

1 obtain the longer-term information on delayed toxicity on
2 quality of life and then extending, as I said earlier, into
3 issues of survivorship. So, to me it's in that setting
4 where the longer-term data collection is the most
5 informative.

6 In fact, a drug that may be approved for use in
7 the metastatic disease setting one could easily imagine
8 might not be approved for use in the adjuvant setting
9 because there might be long-term quality of life issues
10 that counterbalance whatever benefit might occur in the
11 adjuvant setting.

12 So, looking at this from the perspective of the
13 advisory committee to the FDA, I think that that's how I
14 see the issues playing out. It's not simply a matter of is
15 it important to know clinically what the patient's quality
16 of life is up to the moment of death. Sure. As a
17 physician I'd want to know that. The real issue is how
18 does that inform the regulatory decision making.

19 DR. CELLA: Thank you.

20 What I heard -- and then, Jeff, if you still
21 want to say something.

22 To me then the question, based on what I heard,
23 becomes why not. Why wouldn't we want the data? What I
24 heard was that collecting the data does not require you to
25 use it in an analysis, but it enables you to use it in

1 | analyses that have an intent to treat approach where
2 | otherwise you would lose that opportunity from an analytic
3 | perspective. So, what I heard Diane and Nan say is you
4 | lose little by collecting the information and you gain
5 | opportunity to analyze the data in multiple ways that will
6 | help inform the potential value of therapy.

7 | So, I'm trying to figure out, even from a
8 | regulatory perspective or clinical perspective, why you
9 | wouldn't want to have the data available for analysis as
10 | opposed to deciding up front that you're not interested.

11 | DR. PAZDUR: One of the questions that I have
12 | is, are we confusing chronic toxicity with quality of life?

13 | DR. CELLA: No, I don't think so because we're
14 | talking about --

15 | DR. PAZDUR: So, I think what Jody was talking
16 | about was some aspects of chronic toxicity and evaluating
17 | the toxicity of an agent. Really, the evaluation of
18 | toxicity of any drug is not going to be answered only in
19 | one trial or two trials right when the drug is approved.
20 | It's going to be really a longitudinal basis even after the
21 | drug is marketed, et cetera.

22 | The question that I have for you is, is the
23 | science of quality of life, as it exists in the year 2000,
24 | to a point where we can make regulatory decisions and that
25 | it is different that much in the analysis and the

1 | distinction between quality of life and toxicity? But is
2 | quality of life in the year 2000, looking at this
3 | longitudinal basis, there to the point where we can start
4 | recalling drugs, making some assessment, and making
5 | regulatory decisions on that basis of just quality of life
6 | in the absence of toxicity? That's really kind of, I
7 | think, what you're asking here, David.

8 | DR. CELLA: That was a really useful 3 o'clock
9 | direction or directive, but if I can take the risk of
10 | speaking for the committee, I wouldn't be here if I thought
11 | the answer was no. It would be a waste of time. I would
12 | say leave me to be in my office or laboratory or whatever
13 | you want to call it where I do my work to get it to the
14 | point where it's ready. But the truth also is it's only
15 | ready enough. It's not the best it can be. So, while we
16 | try to move that forward and make progress, there's a
17 | sufficient readiness as long as we're willing to accept
18 | some error that was commented on earlier off of Carol's
19 | point to accept that there's some error in the measurement,
20 | as there is in most of medical measurement. I can't think
21 | of too many things, other than survival where there's
22 | virtually no error, where there's not some error in the
23 | measurement. So, there's error in all measurement, but
24 | we've worked out enough of it so that the answer can be
25 | yes, and we need to sort out the guidelines for how to

1 | proceed.

2 | The other thing is that, unfortunately -- and
3 | this will probably always be the case -- patients and
4 | clinicians and quality of life measurement scientists
5 | cannot fully differentiate disease symptoms from treatment
6 | side effects. We can't do it. You can't do it, and people
7 | with cancer can't do it. Fatigue is caused by a disease
8 | and by treatment. Pain is caused by a disease, et cetera.
9 | So, that's always going to be a mix. We need to turn to
10 | the patients, we're saying, to get from them the sum of
11 | that mix and then make as reasoned a differentiation as we
12 | can between how much of this is disease symptom benefit
13 | versus toxicity offset or relative improvement.

14 | If it's right on this point, Stacy, sure, go
15 | ahead, but there are some people in line, and you're second
16 | in line behind Jeff.

17 | DR. SLOAN: I wanted to go back to a question
18 | which has kind of come around here. Why would you want to
19 | measure quality of life, for example, in advanced cancer
20 | patients after the treatment has failed?

21 | And then you also asked, what is the science of
22 | quality of life measurement such that what do we know about
23 | what happens to quality of life shortly before death?
24 | Well, there are a few things that we do know. The most
25 | recent literature suggests, for example, it's intuitively,

1 | one would think, obvious that all aspects of quality of
2 | life drop before you die, going monotonically towards zero.
3 | And that is not true, and there's empirical data to support
4 | that.

5 | Physical functioning and health-related quality
6 | of life related to physical functioning are often confused
7 | with quality of life before death so to speak. Yes, those
8 | scores do drop, and if you look at studies that have been
9 | done by a number of folks around table, for example, in
10 | hospice patients, the physical aspects of quality of life,
11 | yes, will be going down monotonically and it's not
12 | surprising.

