7 imaging facility. There's information that is required from
8 both. It's not hospital-based, so you don't have the same
9 kind of IT infrastructure. And the amount of quality
10 assurance on the data reported was pretty limited. You
11 know, that's quite expensive.

12 So one of the chief objections to the publications
13 from the PET registry were the fact that the main outcome
14 was the physician's self-reported change in diagnosis and
15 management plan. Self-reported really can't be easily
16 validated, and you've got a situation where everybody knew
17 that the results of this study were going to influence
18 future reimbursement for PET, so the incentive to be not
19 fully accurate was fairly high.

20 DR. BERENSON: So, I mean, that's sort of inherent
21 in this approach, right, those kinds of incentives?

22 DR. TUNIS: Right, the incentive that -- right.

1 If the results are known to be potentially influential of
2 future coverage reimbursement, value-based or performance-
3 based stuff, that is a problem and it means that the sort of
4 data validation mechanisms exist by which, through auditing
5 and sampling and auditing, you can validate data. So it's
6 not as if the mechanisms don't exist. But you're correct to
7 point out that you'd want to be, particularly in these
8 studies, you'd want to be -- have pretty strong oversight
9 because of those incentives.

10 DR. KANE: So I was sitting in on a doctoral
11 research presentation a few months ago about reference
12 pricing and one of the findings was that it was -- in the
13 countries that have a lot of it, that their prices tend to
14 stay a little higher over time because the manufacturers
15 just don't want to bring in a lower-priced product and bring
16 the whole group down. Have you seen anything like that,
17 about reference pricing and sort of an anti-competitive
18 effect over time on drug prices?

19 DR. NEUMANN: I have not, and I'd like to see that
20 paper. It's an interesting finding. There have been some
21 studies that have tried to sort of tease out the effects of
22 reference pricing arrangements and impacts on everything

1 from health to spending to R&D and innovation. My sense is
2 it's sort of mixed results and nothing really conclusive
3 comes out of it we can point to as definitive.

4 The other thing I'll say is countries have
5 implemented reference pricing in terms of where they set and
6 how they set the maximum allowable price in different ways.
7 So some countries are essentially pegging everything to the
8 lowest-priced drug in the class. Some are using the
9 average-priced drug in the class. And some are using sort
10 of the third quartile, or not quartile, whatever the word is
11 -- the bottom third price.

12 So the answer to the question of whether it raises
13 or lowers price might depend also on actually how you do it.

14 MS. RAY: And just one other point.
15 Internationally, in some countries, they do both internal
16 reference pricing as well as external reference pricing,
17 where they're linking the drug price to the drug prices in
18 other countries. So that also is sort of a factor in
19 thinking about it.

20 DR. MILSTEIN: I have one question for Sean and
21 one for Peter. Sean, for better or for worse, our country
22 is organized around a, to say the least, multi-payer system.

1 One of the challenges in generating public goods like the
2 kind of information you're talking about in a multi-payer
3 system is it's so easy for a subset to free ride, you know,
4 off and on Medicare. So since we're going to have to change
5 the law in order to make progress here, what are your
6 thoughts on using our current, I'll call it common pathway,
7 which is the FDA, by expanding their authority, versus
8 giving CMS authority and then hoping somehow that CMS can
9 persuade their payers not to free-ride on all the resources
10 that CMS might be investing. That's my question for you,
11 Sean. I'll hold off Peter until Sean has answered.

12 DR. TUNIS: So I'm not sure if it would look good
13 for me to speculate on the idea of FDA increasing their
14 authority, you know. I mean, so at an entirely conceptual
15 level, I understand the problem it solves. But whether or
16 not in some way the -- in some way, the general suggestion
17 that the FDA demand more real world evidence or evidence of
18 comparative effectiveness as part of their regulatory
19 considerations, you know, is -- it would need a lot of
20 thought to see if that actually is moving the bar in the
21 right direction in terms of the balance between innovation
22 and evidence-based policy making. So I honestly don't know

1 if it's a step forward in public health.

2 So to me, the free-rider problem with Medicare, I
3 guess it doesn't seem impossible to me to envision that for
4 certain technologies, there would be some, whether it's a
5 government entity or a private sector entity, identifying
6 promising emerging technologies, developing study protocols
7 that would provide useful information on those, and then
8 kind of allowing Medicare or any private payers to sort of
9 decide to join the study and say, as part of our benefits,
10 we'll reimburse for this promising procedure for any patient
11 that's enrolled in one of these kind of approved studies
12 that is developed with input from multiple payers and the
13 clinical community, et cetera.

14 So I think you could find work-arounds to the
15 free-rider problem.

16 DR. MILSTEIN: Peter, my question for you is there
17 is a fair amount of evidence that within an average
18 effectiveness of any particular therapy, there's massive
19 variation for many therapies based on operator skill,
20 clinician skill. I think this was highlighted in a recent
21 New York Times article on robotic surgery, saying it can
22 outperform some of the surgeons that are the aces, but

1 rarely. And it's a huge variable. How is it -- what are
2 the challenges in bringing, I'll call it operator
3 experience, operator performance into the calculation so
4 we're not making judgments based on averages when, in fact,
5 any given Medicare beneficiary is going to face a huge range
6 in likely effectiveness depending on the operator skill.

7 DR. NEUMANN: Right. Well, I think there's been a
8 real challenge in implementing these performance-based
9 agreements for a whole series of reasons, but they tend to
10 be very complicated for the reason you suggested and others.
11 Most of them have been tied to pharmaceuticals as opposed to
12 diagnostics or devices or procedures where perhaps there's
13 less of a concern about operator skill. But I think the
14 fact that we haven't seen them in these other areas is
15 perhaps due to the reason you identified.

16 Even with pharmaceuticals, there are lots of
17 challenges with heterogeneity in populations and effect
18 sizes and so forth. The ones that seem to have succeeded
19 better than others are ones where you have more objective
20 measures. For example, the MS arrangement has proven
21 difficult, in part because it's difficult to measure or more
22 difficult to measure response. The Velcade example, where

1 you're looking at a biomarker that seems very predictive of
2 tumor response, has proven more successful.

3 MR. BERTKO: This is for either of you guys. Is
4 there a dollar threshold or a population cost threshold for
5 which any of these mechanisms become really useful and below
6 which they are probably not effective?

7 DR. TUNIS: I think the -- you know, in the case
8 of kind of evidence development, there's actually a formal
9 quantitative approach, value of information analysis that
10 Peter can talk about, which is kind of how much resources
11 would it be worth to generate certain evidence to reduce an
12 uncertainty. So you can actually figure it out. And I
13 think -- but I don't think there's a -- I don't kind of
14 intuitively think that there are certain services for which
15 the population is so small or the cost so low that it
16 wouldn't necessarily be worth doing it. It all depends on
17 what the uncertainty is and how much it would cost to reduce
18 it in a way that would change decision making. So anyway, I
19 just don't think that it's only for big-ticket items that
20 affect lots and lots of people.

21 DR. NEUMANN: I'd agree with that. You are sort
22 of asking when is it worth it to actually take the trouble

1 to implement this. And I'd agree with Sean, I think it's
2 hard to sort of draw generalizations and make a blanket
3 conclusion.

4 Obviously, you'd like the payoff to be worth the
5 cost implementing it somehow, and that could be the case for
6 different kinds of arrangements. I think it's going to
7 depend a lot on the specifics at hand.

8 MR. BERTKO: So as Sean was, I think, suggesting,
9 is that part of the study design process that happens on
10 this?

11 DR. TUNIS: I think more in the priority-setting
12 process of, you know, selecting -- in CED, anyway, selecting
13 the technologies and services for which it would be a
14 reasonable approach to look at the resources involved in,
15 you know, designing and implementing the study, funding the
16 study. And, again, I think you've probably worked on value-
17 of-information analysis. And there are lots of people out
18 there in the CER world thinking creatively about how to use
19 value-of-information analysis in priority setting in CER,
20 and probably with slight modifications you could say, well,
21 a subset of those questions really ought to be approached
22 using CED.

1 DR. CASTELLANOS: First of all, it was great
2 presentation. I appreciate you both being here.

3 We've been watching the PET emerging technology,
4 and this is really, I guess, a question for CMS more than
5 anything else. When it was approved, it was approved for
6 cancer. And we know that there are certain clinical
7 applications where it has no value at all, and that
8 information should be disseminated to the medical community;
9 i.e., in prostate cancer it really has no value. It is not
10 a hypermetabolic condition. Yet it is approved on a
11 financial basis.

12 So how can we disseminate not just the value of
13 the PET but the clinical applications?

14 DR. TUNIS: I know there are folks behind me who
15 know these facts better than I do. I think actually that
16 FTG PET in prostate cancer is specifically non-covered by
17 Medicare.

18 DR. CASTELLANOS: I gave that as an example as
19 it's not indicated, but there are other cancers where it is,
20 it's approved but it's of minimal, if any, value.

21 DR. TUNIS: Right. And certainly that's not just
22 true for PET scanning. There's lots of services that, you

1 know, Medicare and other payers pay for that are, you know,
2 pretty generally believed or thought to be ineffective. And
3 I think your question is really about educating physicians -
4 -

5 DR. CASTELLANOS: Absolutely.

6 DR. TUNIS: -- and sort of -- and I guess I would
7 say there that, you know, while Medicare and other payers
8 have a platform to educate physicians and perhaps a
9 motivation to do it, you know, the physicians don't
10 particularly look to Medicare as an educational resource.
11 You know, it seems to me that the professional societies --
12 and many of them already do, as you know, like the American
13 College of Cardiology, with their whole guideline program,
14 you know, has been pretty active in identifying what's
15 appropriate or inappropriate in trying to educate their
16 membership.

17 I don't know if part of what you're wondering is
18 whether Medicare should be sort of investing more energy in
19 that as well, in reaching out to physicians?

20 DR. CASTELLANOS: I really am. I think that would
21 be -- it's another service that we would like Medicare to
22 do, but I think it's very, very important.

1 DR. STUART: I would like to add my thanks for
2 coming. These were both very interesting presentations.

3 This is a question for Sean, and I've read the
4 case studies, and I take away these little bits in terms of,
5 well, there's a problem here, there's a problem here, and
6 what I'm left with and what is our charge here at MedPAC is
7 to say, well, how do we put that together and develop a road
8 map. Let's just say that we think that this idea of CED has
9 real potential that has been unrealized. Can you help us
10 with that road map? Are there things that need to be done
11 first? Is there an order of things? Is there some dollar
12 amount, a magic amount that should be put toward this before
13 we can say, all right, it's worth it, or it's not?
14 Something that would help us move to reconcile some of these
15 problems.

16 DR. TUNIS: So I think, you know -- and I agree
17 with you that when you read the case studies, there are
18 little insights here and there. I tried to pull those
19 together into sort of the three domains of where I think
20 sort of critical changes are essential in order for the
21 approach to work: the statutory authority, priority
22 setting, and the funding. So I would say of those three --

1 and I'm not sure exactly what order. I'd have to say that
2 it seems to me that without some sort of recommendation on a
3 more specific statutory authority to do this in Medicare, to
4 somehow link reimbursement to a requirement for study
5 participation, that it doesn't seem like any of the other
6 problems can be solved until Medicare has a more stable
7 platform to actually, you know, pursue this approach.

8 Then the second thing that is equally critical is
9 there's got to be money available to sort of quickly and
10 efficiently pay the research costs of the studies because it
11 turns out it's not enough for just Medicare to agree to pay
12 for the costs of the clinical services. It's just not --
13 you know, it's not a sweet enough deal. And, again, what
14 we've seen in numerous cases is that it has taken a lot of
15 time and a lot of energy to identify a poor of resources to
16 answer the questions that are most important to Medicare.

17 One example of that which I didn't mention already
18 is the original point of the defibrillator registry, the
19 implantable defibrillator registry, was to see if we could
20 better identify the 80 percent of people whose ICDs never
21 fire. So of all the ICDs implanted, 80 percent never fire.
22 So it would be really useful to be able to say these people

1 are at high likelihood of firing or low likelihood of
2 firing, so a risk stratification study.

3 To do a risk stratification study, you need
4 patient demographic characteristics and you need outcome
5 information, like whose defibrillator fired? Well, it took
6 five years to actually get funding arranged -- finally, you
7 know, AHRQ came through with it -- to actually start to
8 collect data on outcomes in the ICD registry. It started in
9 January 2005. Sometime this year we will begin to have
10 outcomes data in the registry. In the meantime, we've
11 spent, Medicare has spent somewhere north of \$15 billion on
12 implantable defibrillators, 80 percent of which will never
13 fire. How stupid is it -- let me correct that. It would
14 seem to --

15 [Laughter.]

16 DR. TUNIS: It would seem to be more sensible to
17 spend some portion of that money on, you know, collecting
18 that information.

19 Are we allowed to correct the record?

20 [Laughter.]

21 DR. BORMAN: I recognize, for example, with drug-
22 related coverage things that we no doubt get information

1 about adverse reactions or side effects or whatever we want
2 to currently label them. But as we think about some of the
3 other things here, procedures, imaging, so forth -- well,
4 procedures is a little easier because presumably then we do
5 collect complications. But, for example, things like the
6 Oncologic Diagnosis Panel, do we typically set up a
7 mechanism to identify the people in whom something turns out
8 to be positive that turns out to be not clinically relevant
9 and then gets pursued or is non-useful, which is a cost, an
10 added cost to the system, potentially a bad thing for the
11 patient, their physician, and so forth. And it seems to me
12 that as we think about outcomes to collect, for example, on
13 PET, do we -- as we think about the whole world of advanced
14 imaging, we need to be thinking about ionizing radiation
15 exposure and other things to our patients and the
16 consequences of that.

17 So as we sort of step back and strategically look
18 at these various ways to collect information in the context
19 of Medicare service delivery, do we require any attempt to
20 collect that sort of information, too? Or is that sort of
21 dependent on the design of the trial? Do we pay any
22 attention to that?

1 DR. TUNIS: I think mostly, you know, at least in
2 the kinds of studies we've been talking about, registries or
3 randomized trials, other prospective studies, you'll either
4 have the information you decided to collect because, you
5 know, people thought about it and determined it would be
6 important to collect, like, you know, exposure to radiation
7 might very well be information that's collected. In some
8 cases, the hope would be that, you know, registries could be
9 linked to administrative databases, claims databases,
10 electronic medical records, that there would actually be
11 ways to, you know, gather and analyze information that maybe
12 wasn't conceptualized as part of the prospective study but
13 is available if you could link to other sources of data.

14 DR. BORMAN: So do we or should we require that
15 the set-up of some of these activities be sort of
16 interoperable to other parts of data -- or other databases
17 that CMS or other government entities may have? Should that
18 be something that we're thinking about as if we say what is
19 going to be the best way to utilize this mechanism in the
20 context of the program? Are there some things we could
21 specify up front that would potentially -- that we've
22 learned would potentially broaden the impact of any given

1 investment because we could link it later to these other
2 databases that we weren't smart enough to think about in
3 advance? Is there that option?

4 DR. TUNIS: I think it's a great point to ponder.
5 You know, my kind of off-the-cuff thought is that, say, the
6 \$400 million that Secretary Sebelius has available to spend
7 on comparative effectiveness research, lots of which is
8 going to be focused on building infrastructure for data
9 collection, and including opportunities to link databases
10 with registries and other -- you know, I'm not -- that
11 probably will be useful in a service for CED studies as well
12 as any other comparative effectiveness research study. And
13 I'm not sure that there's something unique about
14 infrastructure development to CED that isn't already somehow
15 being thought about in the broader thinking related to
16 expanding the CER infrastructure generally.

17 MR. HACKBARTH: So the two of you have described
18 several different strategies that might be used for
19 increasing the value that we get for investing in new
20 developments, and each is appealing in its own way. But it
21 seems to me that it all depends on there being a
22 willingness, the political will, to limit the flow of new

1 stuff into the system until it has proven its value.

2 If you have that political willingness, then you
3 have various strategies that you might deploy, and the
4 strategy may be dependent on the nature of the technology.
5 But absent the political willingness, it becomes very
6 difficult to use any of these strategies. In a way, sort of
7 the reference pricing concept to me seems sort of
8 foundational in the sense that, look, you can come in, but
9 we're not going to pay you more until you prove you are
10 better. And the burden of proof is on the innovator to
11 establish that value. Until you have the willingness to
12 enforce that mentality, you're going to have a problem with
13 any of these strategies, making them work.