13 | What is surprising, however, is some of the
14 | other dimensions, some of the other aspects of quality of
15 | life will actually retain their status from pretreatment
16 | and, in fact, get better for a lot of reasons, which I
17 | won't go into at this point.

18 | But let me give you an example of where it was
19 | useful for us to assess certain aspects of quality of life
20 | in a cancer control study dealing with hot flash activity
21 | just recently looking at the use of SSRIs, selective
22 | serotonin reuptake inhibitors. There are some
23 | antidepressant effects here that potentially confound the
24 | issue of controlling hot flashes in post-mastectomy and
25 | post-orchietomy patients.

1 It was important for us to know, even if a
2 particular agent would have failed, would the impact on
3 mood, for example, impact the patient's emotional quality
4 of life, which we now know in the advanced days and later
5 days actually does stabilize due, if for no other reason,
6 to a response shift that happens in a patient accepting
7 mortality and certain circumstances as long as they're
8 relatively stable, not involving immediate hospitalization.
9 Quality of life in many dimensions remains relatively high.

10 If some agent were to mess up that, especially
11 again going back to the idea of how do we determine
12 clinical significance -- if a priori we have a reasonable
13 scientific hypothesis to suggest that, yes, there are some
14 aspects of quality of life that may be impacted by this
15 particular agent, even after it's failed, then that does
16 offer us another question as to whether or not we should
17 continue to give it even after it's failed or whether there
18 will be lingering after effects.

19 So, again, I think there are situations where,
20 yes, it would be useful, but again it goes back to what we
21 said I think in the second session this morning. They have
22 to be scientifically justifiable as opposed to just going
23 on a fishing expedition, and I think that's what we're all
24 kind of coming to hopefully.

25 DR. CELLA: Stacy?

1 DR. NERENSTONE: That was going to be sort of
2 my point, that for instance you asked, David, well, maybe
3 the rate of progression is less after you stop this drug,
4 even though it doesn't have an effect. And I would say
5 that we don't have the technology to figure that out. That
6 would have to be designed at the very beginning of the
7 trial looking at that specific question which I think is
8 going to happen with the antiangiogenesis, those new
9 agents.

10 I have no problem with collecting the data. I
11 think you have to be very specific about how much data is
12 really necessary because then it becomes an undue burden on
13 both the physician and the patient. You do want to sort of
14 know what you're going to do with it, even if it's just to
15 assess for toxicity, which is what I think most people are
16 saying. But to try sort of culling the data and then say,
17 oh, see, look, we had delay of time to progression, without
18 really knowing beforehand that that's what you were going
19 to look for I think is really not valid. And just that one
20 example, that's unknowable right now in terms of delay in
21 time to progression.

22 DR. CELLA: I'd like to be clear and say that I
23 was never suggesting this as a fishing expedition, nor was
24 I suggesting it as a way of finding something that's there
25 that we don't yet know about.

1 What I'm saying is I hear a stronger argument,
2 frankly -- I sort of feel in the middle of this one because
3 I am clinically trained and I do see patients. I feel a
4 stronger argument from the statistics side that says you
5 want to have the data because analysis options remain open
6 when you have the data and the door is closed when you
7 don't have the data. I don't see enough of a reason to not
8 collect the information.

9 I'm not speaking to what you put in the
10 protocol up front. If you put in the protocol up front
11 that you're going to study time to symptomatic progression
12 or that you're going to compare groups of patients up until
13 the time they announce their progression, then that's what
14 you study. You should stick with what you committed to
15 when you start the trial, and I'm sure that will come
16 through as a recommendation from us to ODAC and the FDA.

17 I'm just saying that I haven't heard enough of
18 an argument for not collecting the information. Deciding
19 about how to use it in an analysis is a different matter.

20 Any other comment?

21 We actually have really only talked about one
22 issue, and clearly we need to, on that issue, come forward
23 with some draft text and then see how it feels. I mean,
24 one of the really rich things about this group is that it
25 is admixture and a relatively small admixture of

1 | statistically oriented people, measurement oriented people,
2 | and clinically oriented people. I think anything that we
3 | write and review is going to have to pass all three screens
4 | in order to be acceptable, and that's going to be an
5 | interesting process. But I think it will be fun.

6 | We have other topics that were raised. We only
7 | have time for maybe --

8 | DR. FAIRCLOUGH: Dave, are you going to the
9 | questions?

10 | DR. CELLA: Well, we can do that too. Let's
11 | review the questions. That's a good idea.

12 | DR. FAIRCLOUGH: I have two more slides.

13 | DR. CELLA: Diane has two more slides that
14 | address the questions?

15 | DR. FAIRCLOUGH: That address the questions.

16 | DR. CELLA: Okay.

17 | DR. FAIRCLOUGH: Well, to some extent.

18 | DR. CELLA: The questions are what are the
19 | strengths and weaknesses of the major types of analytic
20 | approaches, i.e., longitudinal modeling versus univariate
21 | techniques.

22 | And the second question is what analytic
23 | approaches should be taken to assess the type of missing
24 | data, informative versus non-informative, and handle them
25 | in the analysis. Example, various imputation techniques,

1 pattern mixture model, et cetera.

2 We've talked a bit more about the second, so
3 why don't we start with the first? And no advertising.

4 (Laughter.)