14 So that makes me think that sort of the most
15 important question is ultimately: Is there a way that we
16 can create a decision-making process that's sufficiently
17 insulated that you can create the necessary dynamic?

18 Let me stop there. Do you see the logic of what
19 I'm saying? And I'd welcome your reaction to it.

20 DR. TUNIS: So one thought is, you know, you're
21 sort of framing it as political will, and obviously
22 political will is in some way, you know -- the more public

1 support you have, the less political will you need, right?
2 So the question in part related to CED is: Is it a concept
3 that is actually appealing to folks other than payers or
4 policymakers? And, actually, I think that there is lots of
5 potential support. I think the clinical community would not
6 intrinsically be opposed to CED because they're as
7 interested in having good evidence and using things, you
8 know, thoughtfully and rationally and in an informed way.

9 I think even the patient/consumer universe, while
10 there is often strong demand for access to new technologies,
11 they also want to be informed about, you know, how they work
12 relative to other options, particularly as they become more
13 financially responsible for the impact of their health care
14 decisions.

15 In the United Kingdom, their version of CED is
16 called "only in research," so the National Institute of
17 Clinical Excellence will sometimes approve services only in
18 the context of research studies, and they did one of their
19 Citizens Council meetings where, you know, all of -- just
20 consumer representatives that advise NICE on the topic of
21 only in research, and there was overwhelming support for
22 that approach as one of the policy tools that could be used

1 at NICE.

2 I know the Brits are quite different from us in
3 many ways, but, you know, it at least makes me hopeful that
4 there would be some support.

5 MR. HACKBARTH: Let me ask you this, Sean. One of
6 the issues that you laid out about CED was the murky
7 statutory authority. Was there any effort made to go to the
8 Congress and say give us unambiguous statutory authority for
9 this? And what happened?

10 DR. TUNIS: None of my bosses at CMS suggested I
11 do that. I don't know. Herb, maybe this is a question for
12 you.

13 [Laughter.]

14 MR. HACKBARTH: You thought you got away from
15 this, Herb.

16 MR. KUHN: I was afraid of that. It was talked
17 about, it was discussed, but I think Sean said it right,
18 there are certain components, there are certain people in
19 the community that will support this and others that are
20 less favorable to it. So there is some need for building
21 more support for it.

22 DR. NEUMANN: My thought on your question is

1 certainly you need the political will, as you say, to
2 implement these strategies. It does strike me that, to the
3 extent the strategies are grounded in evidence, it might
4 feed back into the political will; that is, you know, if we
5 could agree on the process and on the sort of contours of
6 the strategy and it's going to be grounded in evidence and
7 people agree on the protocols to collect that evidence, it
8 might have positive feedback on the political will. There
9 are a lot of questions about it, how you collect the data
10 and so forth. But I think, you know, the conceptual appeal
11 of these strategies is such that, you know, it might help
12 the political will.

13 MR. HACKBARTH: Okay, so we are now into round
14 two. Let me see hands. Okay. We'll start down the row.

15 DR. DEAN: As a primary care doc, I find these
16 things incredibly appealing because so often we are faced
17 with decisions when we just simply don't have the evidence
18 that we need, and so we make the best judgment we can. And
19 so I guess I would -- and I've said before that some other --
20 -- it's relevant to what Ron and Arnie said. So often the
21 pharmaceutical people will come with a new product, and they
22 will say, "This is better than placebo." Well, I say, "So

1 what?" You know, that doesn't help me a bit. What I need
2 to know is how does it relate to what I already have
3 available. And almost never is that information easily
4 available.

5 And, of course, you know, part of it relates to
6 what we pay for, but even in terms of what we as clinicians
7 decide, we really need this comparative information. And I
8 realize I am -- you know, I'm sure there's no argument about
9 that. But it just seems to me that these are mechanisms
10 that are doable, even though there are obviously some
11 barriers.

12 But it just seems to me that it is really crucial
13 that we move forward with providing or trying to get the
14 Congress to provide whatever authority and resources we need
15 to move in this direction if we're ever going to get to
16 really an evidence-based practice.

17 I urge you to push as much as you can, and
18 certainly I'll be as supportive as I possibly can because I
19 think this is terribly important stuff.

20 DR. TUNIS: Do you want us to in any way respond
21 to this or not?

22 MR. HACKBARTH: If you want to. As we discussed

1 beforehand, I am eager to get a round for everybody in the
2 second round. So you can just nod your head and say, "Right
3 on," or --

4 DR. TUNIS: Yeah, yeah. Well, I'll say that, but
5 the only thing, it actually raises a couple of important
6 points, which is, as we were talking about before, related
7 to your question of political will, it is really important,
8 I think, to have the support of the clinical community, you
9 know, behind us just in the ways that you stated, and also
10 the folks delivering clinical care are actually going to be
11 called upon to be willing to enroll patients, you know, and
12 do the work. It's incremental work, actually. And, in
13 fact, one of the -- we didn't put it as a suggestion here,
14 but I actually think that there ought to be, you know, a
15 billable service to enroll patients in clinical trials
16 because, you know, it's important work to be done, and
17 there's no reason to think that docs should necessarily do
18 that without at least considering whether, you know,
19 compensation -- if compensation for that would make it more
20 likely that patients would be enrolled in the studies and
21 that the data would be high quality, then that's something
22 also important to think about.

1 MS. BEHROOZI: Yes, thanks. It's wonderful to
2 feel like we're really pulling things together in terms of
3 some of the things that we talk about were going on out
4 there. And I would just bring back in what I was saying
5 yesterday about the connection between this work and what we
6 were talking about yesterday with respect to the potential
7 benefit redesign.

8 I understand that, you know, the way it is posited
9 today, it is about research, kind of, you know, and getting
10 more evidence, but weaving it back into how we incent
11 providers to reduce the variability of care provided to
12 beneficiaries and for beneficiaries to have ways of making
13 more informed choices, but also recognizing the political
14 realities that you alluded to, Glenn, what you use the
15 information for, what you do with it in terms of something
16 like benefit design. Obviously, that is where the rubber
17 meets the road, or whatever. And I think, Peter, you raised
18 a really important point about the lack of focus on low-
19 value services in value-based insurance design, and that
20 kind of goes to some of what I was referring to and John,
21 you know, proposed a tiered co-payment structure or whatever
22 that would be just sort of flat dollar payments for seeing a

1 specialist or whatever. But, you know, I encourage the
2 Commission staff to focus a little more on discouraging low-
3 value services by going a little farther maybe than a flat
4 \$25 co-payment if a service is really unnecessary, which
5 will obviously need certain other tools in order to
6 implement that, whether it is some kind of prior
7 authorization or that kind of thing.

8 But I feel like we are really developing a lot of
9 information and our own sort of evidence base here for
10 thinking about benefit redesign. So thank you.

11 DR. NEUMANN: I will just say quickly, if I may,
12 it certainly seems to have proven easier to waive co-pays to
13 do good things than to impose them to do bad things. And
14 waiving co-pays to do good things is certainly admirable and
15 attractive and appealing, but there are no losers in a sense
16 if it works. And the hard part about the other side is you
17 do create losers.

18 MS. BEHROOZI: I would just say that reference
19 pricing is a way of penalizing the bad thing or whatever you
20 want -- not necessarily the lower-value thing. So, you
21 know, it's a little bit about how we articulate it.

22 DR. TUNIS: Since it hasn't been said explicitly,

1 but I think this point highlights it, it's worth realizing
2 that CED kind of fits into the overall paradigm of value-
3 based insurance design in that, you know, you can have
4 different co-pays for high-value or low-value services, and
5 then for services of uncertain benefit, you have a situation
6 where the coverage is contingent on participation in a
7 study. So, conceptually, actually it fits within the value-
8 based framework.

9 DR. CHERNEW: I have a whole series of comments,
10 and I'll try and say them all quickly.

11 The first one is it's interesting that so many of
12 these things are related to drugs, because in the Part D
13 system there's a whole separate set of rules that one would
14 have to think about when one thinks about coverage or not
15 coverage and how that works. And so I think that's some of
16 the examples that were given for coverage, evidence
17 development, of course, have been things that aren't drugs,
18 but many of the ones for things are drugs, and I think how
19 the Part D system fits in matters. That's my first comment.

20 The second comment is I just want to go on record
21 -- and I'd love for everyone to stand up and say something
22 about this collectively, including the audience -- which is

1 I think that the coverage for evidence development is
2 central, but there's a broader issue of general access to
3 the data that exists for the Medicare program that could be
4 used in successful, completely independent of any coverage
5 or non-coverage decision, and the ability to get that data
6 to evaluate things that are clinical, to evaluate things
7 that are systems, even when there's demonstrations for
8 general researchers, I think is much harder than it need be
9 if we wanted to have an ongoing management of the system for
10 value.

11 And so until we have a data system that both
12 protects privacy but allows researchers generally to access
13 the data to evaluate things that we know Medicare has done,
14 that we would like to evaluate but we can't for a number of
15 reasons, I think it's going to be very hard to get the
16 value, and I think the aspects of coverage of evidence
17 development is just a part of it. And even figuring out
18 exactly how we would implement the reference pricing or not
19 is a little bit beside the point to the basic notion that we
20 just can't get the general data to do a whole series of
21 evaluations.

22 I think that's particularly important because in

1 many cases in these situations you face the argument that,
2 well, the evaluation was done in a very rigorous design for
3 the way we did the procedure three years ago, but now we're
4 doing it differently; so the evidence that you have is no
5 longer relevant, and we're not going to implement it.

6 So a continuing approach -- these are typically
7 not one-time studies. It sort of needs this notion of this
8 continuous approach, and in order to do that, I think we
9 need a broader system of available data to do evaluations of
10 clinical things and system-oriented things.

11 The last point I'll make is I think it's really
12 important to think about how all of these things fit with
13 the general fee-for-service payment system. Of course, if
14 we move away from the fee-for-service payment system, some
15 of these issues change how we think about it one way or
16 another. And I think that matters.

17 I think it's also related important to think about
18 some of these areas are patient-oriented type decisions
19 where you could think about things like value-based
20 insurance design, which you know I support. Others, I think
21 really the incentives and the information have to go through
22 the physician. And it just depends on the nature of the

1 service how you would adopt various aspects of things and
2 how that would fit in with the broad payment system.

3 So my overall thematic comment is that we simply
4 can't afford to manage a system that has the amount of
5 inefficiency in it that our current system has, and the only
6 solution to that seems to be to have a more clinically
7 nuanced system in a whole range of ways. It is inevitable
8 that in that system we will not be able to get it perfect,
9 but we are not comparing the system of the future to the
10 perfect system. We are comparing the system of the future
11 to the current system, which, in my opinion, is sufficiently
12 far away from the perfect that we can find areas of
13 improvement that will be easier if we have better access to
14 data and better support of broad types of research.

15 I am done.

16 DR. NEUMANN: So you raised many good points, and
17 I'll try to address them briefly.

18 First, it certainly seems to be the case that most
19 of these experiments are related to drugs and not to other
20 types of services, at least value-based insurance design and
21 some of the performance-based agreements.

22 We did, just to note, find the Oncotype DX is an

1 example of at least showing that it's possible to do such a
2 thing with a diagnostic. And we even found an example
3 that's just started of one pair that's experimenting with
4 value-based insurance design for minimally invasive surgery,
5 to waive co-pays if someone does that. So I think we'll see
6 in the future -- why it's been the case that it's related to
7 pharmaceuticals, you know, we can speculate that the data
8 are better and, you know, perhaps some of Arnie's points
9 about less variation related to operator and so forth.

10 Your point about access to Medicare data, I think
11 that's the kind of question I would just say, "Right on,"
12 and I don't have to say anything else.

13 Then the final point I just want to say, I agree
14 with you about the global -- the incentives, and just
15 because we change the global incentive, if the actors
16 implementing those incentives are not facing different
17 incentives -- fee-for-service medicine, for example -- I
18 agree, I think we need to think about how everything fits
19 together, and we may not sufficiently address the problem.

20 DR. TUNIS: You know, I would just add I think
21 this general notion of -- I was just thinking about your
22 term, in order to get better value, we need a clinically

1 nuanced system and a clinically nuanced set of policies that
2 are sensitive to kind of, you know, value from a clinical
3 benefit point of view. And, you know, it totally agree with
4 that because the only other alternative is a clinically
5 insensitive system, which, by definition, seems less
6 appealing.

7 The only caveat to that is, you know, clinically
8 insensitive approaches to cost containment are, you know,
9 politically relatively simpler. Like it's easier to just
10 say we're cutting, you know, rehab stays by five visits, you
11 know, five days, and you're not discriminating against
12 anybody. You're just saying we're going to save that much
13 money because we're not going to pay for five extra days.
14 When you actually say we're going to ask you to pay more for
15 your proton beam treatment for your prostate cancer because
16 we think the evidence does not suggest that it's better, you
17 know, you are picking on people with prostate cancer. And,
18 you know, it raises a whole new set of --

19 MR. HACKBARTH: Identifiable lives versus
20 statistical lives, sort of.

21 DR. TUNIS: But, you know, that being said, it's
22 sort of yes, that's the path through the brier patch. But

1 avoiding the brier patch just means it's the clinically
2 insensitive meat cutter approach.

3 MR. KUHN: Two questions or observations here to
4 kind of help us think as we go forward on policy stuff here.

5 One, to revisit something that Arnie raised the
6 issue on, and that was the FDA. And I think, Sean, you gave
7 a good response there, but, you know, for more than a decade
8 now, people have been opining on this issue of parallel
9 review with CMS and FDA. And in a way, to kind of go back
10 to the beginning when developers come to FDA but also have
11 the payer there at the same time to start their discussion,
12 and I think it is one way to deal with the issue that you
13 raise, Sean, that is, reconcile the need for evidence with
14 also advancing new technology out there.

15 So I would be curious of your thoughts on a
16 parallel review process that we could think about be FDA and
17 CMS, and then at the same time, Peter, it would be
18 interesting to think about that in terms of pricing, because
19 one of the things that payers see is -- we've been talking
20 about drugs, but at least, say, on the device side, a lot of
21 device manufacturers will come through the 510(k) process,
22 which basically says the device is very similar to another

1 product in order to accelerate through the process, and then
2 they get it approved, and they come to the payers and say,
3 well, that's what I told FDA it was, but here's what it
4 really is, and I want five times X what the reference was
5 through the 510(k) process. And it gets a very difficult
6 process. So I was wondering if a parallel review with CMS
7 and FDA might help both on pricing as well as the evidence
8 development.

9 The second issue I just wanted to ask about a
10 little bit is that, you know, one model I saw back in 2008
11 that I thought was real interesting -- and, Sean, maybe you
12 can opine on this as well -- whether this might be something
13 -- there is some learnings for us here at MedPAC, and that
14 was the compendia regulation process that CMS went through.
15 Remember that within statute there were three compendias,
16 and two of them basically went out of business, and so there
17 was one left, and the community said, "We need more of
18 those." And so CMS went through a process in about four or
19 five months where they collected the evidence, approved some
20 new compendias, and that worked very well. So it was a very
21 short time frame. Obviously, other evidence is going to
22 take much longer to gather. But I think there might be some

1 important learnings from that process that could inform us
2 of how that worked, what didn't work in that, and came to a
3 pretty successful conclusion. So any thoughts about that,
4 if you have them, would be helpful.

5 DR. TUNIS: Well, the whole kind of better
6 alignment of FDA and CMS I think is a hugely important and
7 kind of migraine-inducing problem. And it's complicated
8 enough that I only want to say kind of briefly a couple
9 things.

10 One is you can try to better -- you know, the
11 parallel review idea is a great idea, but that's only about
12 aligning the process or sort of trying to make the process
13 more efficient. What's the difficult part is the non-
14 aligned evidentiary requirements or preferences of Medicare
15 and FDA. And, you know, you're not going to sort of sort
16 that out just by having a parallel review.

17 What I think is a real challenge facing industry,
18 both the pharmaceutical and device industry, these days is
19 that Medicare wants different stuff from the FDA, and in
20 some cases what the FDA wants forces them to do studies that
21 actually are by definition not as interesting or meaningful
22 to Medicare. And so I actually think a huge challenge of

1 the whole kind of comparative effectiveness research
2 enterprise, given that a lot of it is going to be funded by
3 private industry, is being able to have a meaningful and
4 genuine conversation between FDA and CMS about, you know,
5 how those kind of requirements for evidence for regulatory
6 approval and reimbursement can be better aligned.