5 DR. FAIRCLOUGH: The strengths of longitudinal
6 and univariate, and I referred to it in some ways during
7 the presentation. When we're talking about univariate in
8 the context of repeated univariate t-tests or even repeated
9 univariate changes from baseline, we're making those
10 missing completely at random assumptions. And we also have
11 the problem of multiple endpoints. So, I would strongly
12 suggest that we don't use repeated univariate analyses in
13 the presentations. I think there are easily accessible
14 alternatives so that that should be something we eliminate.

15 When we go to longitudinal models and we use
16 all the available data, we've relaxed our assumptions to
17 the missing at random, and I think that should be the
18 minimal criteria for an analysis.

19 There's another way to get to a univariate
20 endpoint and that's to do some type of summary measure that
21 takes the longitudinal data and converts it into a single
22 measure. If you've got a very appropriate choice to that
23 summary measure and you have a way to construct that
24 summary measure in the presence of missing data, then that
25 may be a very nice and interpretable strategy.

1 What's very difficult, though, is how you deal
2 with the missing data and trying to set up rules to deal
3 with it on a case-by-case basis. It will drive you
4 absolutely nuts to do it, let alone to document how you've
5 done it and justify it. So, you may actually end up
6 developing a summary measure from your longitudinal
7 multivariate model. So, instead of constructing an AUC for
8 each individual, what you do is you get the quality of life
9 versus time curve for the entire population, and that
10 becomes your summary measure and it's a function of your
11 estimate.

12 So, I think that addresses some of those
13 issues.

14 Claire?

15 DR. GNECCO: Diane, for something like area
16 under the curve, for instance, wouldn't you also like to
17 see some kind of longitudinal modeling to put that in
18 context? I always get the feeling that you could be losing
19 information with an area under the curve approach.

20 DR. FAIRCLOUGH: You mean not seeing
21 descriptively what's happening in the two arms?

22 DR. GNECCO: Yes.

23 DR. FAIRCLOUGH: Again, it really depends on
24 the question, but I think that the descriptive plots of
25 what those two arms look like in terms of the quality of

1 | life over time may very well be appropriate to the
2 | interpretation.

3 | DR. GNECCO: So, the more complete the
4 | graphical presentation, the better. Thanks.

5 | DR. FAIRCLOUGH: I think the missing data is
6 | the one that we have been dealing with. The first part of
7 | the question asked about testing for it, and again
8 | reemphasizing that there's not a formal way of testing for
9 | non-ignorable data, but when we have missing data
10 | associated with morbidity and mortality, it's highly likely
11 | that we have -- and it just really requires that we really
12 | understand the disease process and the treatment that we're
13 | giving, and to do it naively, stick it into a package could
14 | get you in trouble. So, you need to think about what could
15 | be the things that you are measuring, make sure you're
16 | measuring them, and see if they're associated.

17 | Then you need to do an analysis that's
18 | appropriate or at least a sensitivity analysis when it's
19 | suspected there's no simple and single approach. I think
20 | the really critical thing is -- and it takes about a day
21 | and a half for me to go through this in a formal way -- is
22 | to really understand the assumptions of each one of those
23 | methods.

24 | Multiple imputation, if done very thoughtfully
25 | and with really good clinical information, can be really

1 | powerful. If it's done in a naive manner and you happen to
2 | omit those important clinical correlates, it just makes the
3 | problem seem like it has gone away, but it hasn't. So, you
4 | really have a danger there. And we have to do sensitivity
5 | analysis.

6 | So, the pattern mixture models -- I don't know
7 | how you implement those easily because you have to make
8 | such strong assumptions about what happens to the patients
9 | in that group, let's say, one of your patterns is those
10 | people who only had baseline. So, what do you infer about
11 | the quality of life of those patients after that? Those
12 | that drop out after the first assessment, what do you infer
13 | about their trajectories? There's a lot of assumptions
14 | there.

15 | So, every method has a lot of assumptions, and
16 | if they're done well and justified well, then you have
17 | something meaningful that can inform you, but if they are
18 | done without understanding the assumptions, you just dug
19 | your hole deeper.

20 | DR. CELLA: Stacy.

21 | DR. NERENSTONE: Yes. I just have a question.
22 | There's always this discussion, when looking at the quality
23 | of life data, that data is missing. But in fact, we also
24 | know a lot about those patients because the investigators,
25 | to pull somebody off study, have to say why they dropped

1 out of study.

2 So, on the one hand, you're saying you have to
3 infer about the trajectories they're taking. But in fact,
4 you know certain things about them. Somebody has to decide
5 whether they're progressing and so they're being pulled off
6 because of disease progression, that there's toxicity from
7 the treatment. That means that they're taken off because
8 of toxicity, or both, or neither. They've moved away.

9 Is there a statistical way of folding that into
10 the model? Because it's no longer the patient giving their
11 quality of life, but it's also not missing data. We have
12 information. We just don't know how to use that
13 information in the mathematical models that have been
14 constructed.

15 DR. CELLA: Well, I think it's guiding
16 information. It's good information to have, and it can be
17 used. Diane, if you want to explain details on how you
18 might use that. But the short answer is that the more
19 information you have, even if it's not patient self-
20 reported status on a questionnaire, will help in the
21 modeling.

22 DR. FAIRCLOUGH: It will help in the modeling,
23 but you still have to make an assumption of how that
24 information relates to the specific value of quality of
25 life that you're going to infer that that patient has.