7 One interesting place where this could actually
8 play out, I think it's in Section 114 of FDAMA, but I might
9 have the section wrong. But basically it's about the kinds
10 of studies that industry would be allowed to share with
11 payers and purchasers and not be in violation of marketing
12 restrictions. So FDAMA actually asked the FDA to develop
13 guidance about, you know, what sorts of studies would meet
14 that. Well, that's kind of this perfect territory about
15 where, you know, the payers, CMS and even the private
16 payers, should be sort of involved in that conversation
17 about deciding what kinds of studies should actually be
18 meaningful or sort of identified as adequate in the FDAMA
19 guidance. As far as I know, nothing is going on to develop
20 that, and I think when it happens, it would be really
21 important for CMS and FDA to both be in that conversation as
22 well as private payers.

1 All that is my way of saying, you know, trying to
2 develop a parallel process of review would be important
3 mostly because it would force the conversation about the
4 incompatibility of the evidence.

5 MR. HACKBARTH: Before you begin, Peter, I just
6 wanted to do a time check here. We have about 35 minutes
7 left in the scheduled time for this. Two hours seemed like
8 a lot of time an hour and a half ago, and this is an
9 incredibly rich discussion. But I do want to try to make
10 sure we get all the way around again. So I'd ask everybody
11 to keep their questions limited to one and please, Peter and
12 Sean, try and be real concise in your responses.

13 In particular, as I go around, after we finish
14 here, I'm going to ask for people who have not asked any
15 questions at all and give George and Peter and some others a
16 chance before we get anybody else in.

17 DR. NEUMANN: I just wanted to briefly address the
18 point you raise about the disconnect between the 510(k) and
19 the demand for higher reimbursement. I think it's a very
20 interesting point, which I haven't thought a lot about, but
21 it does strike me, on the one hand, it seems that there is a
22 fundamental disconnect. How could it be that they're

1 substantially equivalent and yet there's a demand for a
2 higher price?

3 But perhaps it could be the case that there really
4 is from a narrow clinical sense substantial equivalence, but
5 there is some difference that would warrant different
6 payment, or at least patients might value a certain -- at
7 one level, two drugs might be very equivalent, but one has a
8 much more favorable dosing profile or convenience profile or
9 side effect profile. And, you know, conceivably, there's a
10 higher willingness to pay, and there could be a parallel to
11 the device world. I think it gets to the different
12 statutory missions of FDA and CMS.

13 MR. HACKBARTH: Who hasn't had any chance
14 whatsoever to ask questions?

15 MS. HANSEN: First of all, I apologize for having
16 missed your earlier part of this, and you may have covered
17 it. Given how difficult doing this research is to begin
18 with, you know, one of the areas we consistently try to
19 cover is that of different populations, so whether we're
20 talking about race, ethnicity, or lower-income individuals.
21 Has there been any success in doing work that is designed in
22 a way with an effective execution to cover these segments of

1 populations?

2 DR. TUNIS: I mean, I think that that continues to
3 be a challenge, and I am trying to think of good examples in
4 the past that have really focused on it. But for the sake
5 of time, I would say that within the CER conversation, you
6 know, vulnerable and underrepresented populations and
7 minority populations have clearly been targeted as a
8 historically underrepresented population and lots more needs
9 to be done to get those folks into these studies.

10 One place where I think we need to be looking at
11 the CED approach, you know, is with the Medicaid programs,
12 which haven't to date been heavily involved in the idea.
13 But certainly if you want to get lower-income individuals
14 and some minority populations in these studies, it's going
15 to be through payers other than Medicare and some of the
16 other private payers.

17 So I just take your point, it's a problem that
18 needs to be addressed.

19 DR. NEUMANN: And I would agree with that and only
20 say that any discussion of these arrangements that we've
21 been talking about sort of quickly begs the discussion of
22 sub-groups defined in all kinds of ways. Typically, in the

1 value-based policies we've looked at, or the performance-
2 based policies, it's sub-groups tied to clinical
3 characteristics, so the Oncotype DX predicts recurring
4 scores and certain types of patients based on their
5 characteristics.

6 It certainly could be the case that these value-
7 based policies should follow other characteristics related
8 to demographics -- race, ethnicity, and so forth.

9 MR. BUTLER: So my question relates to kind of the
10 size of the opportunity of what we might put under the CED
11 umbrella. But first, you know, you kind of had me with the
12 \$15 billion -- \$12 billion of which you said has never been
13 used, in effect, because 80 percent is never fired. That's
14 a big number for sure.

15 Then also I think about things like the drug-
16 eluting stent, which is not on the list of the ten and had
17 its own interesting messy process associated with it.

18 And then as I look at the ten that have been
19 looked at, I think about eight of them -- two are drug and
20 eight are technologies or so forth.

21 So what I'm trying to get my arms around is that
22 if you were to have statutory authority, if you were to

1 prioritize, if you did have the funding, what might be the
2 pipeline or the size or the number of things that we might
3 be looking at if this were really humming along.

4 DR. TUNIS: That's a good question. You know, I
5 think if you really had sort of the funding and an
6 infrastructure to sort of quickly design and implement these
7 studies, like, you know, that was all facilitated, I think
8 there's probably -- you know, every year there's probably
9 two or three technologies in any clinical field, you know,
10 domain, that are important, promising, getting attention,
11 and could really benefit from some accelerated, organized
12 evaluation. So maybe, you know, if you looked across all
13 services -- and obviously this is just wild guessing. You
14 know, 40 or 50 a year, I mean, some reasonable number of
15 things that would be -- you know, for which this approach
16 would be applied.

17 Again, I think in some ways there are ways in
18 which you can imagine that almost every new technology that
19 is of, you know, any meaningful, potential importance that's
20 approved by the FDA will benefit from additional collection
21 to look at comparative effectiveness, effectiveness in new
22 populations, et cetera. And a vast majority of those

1 studies never get done. So, you know, you could -- I could
2 almost think of CED as becoming the rule rather than the
3 exception for, you know, when decisions are made to
4 reimburse meaningful new technologies.

5 MR. GEORGE MILLER: To follow along Peter's train
6 of thought, should you have the statutory authority, I guess
7 my question is: Does CMS have the infrastructure to
8 implement all that we've discussed here today? I remember
9 at another meeting that there were discussions concerning
10 trials -- demonstration projects, I'm sorry, demonstration
11 projects, and part of the problem with those demonstration
12 projects is that CMS did not have the funding in place to
13 help to evaluate them.

14 So my question really boils down to is there --
15 and this is probably a dangerous statement to make. But is
16 there enough funding authority to implement these processes
17 from your perspective? Or will part of this whole
18 evaluation need to make sure there's enough authority for
19 the infrastructure to make sure that this process could be
20 implemented?

21 DR. TUNIS: Yeah, so, you know, in addition to
22 needing to identify funds to support the research costs,

1 security would clearly need at CMS a larger number of people
2 with the kind of scientific and clinical expertise to be
3 able to really meaningfully, you know, address these things.

4 You know, the coverage staff currently I think has
5 as many folks in it as the staff at the FDA looking at
6 incontinence devices. You know, it's a tiny -- and the
7 coverage staff at Medicare is supposed to do the entire
8 universe of drugs and devices and procedures. So there
9 isn't -- you would need more infrastructure capacity, you
10 know, staffing and different kinds of technical expertise to
11 be able to pull this off.

12 MR. GEORGE MILLER: I'm curious. What does that
13 look like?

14 DR. TUNIS: You mean how many new people?

15 MR. GEORGE MILLER: No. Just dollar amount. Is
16 there a ratio to the budget? Just trying to get a feel of
17 what does it look like from a budget standpoint, not people.
18 You all have to --

19 DR. TUNIS: Well, yeah, you know, you would
20 clearly use a lot -- you would borrow a lot of resources and
21 technical resources from NIH and AHRQ and FDA and CDC. So,
22 you know, the incremental new staffing, you just need more -

1 - you know you probably need, to start off with, two or
2 three times the number of people currently at CMS to even
3 make kind of a meaningful run at doing this in a kind of
4 noticeable, measurable way.

5 MR. HACKBARTH: Okay. Have I missed anybody else?
6 Has everybody had a chance?

7 DR. SCANLON: To go back to the issue of capacity
8 and so that we're not starting any of these things sort of
9 at square one, sort of when we kind of get the bright idea
10 that this is a particular application that we want to use,
11 I'd ask you to think about the data that's required for
12 this, both in terms of the types and the volume and what
13 kind of a relationship there might be to take advantage of
14 the meaningful use sort of requirements that we're going to
15 have for this investment in IT that we're making.

16 The sense would be that we would want data in the
17 systems that was retrievable and, you know, code-able so
18 that it could be manipulated. But there's a question of
19 sort of could we make real inroads there in terms of the
20 kind of data that are needed if we do make those kinds of
21 requirements for electronic health records that we're
22 investing in. Or is that too pie in the sky? Are we always

1 going to be tailoring things for particular applications
2 that are -- you know, you can't in some respects sort of
3 build the general purpose, the Swiss army knife for these
4 kinds of interventions?

5 DR. TUNIS: I think, you know, as many people have
6 pointed out, there are so many comparative effectiveness
7 questions all the time that it's just going to be impossible
8 to design individual de novo studies and, you know, make a
9 dent in the ocean, or whatever the metaphor should be. And
10 so I think this idea of thinking of the meaningful use
11 provisions in the context of what would support good
12 comparative effectiveness research, including CED, you know,
13 is important and it hasn't been a big part of the
14 conversation, although it has not been entirely overlooked.
15 I think there was a White House task force at OSTP that has
16 been thinking about CER and meaningful use and some of those
17 issues. But it's not pie in the sky at all. I think it's
18 probably essential.

19 DR. NEUMANN: I would just add, for some of the
20 performance-based agreements that I mentioned, it really
21 requires a level of data that you may not have right now.
22 The Alc levels, the biomarker for the Velcade example, the

1 multiple sclerosis score, which is sort of a function and
2 cognition combination -- that's the kind of clinical detail
3 that you might get out of an electronic medical record
4 eventually or out of some other database but you probably
5 don't have right now.

6 DR. CROSSON: I would like to return just for a
7 minute to a topic I brought up earlier. A lot of this
8 discussion has been focused in on, you know, what to do
9 about technology or new technology where the effectiveness
10 or the indications for the technology are not fully
11 understood, and we spent a good amount of time and an
12 appropriate amount of time on that.

13 One of the things that you talked about, Peter,
14 still strikes me, and that's this question of using the
15 performance-based agreements to look at the appropriate use
16 of a technology when the appropriateness is known. You
17 know, there are a couple of attractive things.

18 Number one, I could imagine that this sort of
19 agreement would be much speedier than, for example, waiting
20 for information about the ultimate outcomes of a therapy
21 which could last over many years. You could imagine getting
22 to appropriateness determinations within the course of a

1 year and then acting on that, and as in the case of the
2 Oncotype DX, getting a change in behavior on the part of the
3 sponsors of the technology in a relatively short period of
4 time. So there's a certain attractiveness to it.

5 But as I said initially, to do this you sort of
6 have to have a technology going in where you're pretty sure
7 what the appropriateness is, and a lot of the things we've
8 discussed, for example, lung volume reduction surgery, of
9 course, you didn't know.

10 So the question is, you know, just roughly, are
11 there enough things in this arena where the appropriateness
12 is known going in and the problem is misapplication over
13 time, promotion of uses beyond the envelope of
14 appropriateness, to make that a viable policy direction?

15 DR. NEUMANN: Right. So a couple of things strike
16 me. First, I certainly agree to the extent you have
17 knowledge about appropriateness going in and you're looking
18 is the right person or patient getting the right technology,
19 it's a lot easier than trying to sort of adjudicate an
20 outcome later on, and cheaper and more straightforward and
21 presumably more effective. It does presume that you have
22 that knowledge, and how often do we have that? I'm not sure

1 how to answer it. Certainly there are clinical guidelines
2 in place sometimes that would allow us to say that. I think
3 we could look at plans that are trying to tie drugs to on-
4 label indications, which is, you might argue, a form of
5 appropriateness, I suppose.

6 The Oncotype DX case, as I mentioned before, was
7 an example where they actually had some data showing
8 empirically recurrent scores as the measure of
9 appropriateness. So there are probably other examples we
10 could think of, and maybe that's a good way to separate the
11 world into appropriateness, as you're saying, and what you
12 might call outcomes agreements where we're really trying to
13 understand appropriateness in a sense, or at least trying to
14 learn about outcomes down the road.

15 DR. TUNIS: You know, I think there is a lot of
16 data out there that could be used to sort of determine
17 appropriateness and apply, you know, performance-based
18 incentives, et cetera.

19 That being said, you know, and I think you were --
20 you know, both of these pieces of the puzzle need to be
21 addressed. It is sort of, you know, doing what we can with
22 the evidence we have today and making sure that we're not as

1 ignorant five years from now as we are now, because there
2 are so many examples -- you know, looking at the
3 appropriateness and rewarding how people use angioplasty or
4 revascularization procedures, and we still don't have a
5 definitive study that shows that revascularization is better
6 than maximal medical management.

7 So you can apply all the financial incentives you
8 want. You have no idea if you're doing the right thing. So
9 at least, it seems to me, you need to be paying attention to
10 both, which is, you know, generating better knowledge over
11 time and also trying to apply as best you can what you know
12 today.

13 DR. KANE: Yeah, I'm just trying to listen in to
14 this. I'm not very familiar with a lot of the internal
15 bureaucratic and legal issues surrounding this process,
16 although I have sort of tracked it from afar. But it seems
17 to me there are sort of two subjects we're on here at once,
18 and I'm a little -- maybe it would help to get it clarified.
19 One is sort of how do we figure out what constitutes value,
20 what kind of research can we be doing, and to me that sort
21 of all fell into this comparative effectiveness area. And
22 when we talked about that in the old days, you know, a few

1 months ago, I thought we were talking about sort of an all-
2 payer, multi-funding source approach to getting at this data
3 and developing the evidence. The developing-the-evidence
4 process I kind of thought would be no Medicare specific, but
5 a much broader group of payers and funding sources.

6 So when I looked at the title of today's topic, I
7 thought the next step would be, okay, so this evidence does
8 get produced somehow, however the comparative effectiveness
9 works. Then what's Medicare's ability to use the evidence?
10 How do they get that implemented into practice using, you
11 know, benefit design and, who knows, coverage decisions, et
12 cetera? And to me those are two distinct things, yet
13 somehow we're -- and I'm not sure which one we're really
14 talking about here, and I think we've just of mused them
15 together. And certainly when you're starting to talk about
16 financing the collection of data to figure out what is
17 effective, that falls, I think, back up there in that whole
18 topic of all the payers coming in to some broad agency.

19 And so I guess I'm a little lost as to exactly
20 which topic we really mean when we say enhancing Medicare's
21 flexibility to implement value-based policies. I'm just
22 trying to help frame the discussion a little bit so that

1 it's a little more meaningful to me, but maybe I'm just
2 completely missing the point.

3 DR. TUNIS: I think that's a good point. I think,
4 you know, maybe the simple answer is that, you know, just by
5 giving \$1 billion to comparative effectiveness research, and
6 even if you could get payers to put into a pool and have
7 another couple billion, it isn't close to what's actually
8 going to be needed to provide the resources to answer all
9 the important questions. And some of what we're talking
10 about is still other additional -- or the mechanisms that
11 will be necessary in order to continue to generate the
12 evidence, which can then be implemented through various
13 approaches to -- you know, value-based approaches, et
14 cetera.

15 CED, coverage with evidence development, I guess,
16 you know, it sort of straddles the two issues because it's a
17 tool for generating evidence and it's also a benefit design
18 tool for promoting, you know, for kind of applying the use
19 of evidence. So it does sort of straddle it. But maybe the
20 confusion is that, you know, this all-payer pool of money to
21 fund comparative effectiveness research is a great start and
22 it's just not the whole solution to the problem.

1 DR. NEUMANN: I agree, you raise a good point, and
2 I guess the way I've been thinking about it, at least in my
3 section, we were focusing on strategies or structures or
4 frameworks to change the way Medicare pays based on evidence
5 and value and so forth. But it quickly begs the question
6 about the quality of the evidence and who's producing the
7 evidence and where it's coming from. So we sort of
8 naturally get into that discussion.