1 | Does disease progression mean that they've dropped 15
2 | points or does it mean they've dropped 25 points? And
3 | you're going to have to have some way to inform that. And
4 | if you have no quality of life measurements on the people
5 | that have progressed, then you can't make any inference, or
6 | if you have no quality of life on the patients who had a
7 | grade 3 toxicity, you're not going to be able to go
8 | anywhere with it.

9 | DR. CELLA: Diane, I have a question, which is
10 | sort of a general question. Do you think that we're ready
11 | to -- this is kind of like along the lines of Rick's "are
12 | we ready" -- have some general guidelines? You're
13 | mentioning how there needs to be a sensitivity analysis.
14 | It's hard to you envision when there's missingness in the
15 | analysis which we can expect will always be there, at the
16 | very least because patients die, but also because they
17 | don't fill out the questionnaires.

18 | Are we ready to have a list of options with
19 | some in a sort of preferred category? You have eliminated
20 | some, but among the ones you haven't eliminated, would you
21 | put them all in the same class? Would you say select this
22 | under circumstances A, B, and C versus select this one
23 | under circumstances C, B, and A, with sensitivity analyses
24 | done by the remainder or by two or three other approaches?
25 | I'm wondering if we're ready for a distilled kind of set of

1 suggestions, recommendations, if you will, for protocol
2 development and planning.

3 DR. FAIRCLOUGH: The answer is no. I think one
4 of the things is that there's so much development of
5 methodology right now, and we're on such a strong curve. I
6 mean, it's like the hot dissertation topic to deal with
7 non-ignorable missing data. So, I would hate to write
8 something specifically in guidelines that would, by the
9 time we got it printed, there were three more articles that
10 came out that would inform us. There might be better
11 methods that then wouldn't be used because they weren't on
12 the approved list.

13 The other thing that's probably even more
14 compelling is I don't think that we can envision every
15 scenario of every focused type of question and how it would
16 play out in a particular disease or treatment well enough
17 to make that kind of contingency plan. I think we can put
18 guiding principles that will be informative, but I don't
19 think we can have a checklist.

20 DR. CELLA: Maybe we'll start with -- I didn't
21 mean to suggest checklist, but a list of sort of acceptable
22 approaches under varying circumstances without necessarily
23 putting them in rank order. But maybe we'll have these
24 guiding principles and then be able to work from there to
25 lay out some examples of typical phase III trial planning

1 | situations, with this is a reasonable approach. And we may
2 | need to have several examples so that people don't get the
3 | idea that we're saying there's an imprimatur on this one
4 | approach. It seems to be part of the concern.

5 | But it's going to happen. It is happening.
6 | There are trials being planned today where people want to
7 | know what's going to pass muster and what do I need to be
8 | thinking about to see to it that it's going to be
9 | acceptable given that there are many dissertations that
10 | still need to be done.

11 | Donald, you had a point?

12 | DR. PATRICK: I think I heard a lot more
13 | agreement about what isn't acceptable, and so that might be
14 | one way to go in terms of under what circumstances would
15 | this simply not be able to support the analysis, either the
16 | multiple testing issues or the missing data issues.

17 | You also raised something at the end that I
18 | think has been a little bit of a problem all day long,
19 | rereading the questions in part one, and that is the
20 | phasing of these studies and what can be done prior to the
21 | pivotal phase III study to understand missing data issues
22 | and instrumentation and concepts and validation so that
23 | when the submissions come, you've got enough evidence so
24 | this isn't all hinging on one study. The pattern of
25 | evidence across multiple studies seems to me to be an

1 extremely important issue so that you've had more than one
2 chance to deal with missing data on a particular
3 therapeutic area and within a particular population that
4 would support the approach when you put forward your key
5 trial data. It's very difficult to specify in advance on a
6 single study that this is going to work, depending on the
7 power and the sample size.

8 DR. CELLA: One of the items for the last hour,
9 this post-marketing and ancillary studies, kind of touches
10 on that. What are the kinds of things that should be done,
11 not necessarily within the pivotal trial but surrounding
12 the trial before and afterward to be able to support a
13 claim. And we'll come back to that. So, thank you.

14 Let's take a quick break.

15 (Recess.)

16 DR. CELLA: Well, we have had quite an
17 interesting day. I think there has been a lot of
18 stimulation around the table and a lot of interesting
19 discussion. Several areas have been opened up. Very few
20 have been resolved, but I'll remind you that at the
21 beginning of this meeting I warned you that we had no
22 intention of resolving anything today. And I think we've
23 done a reasonable job of fulfilling that promise and
24 spelling out the three primary issues.

25 But before we move to summarizing on those

1 | three primary issues briefly, and then the other five
2 | issues and any others that are listed on the future plans,
3 | Dr. Beitz from the FDA will offer some reaction,
4 | perspective, and specific requests of the subcommittee.
5 | Julie.

6 | DR. BEITZ: What I was going to start off with
7 | was just the idea that when industry comes to meet with us,
8 | we're often asked by them what instruments should they use
9 | in their studies or, as a corollary to that, is instrument
10 | A or B or C acceptable to the agency. Very typical
11 | question. I would just like to comment on some of the
12 | things I heard earlier today that may speak to this point.

13 | Regarding the overlap of symptoms and health-
14 | related quality of life, we heard this morning that symptom
15 | measurement is a good place to start but may not tell us
16 | all that we would like to know. So, perhaps a topic for
17 | another day, a further discussion, what are the clinical
18 | settings that are appropriate for a symptom-only study
19 | versus what settings would be appropriate to have
20 | additional information with health-related quality of life
21 | instruments.