9 MR. HACKBARTH: My thought, Nancy, was let's
10 assume we have the comparative effectiveness enterprise
11 fully funded and running. I don't think it's going to be
12 feasible to say nothing's covered until it goes through that
13 process and we develop adequate evidence. There's going to
14 be this relentless pressure this needs to be covered now,
15 and this is sort of a safety valve. Okay, what do we do in
16 those circumstances? Are there ways that we can make the
17 coverage conditional on evidence development or performance
18 in the interim?

19 The world's not going to stop just because we have
20 now funded comparative effectiveness research. CMS is going
21 to face these pressures. Private insurers are going to face
22 these pressures. So it's not all that clean, the separation

1 of the two.

2 DR. KANE: I understand, and I guess so then
3 there's a third subject, maybe, which is actually what I
4 think the title suggests, which is once you know what's
5 appropriate, how do you implement it? And I thought that
6 was kind of what -- so, you know, I can see that there is
7 this -- there's a whole lot of stuff that we should be
8 looking at that's already in place, not just new stuff. But
9 once you know what's appropriate, how do you create policies
10 that implement the value that you now know something about?

11 DR. MARK MILLER: A couple of other connections
12 here. If the comparative effectiveness enterprise was
13 running, which is a big giant "if," and a CED decision,
14 coverage with evidence development decision, was made in
15 CMS, some of the funding of the trial or, you know, studying
16 the data that comes out of the CED could be running through
17 the CE process, if you will, one. And two, at least one
18 policy to implement what you -- now that I have some
19 information, what can I do with it, I see as kind of the
20 reference pricing point, which is it's one way to change the
21 argument from yes-no coverage to yes, but based on this
22 evidence, this is where the price -- that's at least one

1 thing.

2 And then, of course, there are the conversations
3 that you guys have had on things like, you know, pay for
4 performance, those types of things, which might indirectly
5 inform on that kind of front.

6 DR. MILSTEIN: My comments really go back to
7 Glenn's point. This discussion is a microcosm of every
8 discussion we have. Our job is to try to improve the value
9 of the Medicare program and, by derivative, you know, the
10 value of the American health care system to the
11 competitiveness of the economy and the workforce, et cetera.
12 And this is such a beautiful microcosm of sort of the bigger
13 picture.

14 You know, I think it completely makes sense that
15 all of us have engaged in this question of, you know, do we
16 have the mechanical tools, are they good enough, to do the
17 evaluation; and then do we have the various tools to drive
18 value and benefit design and pricing and coverage, you know,
19 et cetera.

20 I think that's very important to do because if you
21 can't come to a judgment that what we have is good enough
22 for openers, you know, if you're playing poker, then all is

1 off.

2 But, you know, my view, at least in what I've
3 heard this time and the last several times -- you know,
4 Peter, you've been here to present, and I've heard you talk
5 -- it isn't like -- I mean, I do think -- my personal
6 judgment is the tools are good enough, certainly judged by
7 any private industry standard, to make judgments, and we
8 have a pretty good -- I think we have reasonable evidence on
9 the tools one would use once one knew that a particular
10 treatment provided higher value as to how you might
11 encourage it relative to a lower-value treatment.

12 So for me -- and it's Glenn's point -- we need to
13 assure ourselves that the mechanical part of this is ready
14 to go. But, you know, the shortfall, the voltage drop, is
15 typically not in that ascertainment. It's really in the
16 political will. Okay, now who wants to go forward with it?
17 And the fundamental problem is the ease with which anybody
18 in opposition can demonize the rationalizer. You know,
19 these are demonic bureaucrats who are going to, you know,
20 deprive you of your life and quality of life and individual
21 autonomy.

22 So, you know, realizing that neither one of you

1 are cultural anthropologists, but looking at what the other
2 countries, the other wealthy democracies that have done a
3 little bit better than we have in making sure that
4 innovations coming into the health care system are of higher
5 value rather than of lower value, can you share with us what
6 you think might have been some of the characteristics of
7 their system of doing this that you think may have
8 interfered with the demonization and allowed the public to
9 better trust efforts to improve value of health care
10 delivery?

11 You know, you mentioned a Citizens Council. It
12 sounds like, you know, about 10 percent of us on MedPAC
13 would qualify for that, and I assume having no revenue in
14 any way coming in from the health care system. What is it
15 that in these other wealthy democracies appears to induce
16 the level of public trust necessary to allow value-focused
17 policies, information to drive value-focused policies to go
18 forward?

19 DR. NEUMANN: Well, that's a big question, and I
20 guess just some thoughts. I mean, certainly -- and I don't
21 know that it's that helpful in terms of advice, but
22 certainly as everybody knows, systems and history and

1 culture and everything is very different in other countries
2 and allows solutions and policies that are difficult to
3 implement here. And I think that is, you know, just the way
4 it is.

5 I do think, though, having said that, there are
6 some processes that have been put in place in some places --
7 the U.K., perhaps Canada -- around a citizens council,
8 public input, transparency, posting things on the website,
9 allowing for public comment, allowing stakeholder input, and
10 on and on, that I think have helped the process. And those
11 processes have not been without debate, of course, even in
12 the countries that have done it. But I think it has allowed
13 a kind of -- I don't know -- escape valve or, you know, some
14 way to move the process forward.

15 But the fundamental political will that drives it
16 I think is really more a reflection of those other things I
17 mentioned at the outset.

18 DR. TUNIS: It's a great question, and I don't
19 think I'm even a good amateur cultural anthropologist. But,
20 you know, I would agree that it seems as though these issues
21 of kind of transparency and participation of the end users,
22 particularly the patients and consumers, is, you know,

1 critically important. But it's not as if that has escaped
2 people's attention. I think folks are trying to do that.
3 But I do think the Citizens Council at the National
4 Institute of Clinical Excellence has been a huge asset to
5 them in terms of the legitimacy of the process. They've
6 tried to be very transparent, et cetera.

7 Another big difference is, you know -- and this in
8 some ways begs the question -- somewhere at some point in
9 the U.K. the NHS decided it was going to have a budget. And
10 once you've kind of gotten to the point where you're working
11 within a fixed budget or a budget that at least, you know,
12 is in some way, you know, specifically increased over time,
13 all of your conversations then become how are you going to
14 allocate within this fixed pot for this entire system, and
15 that really changes the nature of the conversation in terms
16 of people's willingness to -- you know, then the whole
17 notion of opportunity costs really makes sense. And, you
18 know, NICE is always talking about opportunity costs. Well,
19 if we pay for this, what is it that you'd like us not to pay
20 for? Or, you know, if we pay for this very low value thing,
21 you know, you have to think about the person who is not
22 getting a higher-value service which we don't -- you know,

1 so it does seem like that changes the conversation.

2 There were some examples at Medicare where some
3 programs were passed that had a fixed budget. I'm thinking
4 specifically of Section 641 of the MMA, which I won't take
5 the time to go into, but it was remarkable how having a
6 fixed pot of money in a program in Medicare really changed
7 the dynamics of the political will and the conversation.
8 And I can tell you about that, Arnie, offline if you're
9 interested.

10 MR. BERTKO: Okay. Ignoring the statutory
11 limitations in terms of getting this done in Medicare, can
12 you guys revisit the private sector and what lessons we
13 could learn there? I'm thinking about the background
14 readings and then the presentation from your today, it seems
15 like most of the private sector stuff was in the nature of
16 performance incentives types of stuff and not so much in
17 turning things down. And I'm wondering how that relates to
18 what I'm guessing is the private sector use of medical
19 necessity to get there. Are lessons in the private sector
20 much limited than what we've talked about for Medicare here
21 today?

22 DR. NEUMANN: Well, I can address the performance-

1 based agreements, value-based insurance design, and the
2 reference pricing. You know, I think one lesson is there's
3 experimentation going on that's, you know, interesting to
4 look at. It certainly raises challenges. I think
5 conceptually all three are appealing, and in practice, they
6 are harder to do than one might realize, particularly the
7 performance-based agreements. The value-based insurance
8 design, there have been some ongoing experiments with it,
9 and Mike Chernew's very involved.

10 My sense until Mike's recent paper, we really
11 don't know the impact. There are a lot of claims about its
12 savings and health gains, but we really haven't had rigorous
13 designed with control groups and, you know, sufficient data
14 and evaluation periods and so forth. And I think the same
15 probably goes for the performance-based agreements. I
16 think, you know, we're in kind of an early experiment and
17 churning phase. I think reference pricing we have more
18 experience, certainly from countries overseas, and, you
19 know, I think we could -- maybe some would argue with this,
20 but I think there's more of a track record and more success
21 with that strategy.

22 DR. TUNIS: I think lessons learned from the

1 private sector in terms of CED, you know, is kind of at the
2 coarsest kind of level is, you know, kind of what I said at
3 the beginning. You know, in the face of uncertainty, the
4 default is often, you know, we pay as opposed to we don't
5 pay. Uncertainty does not work -- you know, the fact that
6 we don't know if proton bean is better is not a good basis
7 to say we're not going to pay for it. That's just not the
8 way it plays out.

9 So the idea of having a third option between yes
10 and no, which is yes in the context of generating
11 information we wish we had today, there's a lot of
12 enthusiasm for that. And one of the major obstacles is, you
13 know, contract language and sort of the state legislative
14 oversight of reasonable -- and the implementation of
15 reasonable and necessary. And I think private payers are
16 equally faced with, you know, not an adequate contractual
17 basis upon which to sort of link reimbursement with
18 participation and studies.

19 DR. CASTELLANOS: I guess it's ironic because
20 we're on a Payment Advisory Commission and, you know, we
21 talk about value, we're talking about the value of the
22 procedure and the appropriateness, but we kind of slip over

1 the cost of the procedure.

2 As an example, you brought up proton just right
3 now, and there's a big difference between the cost of
4 proton, which is \$180,000, and a procedure called
5 interstitial seeds, which is like \$10,000. You know, we
6 don't discuss the appropriateness of cost.

7 I personally think we need to get into that for
8 the clinician to have a better understanding of making
9 value-based decisions. Any comments on that?

10 DR. TUNIS: I'm just trying to think, I probably
11 can't do myself any more damage today, so I might as well
12 weigh in.

13 [Laughter.]

14 DR. MARK MILLER: I was just going to say, you're
15 definitely there, so go ahead.

16 DR. TUNIS: But, yeah, I think sort of two things.
17 One is, you know, for a lot of the work that I've done, I
18 haven't been particularly focused on the cost issue
19 primarily because it has been so obvious that the serious
20 deficiencies in our knowledge about relative effectiveness,
21 you know, unless you know something about comparative
22 effectiveness, you can't say anything about cost

1 effectiveness without any reasonable confidence. So that is
2 one point.

3 That being said, we oftentimes have some maybe
4 uncertain but suggestive information about comparative
5 effectiveness. In those cases, I think large cost
6 differences ought to be known about and become part of the
7 decision-making process, particularly in a context where
8 patients and clinicians are going to be increasingly, you
9 know, sort of exposed to the implications of those
10 differences. So I would just say yes, I agree.

11 DR. STUART: This is a quickie. It's following up
12 on the point that John made, and it's focused to Peter.
13 I've read your three case studies of performance-based
14 agreements, and I guess the question I have in looking at
15 that: Is this a sample of three in a population of three?
16 Or is it a sample of three in a population of hundreds? Do
17 you have some sense of how big this enterprise is in the
18 private sector?

19 DR. NEUMANN: One of the challenges, some of what
20 goes on out there is not in the public domain, and companies
21 are negotiating with health plans, and it's not entirely
22 clear to those of us on the outside what's going on.

1 Having said that, my sense is there's not
2 hundreds. Whenever we've asked -- and we've asked a lot of
3 people about these agreements -- these are the three in the
4 U.S. that come up, and the Oncotype DX come up. There are
5 other agreements overseas that are going on, and we probably
6 could have come up with some other examples. But my sense
7 is there are not a lot of them yet, and we may see a lot
8 more in the future, but I think we just don't have that many
9 examples yet.

10 MR. HACKBARTH: I have sort of a related question.
11 Again, I'm thinking at a high level of abstraction here, but
12 my first question was about political will, and this is
13 related to that. The question is whether we're likely to be
14 more effective in dealing with these very difficult issues
15 if we centralize decision-making or decentralize the
16 decision-making. So, you know, one model is, you know, like
17 the U.K., you have got sort of one-stop shopping. If it's
18 going to be done in the U.K., it's going to be evaluated by
19 NICE and a recommendation made. That focuses all of the
20 pressure or all of the energy on a single source, and, you
21 know, hopefully it's well funded and you have an open
22 dialogue and that system works well.

1 Sort of another very different strategy is to say
2 let's not concentrate the decision in one place. These are
3 difficult questions. Let's allow, indeed encourage
4 variation and have a very decentralized decision-making
5 process. And, you know, if you use private health plans as
6 the basis and people have a range of choices in private
7 health plans, for example, through an exchange, that can be
8 something that influences their judgment. They can choose
9 to enroll in the plan with the very wide open coverage
10 process, or they can choose one that's much more stringent.

11 As you look around the world, any evidence on
12 which of those approaches works better or might work in the
13 particular setting of the United States?

14 DR. NEUMANN: Well, what strikes me is we do have
15 a Part D process where plans could experiment with value-
16 based insurance design and other approaches, and maybe
17 that's a very healthy thing that there could be
18 decentralization and experiments going on by different
19 plans. To me, the challenge is some of the data collection
20 costs and research costs probably couldn't be borne by
21 individual plans, and there might be a natural role for a
22 centralized body of the government, Medicare --

1 MR. HACKBARTH: Well, you can have centralized
2 research, you know, through the comparative effectiveness
3 enterprise and, you know, large-scale public funding, but
4 decision-making about the application of that research
5 decentralized.

6 DR. NEUMANN: Right. And perhaps that's the model
7 that would be workable. I think that would be interesting,
8 you know, to study that further and see, and maybe there are
9 some examples we could draw from.

10 It strikes me that even some of the strategies we
11 talked about, performance-based agreements, might involve
12 some intensive analytic work, additional data collection
13 after Medicare would collect the original data, and whether
14 or not that could be borne by the individual plans I think
15 is still a question.

16 DR. TUNIS: I'm sure there's no right answer to
17 this question. I've heard it debated all different ways,
18 and clearly centralizing the evidence review process,
19 centralizing the priority-setting process, you know,
20 everything but the decision-making process. But, of course,
21 when you decentralize the decision-making process, it
22 becomes, you know, individual organizations that are much

1 less kind of politically strong, and they're, you know,
2 subject to kind of legal pressures and, you know, et cetera.
3 So, you know, there's a trade-off there, and at some point -
4 - you know, I don't know if you've seen the movie "The Hurt
5 Locker," but, you know, somebody has got to put on the suit
6 and go out there where the bombs are. And, you know,
7 there's no magic to -- you know, at some point there's a
8 tough decision to make that is made in the setting of always
9 some degree of uncertainty and great financial and political
10 implications.

11 And so the question is, you know, you can't just
12 toss hot potato around forever. Someone eventually ends up
13 holding it. And, you know, I'm inclined to think that, all
14 things considered, it's got to be, you know, something more
15 centralized than disparate. But it's not obvious to me
16 that, you know, the Medicare program -- you know, to me
17 what's crazy about it is that if it's clinically nuanced
18 decisions, you know, it probably would be better in the
19 hands of physician organizations than government or payer
20 organizations. But, Ron, you know, will know all the
21 reasons why organized medicine isn't any more anxious to
22 catch the hot potato than anybody else.

1 MR. HACKBARTH: Right. Well, maybe the image of
2 "The Hurt Locker" is a fitting place to end this
3 conversation. Thank you, Peter and Sean. That was very,
4 very well done. We really appreciate your help.

5 Okay. Moving on to our final session on enhancing
6 Medicare's research and demonstration capacity.

7 Okay. John, good morning.

8 MR. RICHARDSON: In the last session, you
9 discussed three specific policy areas where Medicare may
10 need greater administrative flexibility to become a more
11 value-based and innovative healthcare purchaser.

12 This session continues on that theme and presents
13 a series of issues and options to increase Medicare's
14 flexibility with corresponding accountability to conduct
15 research and demonstrations of potential innovations in plan
16 policy and service delivery models, and to accelerate the
17 dissemination of promising models into the entire Medicare
18 Program.

19 We seek to engage you this morning in a discussion
20 on these issues to guide further staff work in the area of
21 reforming Medicare's administrative flexibility.

22 As Nancy mentioned at the outset of her session,

1 we plan to return at the Commission's April meeting for
2 further discussions of our respective issues and will then
3 combine that into a chapter in the upcoming June report.

4 Over the last several years, the Commission and
5 other observers have noted that there is a growing
6 disconnect between the constrained resources, flexibility,
7 and resulting output of Medicare's research and
8 demonstration activity, and the urgent need for Medicare to
9 identify and test payment in service delivery innovations,
10 and then to implement those innovations to reduce the
11 unsustainable rate of growth in Medicare's overall costs and
12 improve the quality of care for the program's beneficiaries
13 or, ideally, both.

14 In thinking about options to increase the
15 program's flexibility in this area, it is important to
16 simultaneously consider how to include an appropriate degree
17 of accountability and oversight of the program's activities.
18 Before getting into some possible solutions or options for
19 solutions, I think it will be helpful to spend a few minutes
20 defining the problem we are trying to solve by orienting
21 everyone to what the Medicare demonstrations currently are
22 and how the demonstration process currently works.

1 Within the Medicare Program, research, strictly
2 speaking, refers to data-driven analyses performed to
3 suggest policy options for further exploration, whereas
4 demonstrations are applied research. They change how
5 Medicare operates in a limited geographic area or for a
6 particular group of beneficiaries. A demonstration may be
7 initiated by the Secretary under waiver authority that was
8 granted shortly after Medicare was created, or by the
9 Congress, typically through a provision inserted into a much
10 larger authorization act.

11 Demonstrations usually are designed to test
12 variations for Medicare's current policies governing
13 payments to providers, beneficiary cost sharing, covered
14 services, or service delivery models.

15 By design, demonstrations are time-limited and
16 geographically limited, but the infrastructure at CMS and
17 its contractors needed to implement these mini programs,
18 such as claims processing and beneficiary enrollment
19 processes, can be as complex as that used to operate the
20 full program.

21 Part of this complexity is due to the need to
22 generate and collect the data, in particular, service use

1 and quality data, that is essential to empirically evaluate
2 the effects of the interventions being tested.

3 Finally, it should be noted that Medicare has used
4 demonstrations to develop some of the most significant
5 changes in the program, such as the inpatient perspective
6 payment system, the skilled nursing facility and home health
7 perspective payment systems, the Program for All-inclusive
8 Care for the Elderly, or PACE, which integrates Medicare and
9 Medicaid services to improve care for dually eligible
10 beneficiaries and the hospice benefit.

11 The graphic on this slide presents a simplified
12 picture of how the demonstration process currently works.

13 First, as I mentioned a minute ago, demonstrations
14 are initiated by the Congress or by the Department. Once
15 initiated, the key component within CMS that is responsible
16 for the design, development, implementation, and evaluation
17 of each demonstration is the CMS Office of Research,
18 Development, and Information, or ORDI.

19 After initiation, ORDI will take the concept for a
20 demonstration, bring to bear any supporting research, and
21 develop a design proposal. The design will include plans
22 both for how the demonstration would be implemented and how

1 it would be evaluated.

2 Next, CMS staff and policy officials will work
3 with HHS and OMB staff and policy officials to refine and
4 ultimately bet approval to move forward with the proposed
5 design.

6 The OMB process includes a Paperwork Reduction Act
7 review of all proposed information collection activities
8 that will occur during the demonstration or as part of the
9 evaluation, such as beneficiary and provider surveys and
10 quality measures.

11 OMB also does a separate review of whether the
12 demonstration is projected to be budget-neutral within its
13 period of operation, and OMB will require changes in the
14 demonstration's design until it is satisfied that the
15 demonstration will, at a minimum not result in a net
16 increase in Medicare spending.

17 Once the project is cleared internally within the
18 Executive Branch, CMS begins the process of selecting and
19 contracting with demonstration sites. In most cases, CMS
20 must carry out this step in compliance with the Federal
21 Acquisition Regulation, or FAR, which stringently governs
22 the procurement of goods and services by almost every

1 federal agency and covers Medicare's contracting with
2 demonstration sites.

3 Once contract awards have been made, the selected
4 sites have been given lead time to prepare for
5 implementation, including time to identify potential
6 beneficiary participants for enrollment when the
7 demonstration starts. Once it is operational, the
8 demonstration typically runs between one and five years,
9 depending on the terms of the final study design or the
10 original mandate from the Congress, if there was one.

11 Sometimes, demonstrations are continued beyond
12 their original planned time frame, with one or more
13 extensions.

14 Looking at evaluations, interim evaluations may be
15 conducted during the demonstration and often in forum the
16 extension decisions I just mentioned, and a full evaluation
17 will be conducted after the demonstration is completed. It
18 is important to realize evaluations in their own right are
19 significant efforts for CMS to administer, typically
20 operating in a separate but parallel contracting process
21 from the demonstration itself.

22 Then, the last step in the process is the decision

1 of whether the new policies that were tested in the
2 demonstration should be expanded and will be expanded
3 program-wide.

4 For a demonstration, in our lexicon, expansion
5 requires an act of Congress. For a pilot, Congress gives
6 the Secretary the advanced authority to expand the program
7 after making a formal determination of whether the test
8 program met any pre-specified costs and quality criteria,
9 and I will come back to that distinction in a second.

10 I also wanted to present two recent examples to
11 give you a sense of how long the process I just described
12 can take.

13 This slide shows a time line for the Medicare
14 Coordinated Care Demonstration, or MCCD. The MCCD was
15 authorized by the Balanced Budget Act of 1997. The process
16 of designing the demonstration, getting internal clearances,
17 and preparing for site solicitation took over two years.

18 CMS solicited competitive proposals for programs
19 to be MCCD sites in mid 2000 and completed the contracting
20 process when it announced 15 program site awards in early
21 2002. The programs were initially authorized to operate for
22 four years. And evaluation of the demonstration's

1 performance through the end of the original four-year
2 period, that is, through mid 2006, was completed by CMS's
3 evaluation contract in earlier 2008.

4 As shown in the last line of this graph, there
5 have been two two-year extensions of the demonstration, one
6 that was authorized in 2006, which continued 11 of the 15
7 original sites, and one in 2008, when 3 sites were extended
8 for an additional 2 years. One of those sites subsequently
9 withdrew, so, there are two sites still active.

10 A final evaluation report to the Congress is
11 scheduled to be delivered in early 2011, or roughly 14 years
12 after enactment of the law authorizing the demonstration.

13 The Medicare Health Support Pilot Program followed
14 a somewhat more rapid course. It was authorized in the
15 Medicare Prescription Drug Improvement and Modernization Act
16 of 2003, or the MMA.

17 After a competitive solicitation process in 2004
18 and 2005, CMS awarded three-year contracts to eight program
19 sites, and they began operations between mid 2005 and early
20 2006.

21 It is important to realize here, unlike most other
22 Medicare demonstrations, the MMA explicitly gave the

1 Secretary authority to expand Medicare health support
2 without further congressional action, if she found, based on
3 an evaluation of phase one of the project, that the
4 interventions were at least budget-neutral and increased
5 quality.

6 CMS announced, in January 2008 that, on the basis
7 of its evaluation contractor findings of significant net
8 costs to the program and little quality improvement after
9 the first 18 months of program operations, the agency was
10 going to end the pilot as scheduled at the end of 2008,
11 which is about five years after it was authorized in MMA.

12 It is important also to recognize here, though,
13 the evaluation contractor is still conducting the program's
14 final evaluation, which is scheduled to be completed in 2010
15 or 2011, and that will inform the Secretary's final, final
16 decision about whether to extend the program.

17 So, now we are going to turn to the issues. In
18 analyzing the issues and looking at the options to improve
19 the current state of play in Medicare demonstrations, we
20 have organized them into these three areas shown on the
21 slide: funding, flexibility, and accountability.

22 The overall vision guiding the following

1 discussion is one of a research and demonstration exercise
2 for Medicare that, compared to the current situation, could
3 be more adequately and stably funded, could give the
4 program's administrators more flexibility to more quickly
5 design, test, evaluate, and disseminate promising
6 innovations, and could maintain the program's accountability
7 for results by increasing opportunities for input for
8 multiple external stakeholders, and by requiring more
9 reporting from the Secretary to the Congress on all of
10 Medicare's research and demonstration activities.

11 First, funding. Looking over the last ten years,
12 CMS's total appropriated budget for research and
13 demonstrations was \$138 million in 2001 and has decreased to
14 about \$36 million in the current fiscal year.

15 I want to point out the FY11 figure of \$47 million
16 shown in the far right is the President's budget request,
17 and that may be increased or decreased depending on the
18 appropriations process.

19 If we look over the same period, funding for
20 research and demonstrations as a percent of the total amount
21 appropriated for CMS program management activities, we seen
22 basically the same pattern. The 2010 budget allocation for

1 research and demonstrations, which is \$35.6 million, is
2 about 1 percent of total program management funding for this
3 fiscal year.

4 It is also important to realize that, within the
5 current \$35.6 million budget, only a portion of those funds
6 are available for the actual design, implementation, and
7 evaluation of demonstration projects.

8 This chart shows that, in FY10, about 57 percent
9 of the \$35.6 million budget is allocated to other research
10 activities, most prominently to support ongoing
11 implementation of the Medicare current beneficiary survey,
12 which is a very important research tool both for CMS and
13 external health services researchers.

14 Another 9 percent of this year's budget is
15 allocated to congressionally-mandated research projects.

16 I just want to be clear about what this funding
17 is. This category does not include the cost of performing
18 demonstrations that are mandated by the Congress through the
19 various authorization acts; rather, these are usually
20 targeted funding allocations for specific research projects
21 that are made through the annual appropriations acts.

22 The remaining funding about \$15 million is what is

1 available for other Medicare research and demonstration
2 activities, including projects initiated by the Congress or
3 by the Secretary.

4 A potential alternative to funding Medicare's
5 research and demonstrations through the annual
6 appropriations process would be for the Congress to
7 authorize funding for this activity directly from the
8 Medicare trust funds, for example, following the current
9 funding approaches used for healthcare fraud and abuse
10 control activities, or the quality improvement organization
11 program.

12 Multiyear funding allocations could be another way
13 to build more stability into funding for research and
14 demonstrations.

15 To increase the program's flexibility, one option
16 would be to reduce some of the administrative requirements
17 in the current demonstration process. Medicare
18 demonstrations could be exempted from the Paperwork
19 Reduction Act review during the approval process, and also
20 exempted from federal acquisition regulations during the
21 demonstration site contracting process. These steps alone
22 could shave months, if not a year or more, off of the

1 typical demonstration time line.

2 On evaluations, most Medicare demonstration
3 evaluations currently use a full or partial randomized
4 controlled trial, or RCT, design. RCTs are considered the
5 gold standard for evaluations in health services research,
6 but some observers of this process have raised concerns
7 about whether the RCT methodology is an appropriate approach
8 for evaluating Medicare demonstrations particularly given
9 the amount of time they take, and questions about whether
10 they can produce the information policymakers need on a
11 timely basis to explain why a given intervention succeeded
12 or failed to produce the expected outcomes.

13 To accelerate the evaluation process, CMS could
14 more broadly disseminate the quarterly monitoring reports it
15 already prepares for sites in some demonstrations, and it
16 could investigate if there are ways to use this information
17 to produce ongoing reports of demonstration projects. It
18 could also consider using alternative evaluation criteria
19 instead of the RCT approach.

20 The challenge in any of these alternative
21 evaluation approaches will always be to maintain the
22 appropriate balance between scientific rigor, timeliness,

1 and usefulness of the information to policymakers.

2 The last area of flexibility shown in the slide is
3 how to--is to revisit the concept of budget neutrality and
4 how it is applied during the demonstration approval process.

5 The current application of budget neutrality has
6 been criticized because it is typically calculated over the
7 relatively short operational duration of a demonstration,
8 and therefore does not take into account any potential for
9 longer-term savings or costs. It also does not take into
10 account the potential for an intervention to result in
11 significant quality improvements with relatively small
12 increases in net costs.

13 Then, to speed up the dissemination of effective
14 innovations from these experiments into program-wide
15 application, the Commission and others have observed that
16 Medicare could substantially speed up this process if the
17 Congress gave the Secretary the authority to implement pilot
18 programs without further congressional action, if the
19 Secretary determined that doing so would decrease, or at
20 least not increase, costs, while also increasing or
21 maintaining quality of care.

22 As I mentioned earlier, the Congress adopted this

1 approach in the MMA provision enacting Medicare health
2 support pilot. A refinement of this idea is that the
3 Medicare actuary could be specifically required to
4 independently certify the estimates of costs and savings
5 used in the Secretary's determination.

6 And the, with a positive determination by the
7 Secretary, the agency would be able to expand the policy
8 change program-wide without further action by Congress.

9 So, those are some of the flexibility options.

10 Now, looking at accountability. One option to
11 increase the accountability and transparency of the process
12 by which CMS at the beginning selects and initiates
13 demonstrations would be to require the Secretary to engage
14 in periodic consultation with public and private
15 stakeholders on the agency's research agenda. This could
16 involve the creation of a formal advisory board or body of
17 external experts from other government agencies, such as the
18 Agency for Healthcare Research and Quality, or the Institute
19 of Medicine; it could include academic research
20 institutions, representatives of providers and
21 beneficiaries, and private payers and purchasers who are
22 also working on innovations.

1 Then, to provide oversight in a more narrow sense
2 of how Medicare is performing under the more flexible
3 demonstration process I mentioned earlier, for example, the
4 Paperwork Reduction Act waiver, or the Federal Acquisition
5 Regulation waiver, a third-party entity, such as the HHS,
6 Office of Inspector General, or the Government
7 Accountability Office could periodically audit and report to
8 the Congress on Medicare's activities under these process
9 waivers.

10 And lastly, the Congress could assure more
11 accountability by directing the Secretary to periodically
12 report to Congress about Medicare's research and
13 demonstration agenda, what is being learned from ongoing
14 demonstrations, and what the potential effects could be if
15 they were expanded.

16 These periodic reports also would give the
17 Commission an opportunity to regularly review and
18 communicate its views on both the substance and the process
19 of Medicare's research and demonstration activity.

20 With that, I will conclude. I will put up the
21 three areas of issues that we have organized these into and
22 look forward to your questions and guidance.

1 Thank you.

2 MR. HACKBARTH: Thanks, John.

3 The heading under which I think of this topic is,
4 how do we create a bias towards innovation in how we pay for
5 care? I think the system right now is -- there is a bias
6 towards the status quo, even though the status quo is
7 problematic; it is very difficult to change it. So, as I
8 think about this topic, I am thinking about it in terms of,
9 how do we redesign the system so that there is a bias
10 towards more innovation in it.

11 So, let's open the round one questions, beginning
12 with Bruce.

13 DR. STUART: Thanks, John. I really appreciate
14 the detail that you have gone into here, and I think this is
15 an excellent framework for discussing demonstration projects
16 and the activities that CMS -- how that can be improved.

17 This particular discussion, however, ignores the
18 research part, and I have a number of issues that I would
19 like to raise during the second phase about how the research
20 side of ORDI and CMS in general could be enhanced to not
21 only improve demonstrations, because these two are
22 intricately associated, but also to provide another avenue

1 for obtaining information to help to guide CMS policy.

2 On the demonstrations themselves, I am going to
3 give you a very brief alternative process that Congress has
4 followed in terms of turning demonstrations into active
5 public programs, or benefits under Medicare, and that was
6 the Influenza Vaccination Cost Effectiveness demonstration
7 that was promulgated in 1999 and concluded in, I believe, it
8 was 2003. And this was established, ostensibly, to test the
9 cost effectiveness of making influenza vaccination available
10 as a Medicare benefit, but the way it was set up that the
11 evaluation had to prove that adding the benefit would not be
12 not cost effective to the Medicare program, and I was
13 involved in a research team that spent four years looking at
14 this process, and at the end of that four-year term we
15 concluded that, in fact, we could not prove that adding the
16 benefit was not not cost effective to Medicare. Obviously,
17 you cannot prove a negative. And so, when that project
18 report evaluation was CMS, Secretary Shalala, given her
19 authority said, well, since it was not proved to be not not
20 cost effectiveness, then it became a Medicare as of that
21 moment, and I still have a letter from Secretary Shalala
22 thanking me for helping add this important benefit to

1 Medicare.

2 So, there are other ways that Congress can do
3 this. I am not suggesting that is a good model, but just
4 for the sake of completeness.