22 | As an example, it could be that perhaps where
23 | you really need the additional information from health-
24 | related quality of life might be in an early submission,
25 | your initial pivotal studies where you don't know very much

1 | about the drug. However, once the drug is approved, on the
2 | market, and you have prior information on its toxicity
3 | profile and you're submitting additional studies for
4 | supplemental indications, then perhaps those studies may
5 | only need to have certain symptoms evaluated. That's just
6 | a thought that I had that you could toss around.

7 | Another thing that I heard that I found
8 | fascinating was Dr. Sloan's discussion of how when he was
9 | working on a colorectal cancer trial, that he got together
10 | with the clinical trialists to review the questions that
11 | were most appropriate to ask colon cancer patients, and
12 | from there, going to the instrument that was of interest,
13 | the FACT in that case, and to see how much of these
14 | questions were actually covered by the instrument. And I
15 | guess most of them were, except for a couple of items which
16 | were then written into the protocol.

17 | I found this very interesting, and I just throw
18 | out the question, how frequently is this kind of
19 | comprehensive exercise actually undertaken? And if it were
20 | done routinely and comprehensively, would we actually see
21 | different instruments proposed to us in trials? And would
22 | we get potentially different results?

23 | That brings me to the idea of results, and I
24 | would just echo Diane Fairclough's question to us today
25 | which was, now that we have the data or not, what do we do?

1 I'm not a statistician, but what I did hear was there is no
2 single approach that will probably apply to all the
3 situations that arise in analysis, but that perhaps what
4 could help us are delineation of the pros and cons to the
5 different approaches. I think that if we understood what
6 the strengths and weaknesses were of the different
7 approaches, then we could assess these approaches when
8 they're done in submissions that are given to us and also
9 we could critique our own analyses of these data.

10 So, I would just like to conclude that what I
11 learned today was that to get a handle on the value-added
12 health-related quality of life, if this added value exists,
13 it would be important to have a continued dialogue between
14 quality of life researchers and clinical trialists, and I
15 believe that this meeting is a good start toward
16 accomplishing this.

17 DR. CELLA: Any questions or comments?

18 (No response.)

19 DR. CELLA: Thanks, Julie. It was helpful.

20 Carol.

21 DR. MOINPOUR: I've been talking to several
22 people over the course of the day and there is another
23 committee within the FDA that's looking at quality of life
24 assessment and it would seem to make sense for the two
25 groups to have some way of dialogue or communication. That

1 | might be useful.

2 | DR. CELLA: You're referring to Lori Burke and
3 | that activity?

4 | DR. MOINPOUR: Yes.

5 | DR. CELLA: Well, Lori was involved in the
6 | planning of this meeting and I think is not here because of
7 | a conflict, but my assumption is that she'll be at the next
8 | meeting unless there's another conflict. Is that correct,
9 | Julie?

10 | DR. BEITZ: Right. I think there are folks
11 | actually in attendance here, including myself, who sit on
12 | this other committee. There is a committee looking at
13 | trying to write guidance on this issue, and it is our hope
14 | that at some point we can actually present the document
15 | that we've got to this group for comment down the road.

16 | DR. CELLA: So, you'd like to wait to present
17 | that to us because you want to get it into a condition that
18 | you're comfortable with internally rather than having us
19 | work on it with you, which is fine. I just want to clarify
20 | why. Because the other way to do it, of course, would be
21 | to show it to us sooner for comment rather than later.

22 | DR. BEITZ: Right. I don't want to speak for
23 | Lori. I think she's ready pretty soon.

24 | DR. CELLA: Okay.

25 | Along those lines, there are other documents

1 | that we will circulate to all the subcommittee members.
2 | One of them is from the International Society for
3 | Pharmacoeconomics and Outcomes Research, and it's their
4 | position paper on health-related quality of life claims,
5 | which is also on their web site. I've just downloaded it
6 | from their web site, and we'll see to it that it's copied
7 | and distributed.

8 | The International Society for Quality of Life
9 | Research is not yet circulating its draft document that is
10 | intended to advise on claims in labeling, but when it does,
11 | I'm sure we'll be interested in seeing that as well.

12 | And PhRMA also has a document. I don't know.
13 | I think it was due in the summer, but I haven't seen it,
14 | and I don't know if it's available yet. Maybe others do.
15 | Does anyone know if the PhRMA document has been
16 | disseminated? Anyone in the audience know? Yes, please.
17 | There's a microphone there. If you could speak into that,
18 | I'd appreciate it. Could you tell us who you are, please?

19 | MR. WILLKE: A long way for a brief comment.

20 | I'm Dick Willke. I'm with Pharmacia & Upjohn
21 | and also on the Health Outcomes Committee of PhRMA.

22 | I'd say we're just about on our final draft of
23 | some commentaries from a meeting that was held in March of
24 | 1999 that was sponsored by our group, but we worked with
25 | the FDA DDMAC group to organize it. There are some results

1 | on many of these same issues that are in this working
2 | draft. I can't give you a day when it will be available
3 | exactly, but it should be very soon.

4 | DR. CELLA: Would it be more appropriate for
5 | him to correspond with you or with me, Karen, just to
6 | inform us about when this is a final draft that can be
7 | circulated? Would you be willing to share it when it's
8 | available for circulation?

9 | MR. WILLKE: Certainly.