5 MR. HACKBARTH: Where was the clarifying question
6 in there?

7 DR. MILSTEIN: I have a real one.

8 Yesterday, in yesterday's presentations, we heard
9 over and over again from these exemplary delivery systems
10 that part of making progress is doing a lot better with the
11 sick people. It makes sense: Healthcare tends to offer out
12 more value to sick people than well people. And obviously,
13 Medicare has a perfectly targeted demo that has been going
14 on for many years called the High-Cost Beneficiary demo, and
15 I think I have, every year, said, do we have any results?
16 Because at this point, we are well beyond the end of the
17 third year of the demo. And so, I have been doing my best
18 to essentially understand why there is no evaluation
19 information for us and for everybody else, and what I am
20 told -- and here is my question: I do not really -- I would
21 like to know if this is really possible. What I am told is
22 that, for this particular demo, no funds are available for

1 any evaluation.

2 And so my question to you is, is that under the
3 laws and regs possible, that CMS could -- ORDI could engage
4 in a demo and actually not have been appropriated funds to
5 do an evaluation that would enable people like us and
6 Congress and CMS to actually know what came out of it?

7 MR. RICHARDSON: Specifically, on that
8 demonstration, remember, we looked at this as one of the
9 four things we looked at last year. We were doing a report,
10 a chapter for the June report last year, on a practice
11 research network and, in the course of doing that, looked at
12 three demonstrations in the Medicare Health Support pilot,
13 and I remember looking at an evaluation of the Care
14 Management for High-Cost Beneficiaries demo that related to
15 the quality -- and I think it was--it was an interim
16 evaluation, so it was not a final evaluation. So, I am not
17 sure -- and I could check with my colleagues at CMS to see
18 what specifically they are referring to. I mean, I am not
19 familiar with a demonstration where there was not an
20 evaluation concept and plan built in from the beginning.
21 What they may be referring to -- again, this is subject to
22 verification with them -- is whether there was funding

1 available to share something either before the final report
2 to Congress is available -- this is what I was referring to
3 when I said, one possible option is with increased funding
4 and flexibility an expectation that there would be more
5 information available about the demonstrations on an ongoing
6 basis, and that there would be explicitly some requirement
7 and expectation that they produce reports like that that
8 would allow us to see what is going on in a more open way.

9 DR. MILSTEIN: So, I guess, my question is, today,
10 is it possible that a demo could be conducted -- what I
11 understand has been developed are quarterly monitoring
12 reports which are not suitable for public release or perhaps
13 not even FOI discoverable, but is it possible under the law
14 and regs for one of these things to run and literally for
15 there not to be money available in a publicly releasable
16 evaluation, because that is what I have been told.

17 MR. RICHARDSON: Okay. All of the congressionally
18 mandated demonstrations that I am familiar with require
19 there to be an evaluation. I do not specifically know -- I
20 am thinking about the Secretaries authority under the law
21 that was passed in 1967 to give him or her the authority to
22 do these experiments. I do not think it refers specifically

1 to the need for an evaluation.

2 Let me do a little bit more digging and find out
3 what the exact framework is there.

4 DR. MILSTEIN: We can check the fact point on
5 that.

6 DR. BERENSON: If I could. I mean, this -- I am
7 speculating, and there are people there who will be able to
8 provide the answer, but as I remember, this is a demo that
9 was a CMS demo and not a congressionally mandated demo, and
10 if I were at CMS, I would be giving priority with limited
11 resources to getting the congressionally mandated studies
12 done first and then also do the CMS ones. And so, it may
13 just be in the queue.

14 But I think, to me, the more basic question is, to
15 what extent -- and I assume the answer is self-fulfilling
16 which is, with a limited budget, the agency has to do
17 congressionally-mandated studies as the priority and there
18 are real opportunities being missed because of the Congress
19 or the preempting what otherwise might be a more rational
20 balanced research and evaluation agenda. And so, that would
21 be an issue I would like to understand a little more about.

22 MR. RICHARDSON: My experience is that most

1 agencies will respond to the congressional mandates first
2 and devote resources there, and do the rest, if they can.

3 MR. HACKBARTH: Clarifying questions.

4 MR. GEORGE MILLER: John, I have a similar
5 question to Arnie. If a project is being pursued and there
6 is clear evidence there is not going to be a financial
7 benefit, does the Secretary have the authority to stop that
8 demonstration or does it have to go through the entire
9 process and then be evaluated? Or even with an interim
10 report, it is shown there is no clear value for the
11 beneficiaries --

12 MR. RICHARDSON: Well, for example, in the case of
13 Medicare Health Support, that was an interim evaluation that
14 the Secretary used to decide to suspend the pilot.

15 Often what happens, though, in the Medicare
16 Coordinated Care demonstrations, and a good example of this,
17 there is not good information one way or the other, again,
18 because you have a small sample size or these other
19 empirical reasons that that the evaluations that are coming
20 back -- while it does not appear to be not to be working but
21 it does not appear to be working, either. So, but there is
22 some evidence that maybe some of the sites are, so, if we

1 will just extend them a little longer, maybe we will get
2 some more information.

3 So, the Secretary does have the authority --

4 MR. GEORGE MILLER: That is the question. It
5 does.

6 MR. RICHARDSON: -- to terminate them.

7 But, let me just -- and I discussed this a little
8 bit in the paper, in the mailing materials, often, what will
9 happen is if there is a congressional interest in a
10 particular demonstration, Congress will step in and say, no,
11 actually, we would like you to continue that.

12 The Municipal Health Services demonstration that I
13 mentioned in the paper is a good example of that. It was
14 created in 1978 and ended in 2006, and the interim
15 evaluations -- at least the one that I was able to find some
16 evidence of, suggested that it was not cost effective, but
17 that ultimately Congress decided to keep extending it.

18 MR. GEORGE MILLER: She does have authority, but
19 Congress can override. Okay.

20 MR. BUTLER: I feel that somebody should go to the
21 LEAN Institute down at Denver Health on the cycle time
22 thing, which was a major focus in the -- I am half serious.

1 My basic question is, how much of the cycle time
2 on average you think we could really shrink if we adapted
3 some of the recommendations.

4 And then, related to that, it might even be useful
5 in a chapter show, here it is this way, and then, if we
6 implemented the policies, this project would have gone this
7 way and graphically map that out -- would make the point
8 very visibly, but I do not have a sense of how much we could
9 shrink if we adapted the kinds of recommendations you are
10 suggesting.

11 MR. RICHARDSON: Right, right. And I was thinking
12 about that when I was doing those timelines and, okay, if we
13 had a counterfactual example of Medicare Coordinated Care
14 demo, if some of these options were in place, how much
15 shorter could it be?

16 I guess I would answer that in at least a few
17 ways. One is, at the beginning, some of the flexibility we
18 are talking about is to shorten some of that review time
19 within that Executive Branch process.

20 During the operational part, I mean, by the nature
21 of the things you are experimenting with often plan and
22 policy changes, service delivery models, it takes a while

1 for those to have an effect. So, whether you could have
2 shortened the four-year initial window of time that was set
3 aside for the Coordinated Care demo to have an effect, I do
4 not know. My experience is that often these interventions
5 take time to have an effect.

6 If you have a small N in the sites, it takes a lot
7 of observations to realize that. So, there is a certain
8 amount of time that you really cannot compress too much.
9 But at the other end, and this is a question about the
10 evaluations -- and again, may I just remind you, the
11 tradeoff, how rigorous those are versus whether they are
12 giving you the information you need in a timely fashion to
13 make decisions about, well, this just is not working. Let's
14 just devote the resources to something else or, this part of
15 it, these particular interventions seem to be promising.
16 Maybe we should focus the demonstration more on those and
17 stop doing some of the other things we are doing. Those
18 could reduce the time, but you also increase the probability
19 that you could make some decisions based on incomplete
20 information.

21 But I think your suggestion -- I like that
22 suggestion, thinking about, with these specific issues that

1 we are raising here, if you changed it like this, what would
2 that do to the average time line, if I could come up with
3 something like that. That is a good idea.

4 MS. HANSEN: Yes, on round two, I could probably
5 give you a little frame, also, about the cycle time, since
6 we moved it from demo to legislation. So, I could share
7 that a little bit later.

8 The question I have is relative to demos and
9 pilots and the shift that has occurred.

10 Proportionately, at this stage, what would you say
11 some of the areas of demonstrations vis-à-vis pilots
12 proportionate difference are going ahead, say, right now?
13 Do you know? And when did that shift occur, because things
14 always used to be in the demo mode much more?

15 MR. HACKBARTH: You are asking for -- what the
16 proportion of demos versus pilots is currently?

17 MR. RICHARDSON: To answer the second question
18 first, where I really noticed it was with the Medicare
19 Health Support, and I think that was the first major
20 occasion, anyway, although Bruce has also mentioned the flu
21 vaccine case where -- a little bit smaller, I think. So,
22 there may have been some other ones.

1 But so, let's see, there was the MMA of 2003, and
2 there are not that many, to be honest with you. I think the
3 pending legislation that is before Congress right now has a
4 couple more of those, but -- one example, there are several
5 demonstrations going on with value-based purchasing in the
6 different Medicare provider types, and all of those would
7 require congressional authorization to implement into the
8 full program. So, there are definitely important things
9 that the agency cannot do currently that they are
10 experimenting with but they cannot do program-wide unless
11 they have congressional authorization.

12 MR. HACKBARTH: But by definition a pilot has to
13 be specifically authorized by Congress, because the Congress
14 needs to say, okay, you can go ahead--

15 MR. RICHARDSON: When this is done and evaluated.

16 MR. HACKBARTH: --implemented without coming back.
17 Everything done under the general demonstration authority
18 requires you to go back through the congressional process
19 for implementation.

20 MR. RICHARDSON: That's right, and that is a
21 good--and even in the Secretary demonstration, the Secretary
22 decides to do.

1 MR. HACKBARTH: Yes.

2 MR. KUHN: I would just say on that, I think it
3 really was the Medicare Modernization Act with the Medicare
4 Health Support that we really saw the efforts of Congress
5 starting to extend pilot opportunities to the agency. So, I
6 would agree with that assessment.

7 Going back to Glenn's introduction of the this,
8 when he said, we really want to think about creating a bias
9 towards innovation, one of the things, when we think about
10 this, is really what is the ROI that we see as the result of
11 the demonstrations. There have been the big ones out there
12 that people talk about, the IPPS back in the '80s and maybe
13 a \$15 million investment produced, now, \$25-30 billion; the
14 number might be much higher.

15 The skilled nursing facility, PPS demonstration
16 that cost maybe \$10 million, that is probably well over \$10
17 billion in terms of savings.

18 So, I guess, John, what are we seeing in terms of
19 ROI overall, in terms of the demonstration work that CMS has
20 done, and is that information that we can get to have as
21 ultimately part of our reporting here? I think that would
22 be useful to have.

1 MR. RICHARDSON: I have gotten some information,
2 it did not get into the mailing materials, that I can --
3 from CMS that I can make sure gets into the chapter in June.

4 The demonstrations that I am more familiar with
5 from the work last year, the Care Coordination and the Care
6 Management demonstrations, I think part of the reason we are
7 even discussing this issue is some frustration that there
8 was an investment made in those and they did not see to
9 yield the results. And I think, though, you have to think
10 about not just whether -- consider only successful
11 demonstrations to be the ones where there is a positive
12 return on investment. I think CMS has learned a lot from
13 implementing those demonstrations, and it does give you some
14 empirical evidence to talk to people with certain
15 perspectives who might be saying, well, this is definitely
16 the sliver bullet or this is the way to go. That is a more
17 intangible return but, I think, a valuable.

18 MR. KUHN: Yes, I agree. We have to take the good
19 with the bad and, because not everyone is going to be
20 successful, we will have a hypothesis for a lot of
21 demonstrations that might not pan out, but I think we need
22 to look at both sides so we really can see what they are or

1 why it really is out there, because these are useful
2 efforts.

3 MR. HACKBARTH: It just occurred to me that there
4 is an important exception to what I just said about pilots
5 versus demos.

6 There are instances recently where the
7 Demonstration Authority has been used to basically make
8 program changes. The oncology issue several years ago, and
9 then under Part D, and so, that is sort of a middle ground,
10 a different type of case.

11 DR. SCANLON: True, but legally they were still
12 characterized as demonstrations. They never were -- became
13 the real program.

14 MR. HACKBARTH: Yes, except they affected the
15 whole program. So, and, of course, we expressed
16 reservations at the time in each case about that use of the
17 demonstration authority, but there is that odd set of cases
18 out there.

19 Mike.

20 DR. CHERNEW: I have a question that stems from
21 something you wrote on slide 11, which is the particular
22 bullet point is, "Contracting for Demonstration Sites in

1 Evaluations." My question is, is there ever an example
2 where there are multiple evaluations contracted for as
3 evaluations--do you ever contract for more than one? And
4 are there ever evaluations done that are paid for outside of
5 CMS, say, NIA contracted with somebody to do an evaluation
6 using data from CMS, which would be another to get this
7 evaluation done outside of CMS, or is it really that CMS, as
8 the bullet suggests, CMS contracts for all the evaluations?

9 MR. RICHARDSON: That is correct.

10 DR. CHERNEW: And that is often just one?

11 MR. RICHARDSON: That is right.

12 DR. MARK MILLER: I think there are examples where
13 more than one contractor has looked into a given program.

14 MR. RICHARDSON: We can look into -- there is
15 often a contractor that facilitates the implementation and a
16 separate one that works on the evaluation, but I think for
17 most demonstrations that I can think -- subject to
18 validation with facts, but most of the ones that come to my
19 mind right now, there was one evaluation contractor for --

20 DR. CHERNEW: Like CMS.

21 MR. RICHARDSON: Yes, it is a CMS contractor.

22 DR. MARK MILLER: I should not state my point so

1 strongly, but I feel like somewhere in my experience that
2 there has been examples, but we should move on.

3 MR. RICHARDSON: Yes, we can find out.

4 DR. DEAN: My question has to do with the
5 dissemination. When these things actually do get completed,
6 is there -- are there plans within these programs for
7 dissemination of the information? Obviously, the main
8 consumers are CMS and Congress, probably, but on the other
9 hand, those of us out in the community -- some of these
10 things are very interesting and really do affect some of our
11 decisions in the private sector as how to we structure
12 programs and so forth.

13 And I wonder, is there any central databank or any
14 central way to access the outcomes of these things, or is
15 that part of the provision and plan at all?

16 MR. RICHARDSON: That is part of what we are
17 suggesting here. I mean, CMS, every year, does publish an
18 Active Projects Report, but it has very brief descriptions
19 of what is going on with each of the projects. And I guess
20 the short answer is no, there is no systematic way, and that
21 is why we are talking about things like the Secretary having
22 some requirement as part of the accountability piece of this

1 to have a formal report every year that says, this is what
2 is going on, this is what we are planning to do -- this is
3 what is going on and this is what we have found so far, and
4 which would be much more publicly available than it is now.

5 DR. DEAN: Yes, or even a summary of the ones that
6 have been completed and evaluated and what the outcomes were
7 that would be fairly easily accessible, because I think it
8 has come up in previous discussions that we put a lot of
9 emphasis on gathering some of these data and then very, very
10 little -- we shoot ourselves in the foot because we do all
11 the work and then a lot of times the data does not get out
12 to the people that could really make use of it.

13 MR. HACKBARTH: Okay. Let's turn to round two
14 comments.

15 Bruce is going for a second bite of the apple
16 here.

17 DR. STUART: Thank you very much, Glenn.

18 Well this refers -- my comments refer to the
19 research infrastructure, and they go under four headings.

20 The first is enhanced research staff for
21 intramural research and better preparation for
22 demonstrations and CED projects and other activities. And

1 an important element of what CMS does and ORDI in particular
2 in CMS is to prepare for demonstrations but also to make use
3 of in-house datasets, including obviously Medicare claims
4 and the Medicare Current Beneficiary survey, and at one time
5 that was a significant activity that was undertaken by ORDI,
6 and that has been severely constrained by the budget
7 reductions in the previous year.

8 So, I think enhanced research staff for intramural
9 research is really important, and what that really talks
10 about is, well, what kind of intramural research should CMS
11 be involved in.