10 | DR. CELLA: Could you share it with me and then
11 | I can ask that it be distributed?

12 | MR. WILLKE: Be glad to.

13 | DR. CELLA: Thank you.

14 | I believe that there's no use in our operating
15 | in a vacuum, so I think it's better to have these things
16 | than to not have these things. This is just a downloaded
17 | text from the ISPOR web site, and then there's this paper
18 | that Carol Moinpour actually mentioned this morning by
19 | Nancy Leidy and Dennis Revicky and Bernard Genest,
20 | published in Value in Health last year, on recommendations
21 | for evaluating validity of quality of life claims for
22 | labeling and promotion. So, we'll circulate that as well.
23 | So, look for a package to come in the mail for you to
24 | review between now and the next meeting.

25 | We have another half hour to discuss future

1 | plans. The first thing I'd like to do is just very briefly
2 | review the fact that we've covered these three major areas:
3 | definitional issues, clinical significance/interpretation,
4 | and data analysis. I have volunteered myself to take a
5 | stab at a first draft of a brief summary targeted toward
6 | guidelines, tone if you will, that I'll first circulate to
7 | the presenters and discussants for their comment and then
8 | after getting those comments back and making modifications
9 | that I'm sure will happen, then circulating to the entire
10 | subcommittee. I'll do that well in advance of the next
11 | meeting in June. We'll do it through Dr. Somers so that
12 | she can circulate it to anyone in the agency that is
13 | involved and interested. So, that's just a review of what
14 | will happen between now and the next meeting by way of
15 | clarifying and optimally summarizing what just occurred
16 | today.

17 | The other items I wanted to touch on, as we
18 | consider where we're going to go with the next meeting,
19 | which by the way will, we believe, either be June 5th or
20 | June 7th. My hope was that that would be determined by the
21 | end of today, but I guess that was not realistic. Karen
22 | would like to know. It's dependent upon ODAC which will be
23 | either the 6th and 7th or the 6th only. It's not clear how
24 | many days it will be, or the 5th and 6th or 6th and 7th.
25 | So, it's dependent upon that.

1 But to the extent we inform them about our
2 conflicts, it might also actually be dependent upon our
3 schedules as well. But that all needs to be coordinated by
4 Karen. So, please let Karen know if you have a conflict on
5 the 5th or the 7th, which are the two most likely next
6 dates. If you don't have a conflict, let her know that
7 too. Thank you.

8 So, as far as substantive future plans, there
9 are these five areas that represent some things that we
10 knew we wouldn't have time to get to today, but are also
11 very important. There may be others to add to the list,
12 and I encourage you to do that.

13 The first is when should one study health-
14 related quality of life. We've touched on that through the
15 course of discussion. Julie asked the question about when
16 would measuring symptoms be enough, and implicit in that is
17 when should one study health-related quality of life. So,
18 we need to have some discussion about the parameters that
19 should be guiding our thinking and the FDA's thinking about
20 when it's appropriate to be looking at any of these
21 endpoints.

22 Second is all of the many issues that come up
23 with study design. The question about timing was asked,
24 which is a design question. The question about whether you
25 assess quality of life after an event as in progression was

1 | also asked. These are design issues. There are several
2 | other design issues that were touched upon, and clearly we
3 | need to delve into more specifics on those.

4 | Would anyone like to nominate any design issues
5 | that you think are pivotal, if you'll excuse the term?

6 | DR. GNECCO: What comes up very often is when
7 | you do come up with an assessment schedule, if it isn't
8 | very closely adhered to in the analysis, you can have a
9 | real problem because of measurement error. So, that has to
10 | do with the timing. If they're too widely spaced in time,
11 | you have a greater likelihood of people being outside of a
12 | large window. So, maybe thinking about time windows
13 | associated with the measurement schedule.

14 | DR. CELLA: So, it's both the timing, the
15 | frequency, and also the acceptable margins around which you
16 | can receive data and analyze it.

17 | DR. GNECCO: Exactly.

18 | DR. CELLA: Well, it seems to me that timing as
19 | a topic area is broad enough topic area to merit an actual
20 | set-aside discussion. I see some heads nodding around the
21 | table. Just as we had three main topic areas today, why
22 | don't we assume that the next meeting's agenda will include
23 | a specific discussion of timing?

24 | Questionnaire validity and acceptable
25 | modifications. This is an area that really apparently also

1 | comes up a lot. Julie started with this, saying that this
2 | is one of the most frequently asked questions that they get
3 | from sponsors. Embedded in there are things like how do
4 | you know if a questionnaire is valid. I hope we don't need
5 | this to become a sort of basic primer or 101 course on
6 | validity and reliability. I think the FDA has just had a
7 | seminar on that, and there are certainly available texts
8 | that we can refer people to. But I'm concerned if we get
9 | into too much on that, it will divert us from our charge
10 | really.

11 | But nevertheless, it remains important to push
12 | the envelope, if you will, on determining what are the
13 | minimum acceptable requirements for a proposed set of
14 | questions. Does there need to be a published paper on a
15 | scale that's being proposed? When is it acceptable to
16 | extract items which came up in the discussion today, and if
17 | one did that, what are the sort of acceptable ways of doing
18 | that? What are the things to be concerned about? Is this
19 | an area that around the table we think is something we're
20 | ready to tackle in June? I think it's something we're
21 | going to have to tackle.

22 | Carol thinks it's easier. I think it might be
23 | harder.

24 | (Laughter.)

25 | DR. CELLA: So, validity and acceptable

1 modifications. Is there a better term anyone would like to
2 nominate for that?

3 DR. SLOAN: How about non-standard use of
4 standardized questionnaires?

5 DR. CELLA: Okay, or new uses? Old wine in new
6 bottles?

7 (Laughter.)

8 DR. CELLA: Just acceptable measures, she said.
9 Minimum requirements for acceptability of questionnaires.

10 VOICE: Psychometric integrity.

11 DR. CELLA: Okay, psychometric integrity.

12 So, that's a probable second choice. I just
13 want to run through them before we commit.

14 Post-marketing and ancillary studies. Now,
15 these are not necessarily the same thing, and maybe they
16 don't belong on the same line even.

17 Let's start with ancillary studies actually
18 because this has come up today a couple of times. The idea
19 here is not everything has to be attached onto a pivotal
20 trial. Arguably it should not necessarily be attached onto
21 a pivotal trial, but may provide important supplementary
22 information. It might tie in with this other area of
23 psychometric characteristics, such as new validity data on
24 a questionnaire or the value or preferences that people
25 place upon certain symptoms, whether they're symptoms of

1 disease or side effects of treatment, or the extent to
2 which symptoms drive functional problems or changes. These
3 sorts of things can be studied outside of the trial for
4 information that can be given in support of the
5 application.

6 It seems to me this, among the list, might not
7 be necessarily ready for June but we may need to cover
8 that.

9 Rich?

10 DR. SCHILSKY: I was just going to say to me
11 more important than post-marketing studies might be to have
12 some discussion of what kinds of information could
13 potentially be collected, say, as part of phase II trials
14 that would be useful in facilitating hypothesis generation
15 for testing in phase III trials going forward. Since we've
16 been stressing the importance of hypothesis-driven research
17 in this area, it seems to me that you have to be able to
18 have a minimum amount of information to enable the
19 development of a hypothesis. So, what could you do during
20 phase II that would facilitate that?

21 DR. CELLA: Yes, I agree. I mentioned it
22 earlier and I think that these kinds of ancillary studies
23 that I referred to really don't belong with the post-
24 marketing line. So, I just created a new line, almost like
25 pre-submission ancillary studies, because so far we're

1 | talking about the kinds of studies that might accompany a
2 | submission rather than anything that would be post-
3 | marketing. And that would include the phase II preparation
4 | studies.

5 | Did I get that right?

6 | DR. SCHILSKY: Yes. I guess I'm not sure that
7 | they should all be lumped together. It seems to me they
8 | address somewhat different things, but they're all
9 | important. I'm just thinking in terms of trying to
10 | ultimately provide some guidance to industry and
11 | investigators in terms of how to develop these studies so
12 | that at the end of the day, there's a cohesive and coherent
13 | data set sort of in parallel to what you would get in your
14 | clinical data set. There's phase II data and there's data
15 | from randomized clinical trials.

16 | DR. CELLA: Let's come back to that as we plan
17 | for the next meeting.

18 | Reporting and labeling. How about this area?

19 | DR. PAZDUR: I think that's important to some
20 | people in the FDA, but I think of the topics that we've
21 | described, I think we're going, not in a chronological
22 | order, but order of importance to us as far as the division
23 | goes.

24 | DR. CELLA: I'm not sure the mike picked you up
25 | there. Did you get that? Would you like me to repeat it?

1 He said thinks it's important to some people in
2 the room, but not of as much direct importance to ODAC and
3 to this division of FDA.

4 I think if we could keep that as a future
5 possibility because some of these things we do are going to
6 logically flow right into labeling implications and we
7 don't necessarily need to specifically deliberate on
8 labeling. I think it would be an automatic flow from some
9 of the work we do.

10 Carol, did you have a comment?

11 DR. MOINPOUR: Not about that.

12 DR. CELLA: So, that's a later.

13 Are there any other areas that we'd like to
14 hear nominations for? Stacy.

15 DR. NERENSTONE: In trial design, you didn't
16 say anything about randomization. Is that because
17 implicitly they're all going to be randomized or that
18 they're not going to be randomized, or you don't think
19 that's an important concept for us to talk about? Or
20 should it be added to the list?

21 DR. CELLA: I think it probably should be added
22 to list. I had the assumption, apparently erroneous, that
23 pivotal trials that you look at are all randomized trials.
24 So, I was assuming something incorrect. So, it should be
25 on the list.

1 DR. DICKERSIN: Rich mentioned the phase --

2 DR. CELLA: The phase IIs, yes. But I thought
3 he was mentioning it in the context of work that could be
4 done in preparing --

5 DR. SCHILSKY: There are also occasions when
6 we're asked to consider things that are being proposed for
7 so-called accelerated approval which are oftentimes non-
8 randomized trials. Of course, there we pretty well are
9 focused on a surrogate for clinical benefit, namely
10 response rate. But I think even there, having information
11 about the quality of life of the patients related to
12 whether they're responding or not is important because
13 there's a regulatory decision to be made about whether the
14 drug should be marketed based upon this accelerated
15 approval guideline, and that doesn't require randomized
16 trials.