12 And the other side of that is funds for extramural
13 research on issues of interest to Medicare, and as you
14 undoubtedly know that CMS has a project for contracts -- or
15 has a mechanism for contracting with external researchers,
16 in part through the demonstration process of evaluation
17 contractors, but there are other ways that it can do it. It
18 has something called IDIQ, master contracts. These are
19 indefinite quantity, indefinite duration contracts that are
20 essentially master agreements so that CMS can work with
21 various research organizations to develop -- to respond to
22 contract requests. Those have been cut back significantly

1 in the last four or five years from research contracts to
2 technical assistance contracts. It has been a couple of
3 years since I have seen anything that really has any
4 research content at all in terms of what this extramural
5 contracting has done.

6 And back in the old days, CMS had the -- I think
7 it still has the authority but it does not have any money to
8 issue RFAs for investigator-initiated research projects to
9 help CMS develop areas of interest in which it is looking
10 for the research community to bring in the ideas as opposed
11 to saying, well, these are exactly what we want to do now,
12 and in fact I really cut my teeth on Medicare research with
13 one of these projects back in 1999, and one of the side
14 benefits of having these external funds available for
15 individual researchers is that, once you start working with
16 Medicare data, then -- and you become interested in it, then
17 you develop groups of people who have the capability of
18 doing that, and I have been doing it ever since. So,
19 regardless of the value of what I am doing, it at least kept
20 me in the game.

21 Another element of that, which was an
22 extraordinarily, I think, productive program that CMS ORDI

1 had until about, I would like to say 2004-2005 was the
2 Dissertation Grant Program. Now, this is a really cheap way
3 to develop new researchers in areas, again, interested in
4 Medicare data. They paid \$20,000 a year for research
5 assistants. The graduate student would work with a faculty
6 mentor on a project that was Medicare-focused, because
7 otherwise you would not go to ORDI for that. So, I think
8 that that is a really important element of CMS research
9 activities that has been constricted and should be expanded.

10 The third element, and this was building on what
11 Mike was talking about, is cheaper and easier access to
12 existing data. And I will just give you one anecdote. I
13 have a project funded by the Commonwealth Fund that was
14 proposed to use CMS data, Part D data in particular. I
15 filed a data use agreement in July of last year; it went
16 through a very rigorous process of review, and was finally
17 approved in October. We sent a check to CMS in early
18 November after that approval for \$67,000 for two years of
19 data for a 5 percent file -- which gets to the point about
20 how expensive this is -- for a one-project license. That
21 money was for one project and one project only, and what is
22 it? It is March 4, 5, I still do not have the data. So,

1 this has a real chilling effect on research, because I have
2 a deadline in terms of when I am supposed to finish this and
3 obviously I cannot without the data.

4 So, reduced acquisition cost is really important.
5 Speed it up. Turnaround is important and expedited privacy
6 review -- I mean, this is something that every researcher
7 who works with these data is concerned about. It is not
8 just the local IRBs that you have to go through; this is
9 problematic enough, but having that same process
10 non-expedited at the federal level makes it even slower.

11 And the last point, and maybe even the most
12 important of all, is data development. You need funding for
13 data development. And one of the things we talked about a
14 year ago was a federal regulation that was promulgated by
15 CMS to require that all MA plans submit claims and/or
16 encounter to CMS for all of the activities that they were
17 involved, and we had some discussion about the importance of
18 having data from the Part C plan so that we could evaluate
19 their performance relative to fee-for-service performance.

20 Now, I have no idea where that stands at this
21 moment, but I can tell you it is going to cost, because
22 those data -- first of all, all of the requirements for data

1 submission, I am assuming that has happened, but I do not
2 know, those have to be promulgated. Once the data come in,
3 they have to be checked, they have to be put together in a
4 way that both internal and external users can use them for
5 research. And I think at least from my perspective, that is
6 probably the most important new data development that MedPAC
7 should recommend is that funding -- help make sure we got
8 those Part C data.

9 But there are some other things, and I am not
10 going to take any more time, but just to suggest that there
11 are data issues in terms of data linkages, data quality,
12 missing data elements. Boy, if I could enforce a change in
13 the uniform prescription drug claim form to require that
14 there be a diagnostic code on drug claims so that I could
15 figure out exactly what the doctor was prescribing for, it
16 would really improve research activity.

17 So, without saying another thing, there, these
18 four areas, I think, are really important additional areas
19 where we should encourage Congress to provide additional
20 research funding for CMS.

21 MR. BERTKO: So, John, if you could turn to slide
22 11, I am going to have a question that is narrow in scope

1 and possibly broad in implication, and that is the third sub
2 bullet there, the alternative evaluation criteria.

3 You mentioned, I think appropriately, and I agree
4 with this, that randomly controlled trials are the gold
5 standard for evaluations, and I will agree with that
6 completely and say that is impractical sometimes in terms of
7 application. So, the broad arrangement of it here is, how
8 do you role this out, particularly under any kind of payment
9 reform?

10 Most of you remember Nick Walter who is part of
11 the PGP, Physician Group Practice demo here, and his
12 experience with that controlled trial stuff, at least in
13 sidebar conversations, was problematic would be the most
14 polite phrase that I would give.

15 So, the thing that we want to -- at least, I am
16 suggesting that we be concerned about, and we have had some
17 conversations with this Jeff Stensland from staff who, I
18 think, sat through those -- and me, I have listened to part
19 of the conversations -- is going to alternative
20 methodologies. Randomly controlled trials has a technical
21 problem: Once you get things big enough, you run out of
22 control groups.

1 And then secondly, and this is more my opinion,
2 maybe, than anything else at this point, when you are trying
3 to get payers to shoot towards a goal, I think everybody --
4 all the physicians around here have said, physicians in
5 particular are A students and high achievers, but they need
6 a goal to achieve, and when you have a randomly controlled
7 trial and you are looking at the results of the control
8 group, you do not know what the answer or the goal is until
9 a year or two down the road from when you have your results.

10 So, our Brookings-Dartmouth Group, at least under
11 the ACO stuff, but I think it could apply equally to any
12 bundling type of research to medical homes, to any other
13 payment reforms, would be better set, in my opinion, with
14 having a solid goal to aim at.

15 So, I guess what I am suggesting, John, is you and
16 Jeff perhaps think about some more of those. I am certainly
17 -- on my personal part -- open to revisions, new versions to
18 do this, anything that gets us to having some kind of solid
19 goal -- defined goal to work towards that is, at the same
20 time, meaningful works maybe nearly as well as the randomly
21 controlled trial type of group and is practical.

22 DR. MILSTEIN: A couple of thoughts in terms of

1 our next iteration of this.

2 Number one is, I think it would be nice to
3 essentially have some of our recommendations put in context
4 of all the money that the Federal Government is putting into
5 a delivery system and payment method testing, because we
6 have a lot happening now. We have all the ARRA --
7 competitive effectiveness research, and some of that may or
8 may not be part of a bill that may or may not be passed. We
9 have ORDI working on this, and I think it would be nice to
10 essentially have something that began to essentially say,
11 here is the pool. Now, the job is, how do we deploy these
12 in a fashion that is, A, adequately funded, and, B, as much
13 as Pete was saying, much-shortened cycle time.

14 What you would like is if someone from the lean
15 institute came in to look at our CMS innovation testing
16 funding, it would get an A. It obviously would not get an A
17 either on adequacy of funding or on cycle time.

18 But I think it is hard -- it is very difficult, as
19 the point was made earlier by Bob -- it is not fair to beat
20 up someone for not running a four-minute mile if you have
21 not fed them.

22 And you look at slide 9. Please put that up. It

1 is funny, yesterday, we all intuitively sensed that even
2 though there might be a good statutory rationale for it, we
3 should absolutely not put medical education funding at the
4 mercy of general tax revenues. We said we had to have a
5 secure funding base. Well, I feel the same way about
6 innovation testing, whether it is within ORDI or it is the
7 sum total of everything we are investing in evaluation
8 research is that this suggests that leaving it to the
9 mercies of general tax revenues is problematic.

10 I do not think that anyone from -- that anybody
11 who can -- maybe from the Department of Commerce who can
12 speak to what kind of investment in innovation testing it
13 takes in any organization to get great results, that this
14 likely qualifies.

15 MR. HACKBARTH: And if I am interpreting number 10
16 correctly, this overstates it by half, because basically
17 half the budget is going to the survey.

18 DR. MILSTEIN: So, we are down to less than 1
19 percent. So, it would not pass any common sense test of
20 level of innovation investment needed to drive a big
21 socially and societally important system like Medicare let
22 alone healthcare system.

1 DR. BERENSON: Well, I was going to -- my first
2 point was going to pick up exactly on that.

3 One of the data points in your paper was that we
4 are now spending .007 percent of outlays on R&D, and the
5 rule of thumb I have heard -- not that I am an expert on the
6 area -- is that most enterprises spend about 1 to 3 percent
7 of revenues or something like that. So, even looking at it
8 as a percentage of program management does not get us
9 anywhere near where we would need to be for a real
10 enterprise. So, that is point number one.

11 And so, I think, as yesterday's conversation where
12 we talked about, is there a rationale for looking at
13 mandatory side trust fund money to support outside
14 organizations, the QIOs being the precedent, but we talked
15 yesterday about perhaps limited medical education. Today,
16 we are now talking about, can we do it to support program
17 administration? I think we should be looking at that issue
18 generically. What are the legal issues? What are the
19 unknown side effects of going down that road? There will
20 clearly be a lot of opposition to that. So, I think it is
21 something to look at generically.

22 I want to pick up again on this financing thing on

1 the budget neutrality item. I agree with you completely, we
2 need more flexibility on that one.

3 My understanding, and maybe this is just an urban
4 legend, but I think I was even around at the time,
5 unfortunately. About 30 years ago, a certain Secretary of
6 HHS actually wanted to expand coverage by using
7 demonstration authority and these things were not
8 demonstrations. It was a way to get money to people to get
9 healthcare services, and out of that came an OMB-based
10 process for establishing budget neutrality. I am not sure
11 anybody has looked at that since and whether -- and if the
12 current way in which that is -- well, I would actually be
13 interested to what extent we are captive of what might have
14 been a perfectly reasonable decision made 30 years ago --
15 what kind of flexibility can we put into budget neutrality
16 calculations, consistent with my view that sometimes you
17 actually have to -- in an R&D enterprise, you cannot always
18 be budget neutral in something as you are learning.

19 The second general point I wanted to make is
20 around cycle time, and I am sympathetic with all those who
21 want us to shorten it and get stuff out in the field much
22 more practically, but I would remind people of an

1 alternative that I think happens a little bit too much in
2 the private sector, let's say, health plan R&D in this area,
3 and we hear terms like "nimble" and "flexible," et cetera.
4 When I was doing practicing managed care work two decades
5 ago, prior authorization was the way to go. There was not a
6 lot of transparency about its effectiveness. There was not
7 a lot of, well, basically, proof of concept, even though I
8 think, if done right, there probably is. My experience was
9 it was largely benefit consultants convinced purchasers that
10 they had to have this in their contracts. It was not an
11 evidence-based process. And more recently, I think, is the
12 example of disease management, where every -- you keep
13 hearing, oh, yes, this is very successful, very successful,
14 but in many cases, using flawed methods of regression to the
15 mean and it was only in the Medicare Health Support that we
16 actually had a controlled trial, which proved at least in
17 Medicare's hands it was not effective. Now, some of the
18 disease management companies will say, well, you gave us
19 patients who were too sick and you gave us patients who were
20 too healthy, and if we could have used our techniques to
21 pick them we would have done a better job, and maybe there
22 is some truth to that. But again, we need some

1 transparency, we need some evidence around. So, if it is
2 not going to be the gold standard, randomized clinical
3 trial, we cannot go too far in the other direction of just
4 asking an organization to say, this works, let's go with it.
5 So, let's find a middle ground in this one.

6 DR. CROSSON: I will be quick because I was going
7 to make the same point that Arnie made, and Bob.

8 It is probably unfair to compare CMS to a
9 corporation, but if CMS were a corporation, the spending on
10 innovation would be two to three orders of magnitude lower
11 than what would be expected, and that flies in the face of
12 the fact that, as John said, there are several examples,
13 anyway, of where the return on investment to CMS has been in
14 the thousands of percent. So, it is not like there is no
15 justification for spending more money.

16 So, I think that the general thrust here would be
17 one that we would support, more money, provided it is
18 invested properly.

19 To Bob's point, I would probably say, rather than
20 start with theory as the basis for innovation, start with
21 things that have been proven to work, and then determine
22 that broad applicability or not of those things.

1 So, if we could take Denver Health and just test
2 the most important elements of that, we would probably get a
3 better result than if we just started with some theory that
4 somebody had come up with.

5 So, more money, less time, to the extent that that
6 is possible, more focus, and then, more action orientation.

7 DR. SCANLON: I am also very supportive of
8 increasing the investment, but I wanted just to note that I
9 do not think that it is a total solution to move this into
10 the trust funds, because there are -- my sense is there are
11 two kinds of expenditures coming out of the trust funds:
12 those where we say we are going to support a function, let's
13 say immunizations, and we spend as much as it takes to cover
14 the number of people who show up wanting immunizations.

15 For an activity like fraud and abuse and an
16 activity like research, it very well may be specified as a
17 dollar amount. We are going to spend this amount of money
18 for the next, say, ten years or something like that. That
19 means that that money then has to be renewed at some point
20 in time. All we are doing by moving it in a trust fund is
21 changing the group of, say, 15 people in each house that are
22 going to say to the full house, please approve this

1 expenditure, because it is still going to go through a
2 congressional process periodically.

3 What that implies, I guess, for me is -- that we
4 need to think about is, is there any other alternative and,
5 as well as, that there needs to be continuing attention,
6 both make a point for the Congress to continue to focus on
7 this as well as for future MedPACs to focus on this.

8 MR. BUTLER: Sorry for a brief but albeit vague
9 filter that I would still like us to keep our eyes on. I
10 would reinforce your innovation concept. I often think, are
11 things moving faster inside your organization or outside
12 your organization, as a test of whether you are contributing
13 to the solution. And right now, you feel like it is moving
14 slower inside rather than outside. And if we can somehow
15 make things and use the Medicare leverage to move it faster
16 inside, than I think we can contribute to both Medicare as
17 well as a synchronization with the private side.

18 MS. HANSEN: Yes, I think I had three key comments
19 here, and each one of them has been covered, but I just want
20 to affirm them relative to the proportionality of investment
21 that is evident that does not work.

22 The alternative evaluation criteria is one of the

1 things that, certainly on the ground, when we were
2 demonstrating the original PACE Program On Lok in San
3 Francisco, we found that some of the discussion and the
4 argument about randomized control design for some issues did
5 not work.

6 I will give you a specific example. I started out
7 there as the research nurse, and I would do the -- I was
8 doing the alternative comparison group. And I would go in
9 and visit someone and that person ended up having a blood
10 pressure reading of 220 over 140. So, what I did was I
11 broke the trial, so to speak, I got on the phone, go the
12 person to care. So, there are some things that just,
13 ethically almost, do not work sometimes in these models.
14 So, again, with people who have the rigor and the ability to
15 take a look at this, how do you move a model of practice as
16 well as financing at a time when sometimes some areas of
17 these designs that would be gold standard would be something
18 that would be in very controlled abilities, plus the volume
19 of people. So, it is just something to think about for
20 those of us who have done it on the ground.

21 I think the budget neutrality that was brought up
22 as well, too, again, if we are going to use the business

1 metaphor -- and frankly, when we did this on LOCK and PACE,
2 we had to meet the budget neutrality, so, and we did at that
3 time, and I think we had that opportunity because the amount
4 of inefficiency in the system allowed us to show the budget
5 savings and so forth.

6 But today, I think a different model of when you
7 are doing these much larger pilots or demos, the ability to
8 think of the business model that things do not change on a
9 dime without some investment. So, like, a regular business,
10 it might take three to five years to finally find the ROI.
11 So, again, I am not saying that is absolutely it, but
12 whether it is the innovation, investment, the diffusion
13 ability of the knowledge that I think that Tom was asking
14 about. Can we get this out faster?

15 There are different models to take a look at. So,
16 I think we need to move the research design side to the
17 operational side to the franchising of knowledge and really
18 getting that out there. And so, somehow, we get stuck with
19 all knowledge whether it is structurally because the data on
20 the high-cost beneficiary is not available. There is
21 something that just does not flow real smoothly. So, the
22 speed to market is perhaps another concept to really think

1 about when we have so much money going out on the front end
2 with the services and the benefits, but we innovate and
3 diffuse with such a tiny budget.

4 MR. KUHN: On the three issues for discussion you
5 laid out there on funding, flexibility, accountability, let
6 me at least talk to a couple of them.

7 On the funding issues, in terms of adequacy levels
8 and stability, I do not think anybody can argue with that
9 and I think there is unanimity here. My bias tends to be a
10 little bit more towards trust fund and direct draws on that,
11 but I heard what Bill had to say and if there are other
12 innovative ways we can think about that, but the adequacy
13 has to be there. I think the graphic that you showed us is
14 pretty clear: We need to fund more aggressively in this
15 area, and the stability needs to be there.

16 On the issue of flexibility, we do need to think
17 about ways of speeding up these demonstrations, and a couple
18 areas I can point to that are real road blocks that are out
19 there. One is the whole PRA process, is very cumbersome,
20 and I just do not know if it is that necessary and useful in
21 terms of part of the process. I think we need to look
22 pretty hard at that one.

1 Likewise, I think what Bob said in terms of the
2 budget neutrality issue is something that ought to be looked
3 at pretty hard as well, because as we start to look at more
4 value-based purchasing opportunities, what it does is it
5 creates a bias towards a tournament-type model in terms of
6 demonstrations. And going into the kind of demonstrations
7 -- could be problematic from the very beginning, and I would
8 like us to see if we can avoid that.

9 At the same time, however, if you do not have the
10 budget neutrality in there -- and CMS has to watch this very
11 closely in terms of their stewardship role of the program is
12 that they could get into a demonstration where it is going
13 south real fast and they have to be in a position to cut it
14 off, because you don't want to see money hemorrhaging out
15 the door if you don't have that budget neutrality protection
16 out there. So there is both sides to that.

17 And finally, the issue is really the level of
18 scientific rigor that we have talked a little bit about
19 here. Arnie, during the previous conversation, says, when
20 are we good enough for openers, here? And they might be in
21 a demonstration, and it might be a pilot, and they find out
22 that, after a few years, they are 80 percent certain that

1 this going to work, and what we have seen is, if you really
2 want the 100 percent certainty or 95 percent certainty it is
3 a 10-year process, and I think we are going to have to
4 pretty soon say, qualitatively, this is good enough and
5 let's start moving forward. Now, that means that the
6 continued scientific work needs to follow on behind that and
7 we need to get there, and there are probably refinements as
8 a result of that, but pretty soon we have to say, it is time
9 to jump in and go and not wait for the whole process and
10 then wait another decade before you can launch a new
11 initiative.

12 So, I think helping us think about the scientific
13 rigor, when it is good enough for openers, to move forward,
14 would be helpful, as well.

15 DR. CHERNEW: I want to start by saying I think
16 this is an extraordinarily important topic that deserves a
17 lot of prominence in what we do, and I worry that sometimes
18 this gets put at the very end and in the back chapter and it
19 does not get heard particularly loudly, and I think it
20 actually might be amongst the most important things long run
21 for the program. So, figuring out a way to prominently
22 feature and convey this, I think, is central.

1 The second substantive point that I want to make
2 is that I think it is crucial to have multiple evaluations
3 and many of them outside of CMS. I realize that the CMS
4 evaluation process is important and I am completely on board
5 with all the comments that were made. I want to point out
6 that there is -- I am a member of an organization that
7 looked at an evaluation of one program and felt that coding
8 changes, perhaps upcoding changes, of an evaluation gave a
9 result from the particular single evaluation that might not
10 be the general conclusion one would take, suggesting that,
11 in general, science progresses with multiple people doing
12 multiple evaluations over a continuing period of time, and a
13 system which is, CMS will do a demonstration, they will
14 contract with one evaluator, they will do one report -- is
15 not a system to get you to understand.

16 Things like Part D are being, for example,
17 continually being evaluated by a whole bunch of people
18 funded by places well outside of CMS where there is rigorous
19 competition to get access to grants to do those evaluations.

20 So, I think, in general, the most important thing
21 is to open up the data in CMS to a whole -- there are huge
22 numbers of people around the country, and a lot of funders,

1 some of which inside the government, the government agencies
2 AHRQ, NIH, others outside like RWJ, that would be really
3 interested in funding if you could get the data per Bruce's
4 story, and I think that is really fundamental to maintain
5 not just the evaluation but in infrastructure of continued
6 evaluation that does not have to be controlled from central
7 CMS evaluation, because the scientific community will -- the
8 health services will do a good job of evaluating this if the
9 system is open enough to allow that to happen.

10 MR. HACKBARTH: Okay. I had a few thoughts. Five
11 points and most of them echo things that have been said, but
12 maybe with a little different twist on it.

13 One, I wanted to pick up on Mike's comment about
14 the importance of this. I, too, worry about it being a back
15 chapter labeled CMS R&D, and that is part of what I was
16 trying to address with my opening comment about framing not
17 as about CMS R&D but how we create a system that is more
18 innovative. So, I think -- I am not a wordsmith, I do not
19 know exactly what the right words are, but how we package
20 this and frame it I think is an important part of the
21 subject.

22 Second, I will just echo what people have said

1 about more investment in stability investment. I think that
2 is critically important. And of course, I agree with the
3 comments that Peter and others have made about streamlining
4 the process. I think there is evident opportunities to do
5 that and I agree with that.

6 The last two comments are a little bit more
7 challenging, but I think also more fundamentally important.
8 I would like to see us look at recommending that the
9 Secretary be delegated broader authority to make changes on
10 implementing innovations, in particular on payment policy,
11 as opposed to the current process whereby that expanded
12 delegation of the Secretary is done project-by-project, by
13 Congress authorizing a pilot on disease management or
14 whatever the issue of the day might be. I think there ought
15 to be a generic delegation to the Secretary.

16 Now, as is true with all good delegation, it needs
17 to be constrained. It needs to be delegation within some
18 defined boundaries. And off the top of my head, I cannot
19 tell you exactly what those boundaries should be, but they
20 presumably would include things like, the Secretary would
21 not be authorized to make fundamental changes in the
22 Medicare benefit package or deny beneficiaries free choice

1 of provider, some things like that that are very political
2 sensitive, for understandable reasons, could be constraints
3 on the delegation, at least initially. But then, within
4 that, there ought to be some opportunity for the Secretary
5 to make decisions to improve management of the program.

6 The last topic that seems to me, as a
7 non-researcher -- I cannot emphasize that too strongly -- I
8 have no technical expertise to bring to bear. What seems to
9 me a critical question is, what are we testing for? And I
10 do not think you can answer that question generically. I
11 think it needs to be specific to the intervention, the
12 innovation that is being tested.

13 There are some things that CMS and the Secretary
14 might be testing for with it is appropriate to say, we want
15 to collect definitive evidence up to some reasonable
16 standard of certainty about the effect of this intervention
17 on long-term costs and quality of care. And perhaps,
18 disease management is that project.

19 But it seems to me that there are other types of
20 intervention where we may want to be simply testing for
21 operational feasibility, and falling into that category, I
22 will give two examples.

1 One, the group practice demo. So, here we have a
2 system that is basically based on fee-for-service.
3 Beneficiary choice is not impinged upon, and the idea is
4 that we are going to share savings. The tricky part of that
5 is how you set the benchmarks and how you operationalize the
6 model and how you provide the feedback. I do not think the
7 real issue is the long-term effect on cost and quality. And
8 if we can work out a feasible operational model for
9 establishing what the targets are and data flows and all of
10 that, this is a low-risk enterprise for the Medicare
11 Program. The Secretary ought to be able to work with groups
12 on testing and developing a model and then go for it on a
13 program-wide basis.

14 Similarly, I would say, bundling around a hospital
15 admission. I do not think we need a ten-year process of
16 evaluating the long-term effects of that on cost and
17 quality. I think there are some very trick issues about
18 operationalizing the model, but that is what the pilots
19 ought to be focused on. And then, once the Secretary has
20 some workable models, go for it and do not wait around for
21 long-term evaluations.

22 So, those are just a couple of examples. I think

1 we need to carefully think about what we are testing for in
2 each case.

3 Any other thoughts, comments, questions?

4 DR. MARK MILLER: Yes, just, I think you hit most
5 of the things that I was going to say, but just a couple
6 things to emphasize, and I will start with small and I think
7 go to larger.

8 On the budget neutrality stuff, I think you guys
9 in your exchanges hit well the two sides of those concerns,
10 and why some of that came into play. And I think some of
11 the things to think about beyond the methods that John has
12 brought up, which I think we have some ideas on, are things
13 like the time frame and also whether you limit the amount of
14 money that goes out to some activity so that you understand
15 that your overhead is limited in some degree.

16 I would focus a lot on the speed of innovation.
17 And I think again we got out a good point here, which is
18 there are certain parts of this infrastructure that you
19 probably cannot collapse the time on. These things are hard
20 to do. It is hard to get your participants in. It is hard
21 to design these things -- and that we should focus our
22 efforts on the places where we can speed things up. I think

1 some of it goes to what happens when all is said is done?
2 Can you get it out into the field -- what Glenn just said.

3 But the other part of this conversation is the
4 process, the internal processes that CMS has to go through
5 to get these done, and I am just warning the Commissioners,
6 there are going to be things that are going to be fairly
7 arcane and sometimes can be unhappy to talk about just
8 because they are so arcane, but just heads' up. These are
9 probably the things that can make a difference, in terms of
10 what you have to go through for contracting, what you have
11 to go through to even pull a group of people together and
12 ask them what their ideas are. I mean, they are not as free
13 to do those things, and so, there may be some things there
14 that are important to move, where you could get time, but
15 will not be happy and fun to talk about, just on that.

16 I am also very happy that we got to the money
17 conversation. I think it is very important, and everybody,
18 I think, sees this point. We will have to think very hard
19 to make it stable without being just a -- and have some
20 checks on it that it is not just a bleed. And again, we
21 have some ideas there.

22 And to your point, Mike, I think the whole point

1 of this session and the sessions that are going to follow is
2 so that this is not the last thing in the chapter, that is,
3 oh, by the way, CMS does not have enough resources.

4 You will notice a couple of things. In the March
5 report, in addition to reaffirming that we wanted the
6 encounter data and many other things, we said to the
7 Congress, this is a lot of work for -- this is on the
8 quality recommendations -- a lot of work for CMS. Do not do
9 it unless you can give them the money to do it, and just
10 being very clear that they need the resources to do it, and
11 I think the point of starting this session is to very
12 clearly make those statements to the Congress. So, I do not
13 see this relegated, this is a front end -- and I know you
14 got it, I want to make sure everyone else gets it.

15 And the very last thing I will say is there have
16 been some factual points raised here, and if CMS is
17 comfortable saying anything in the public session that
18 follows, I would encourage them to address any of the
19 factual points that we were searching around a bit for.

20 MR. HACKBARTH: Okay. Should we -- anything you
21 want to say, John, in winding up?

22 MR. RICHARDSON: Thank you for all the advice.

1 MR. HACKBARTH: Okay, thanks.

2 So, let's turn to the public comment period.

3 Let me repeat the ground rules. Please begin by
4 identifying yourself and your organization. Limit your
5 comments to no more than two minutes. When this red light
6 comes back on, that will signify the end of your two
7 minutes. And as always, I would emphasize that people ought
8 to use the other avenues to communicate with the Commission,
9 including our website, where there's an opportunity to post
10 comments and, of course, communicate with our staff.

11 With that, go ahead.

12 MR. LOVE: Thank you. Tim Love, CMS, Director of
13 the Office of Research, Development, and Information, ORDI.

14 First, I wanted to thank the Commission for taking
15 this topic up, and obviously, the interest and the
16 appreciation of not only the complexity but certainly the
17 resource implications, so I do appreciate that.

18 I also have to say that John Richardson did a
19 great job of making some sense and explaining a very
20 Byzantine process, so I just wanted to make note of that as
21 well.

22 There was just one comment I wanted to make

1 regarding Commissioner Milstein's remarks about whether we
2 do the evaluation at the same time as the demonstration.
3 That's a very important point. And as John pointed out, we
4 have -- within the law, we often are directed to do it, so
5 that's the law, and we follow out. Within a discretionary
6 demonstration, it is not the law, but it is certainly a
7 policy that we try our best to abide by.

8 When we send a demonstration up the line -- and
9 the folks who run the R&D shops respectively can attest to
10 this -- I won't let it leave my office unless it's a soup-
11 to-nuts budget, you know, from the beginning of what it
12 costs to think about the demonstration concept to the end of
13 the evaluation.

14 Where it gets a little complicated -- and I think
15 this may be the situation with the high-cost demonstration -
16 - is that demonstrations -- while the demonstration is in
17 the here and now, the evaluation tends to be in next year or
18 even out-years. And I don't have to tell this group about
19 the austerity, the state of our budget. But when we get to
20 having to steal from Peter to pay Paul, there is an
21 opportunity cost that quite often has an impact on the
22 evaluation budget.

1 The other unfortunate part -- I think it actually
2 gets to a point that Herb Kuhn made -- is that ideally, or
3 ideal current state, we have enough to do that sort of
4 scientific rigor, 100-percent certainty demonstration. To
5 do some of this turnaround work, quicker turnaround work,
6 provisional analysis and how can we just get information to
7 policymakers more quickly, that has some evaluation rigor to
8 it as well which has resource implications.

9 So I don't want to say it's all about resources.
10 Sometimes it's just juggling the balls. But we do
11 appreciate that demonstrations and evaluations are really
12 one unit, at least in the view of the folks that work in my
13 office.

14 Thank you.

15 MR. GUTTERMAN: I am Stu Gutterman with the
16 Commonwealth Fund, and I have a couple comments.

17 I wanted to echo Tim's remarks on the presentation
18 and the discussion. I thought you had a terrific
19 discussion. I think the dimensions along which you
20 structured the discussion are the right ones. And I'd make
21 more explicit that Congress, even when they mandate
22 demonstrations, don't always -- in fact, I think relatively

1 rarely -- allocate money explicitly for the evaluation of
2 those demonstrations, so that it ends up being a
3 discretionary process inside CMS with limited resources, and
4 that is what happens sometimes.

5 I'd like to make a couple of other points. I
6 think, you know, the distinction between pilot and
7 demonstration is one that's very vague because there have
8 been demonstration projects that have been explicitly
9 authorized by Congress where the Secretary has been
10 explicitly authorized by Congress to continue a
11 demonstration or to expand it.

12 I would suggest a different distinction between
13 demonstration and pilot in the context of the Center for
14 Medicare & Medicaid Innovation that's in the legislation
15 that at least right now is still alive. And I think it
16 suggests something that CMS I know is interested in and
17 should be interested in in the future, and that is,
18 distinguishing between -- and it is kind of along the lines
19 that Glenn mentioned, distinguishing between projects that
20 focus on specific aspects that you really want to test to
21 see if they work to save money or improve quality, and
22 projects that really are operational to be able to encourage

1 new approaches. You might even give that kind of project
2 the title "Innovation with Evidence Development," because
3 frequently we're asked -- when I was part of the process,
4 frequently we'd get the question: Do you have proof that
5 this is going to work? And my answer would be: That's why
6 it's a demonstration. But that never seemed to hold very
7 much water, that argument.

8 So I think we need to view the demonstrations, the
9 broader innovation process in CMS, as an opportunity to try
10 different approaches, not to test them but to try them; that
11 is, to put some things into place, see if we can get them
12 put into place, and then monitor their effect on the system
13 and continue them if they are having a positive effect,
14 either saving money or improving quality, or both.

15 And one last point on Mike's suggestion of
16 multiple evaluations. Of course, anybody who has ever run
17 ORDI kind of holds their head at the thought of having to
18 fund multiple evaluations when we can't even afford to --
19 but I think the answer really is in the transparency that
20 was on John's list. I think if you make things transparent
21 and you have the data available for researchers, whoever
22 wants to research any aspect of a particular project to be

1 able to do that kind of research, I think that would be a
2 big step in the right direction and also open up the process
3 and give CMS more flexibility to be able to work with the
4 projects that they are developing and implementing.

5 Thanks.

6 MR. HACKBARTH: Okay. Thank you very much, and we
7 are adjourned.

8 [Whereupon, at 12:02 p.m., the meeting was
9 adjourned.]