17 DR. PAZDUR: Yes. It doesn't require
18 randomized trials, but it does require a commitment
19 subsequently to demonstrate clinical benefit after the drug
20 is approved. So, that application would come later
21 probably when we make a phase IV commitment and should be
22 an integral part of that phase IV commitment after the
23 accelerated approval. So, it still would play a part, but
24 probably a step later in an accelerated approval. You're
25 just kind of changing the time line here.

1 DR. CELLA: It seems logically then, assuming
2 that one can produce a reliable indicator of change in an
3 individual and then that can be used to define response,
4 that quality of life response can be taken to be evidence
5 for rapid approval in a phase II setting and even clinical
6 benefit if it was then looked at in the randomized trial.
7 This is a conceivable scenario. It hasn't happened.

8 DR. PAZDUR: In general, what has happened in
9 these situations is taking a look at a response rate, for
10 example, as a predictor for approval. What you're saying
11 in an accelerated approval is that you're approving the
12 drugs on a surrogate endpoint. If you've already
13 demonstrated clinical benefit in your mind, then that leads
14 to full approval of the drug.

15 DR. CELLA: Yes, I'm just thinking. There may
16 be a need for a minimal paradigm shift there in that if
17 this is bought, that a quality of life benefit is
18 meaningful and sufficient for approval, that one could
19 conceive of a situation where you're actually getting phase
20 II data that support rapid approval that actually, by the
21 letter of the law, would also support full approval,
22 although you'd then be approving something on a phase II
23 study. So, there may be a little bit too much
24 unprecedentedness to that, but it seems to me that it's an
25 area that is worth discussing as long as it doesn't get too

1 | philosophical.

2 | What do other people think?

3 | DR. SCHILSKY: I don't think we should get hung
4 | up in this committee on the sort of the letter of the
5 | regulations. That's the FDA's problem. I think what we
6 | should think about is the extent to which we can get
7 | informative data in a phase II trial that would help in the
8 | evaluation of an application.

9 | DR. CELLA: Well, having heard that, let me
10 | suggest three new areas, not new areas, but among what
11 | we've discussed, three areas that we can draw out for the
12 | agenda next meeting. And we don't have to have three. We
13 | could have two because we'll be revisiting these other
14 | three. So, we don't need to pile on ourselves.

15 | Sorry. I think I missed some people that want
16 | to say something. Diane and Jeff.

17 | DR. FAIRCLOUGH: One of the things that I think
18 | would help the committee is if we had a better idea -- we
19 | didn't get any background information on the types of drugs
20 | that are reviewed by this committee. I don't know whether
21 | supportive therapy would be under the review of this
22 | committee or whether it's just limited to drugs that would
23 | have either a tumoristatic or tumor destruction thing. So,
24 | I don't know whether something like the growth factors
25 | would ever be -- and so, I think that would help us focus

1 | when we're trying to answer the questions. I think it
2 | would help us to know a little bit more about the process
3 | and the group of drugs that we're working with.

4 | DR. PAZDUR: I think the next time we could
5 | bring that up because it's quite complicated because some
6 | drugs are handled by CBER, biologicals that could be
7 | considered oncology products as such but not drug products,
8 | supportive care medications. For example, antiemetics
9 | would not be handled by this division. Pain medications
10 | would not.

11 | DR. FAIRCLOUGH: It would help just to have a
12 | short summary of that for us to help define things a little
13 | bit.

14 | DR. CELLA: We were chatting -- I'm sorry --
15 | side-barring a little bit, but I think you were asking for
16 | a summary of the kinds of submissions that have been
17 | received over the recent past, and Rick said that that can
18 | be provided, so something that would be hopefully not the
19 | full transcript of the meetings but a distilled summary of
20 | the meetings. The full transcript is on the web, I'm told.
21 | We can tie it together with this packet that we're going to
22 | send around.

23 | DR. SLOAN: I wonder, for example, you said
24 | that pain meds and antiemetics would not be included.

25 | DR. PAZDUR: It's done by other divisions.

1 DR. SLOAN: What the other divisions have by
2 way of guidelines as well might be helpful to make sure
3 that we're not saying things totally at odds, for example.

4 DR. BEITZ: There is no formal FDA guidance on
5 this issue.

6 DR. CELLA: We're blazing the trail.

7 DR. BEITZ: You're making it up as you go along
8 here.

9 DR. CELLA: We'll see how much this can help
10 their work.

11 DR. PAZDUR: But I think I would not want to
12 lose focus by going in multiple directions here of multiple
13 drugs. I think specifically what we're interested in is
14 oncological drug products, and let's probably say for the
15 sake of it, drugs that are producing either an antitumor
16 activity or a cytostatic activity because I think since we
17 do not handle pain medications, antiemetics, that probably
18 is more of an issue for the agency in toto and this other
19 group that is looking at quality of life. I think if we
20 get diverted in multiple different areas of how to develop
21 pain medications, how to develop --

22 DR. CELLA: I think the interest was just to
23 see what's available to get some ideas and perspective.
24 But if there's nothing available, then that makes it easy,
25 at least on one level.

1 Dr. Justice, did you want to say something?

2 DR. JUSTICE: Yes. I just wanted to go back
3 briefly to the question of blinding of trials, and this is
4 a design issue. The question might be how do you interpret
5 unblinded trials where quality of life is an endpoint.
6 When can you interpret them? We deal with this day in and
7 day out. We're told we can't blind the trials. So, I
8 think we have to come to grips with two scenarios. One
9 would be a double-blind trial and the other would be our
10 typical oncology unblinded trial. What are the different
11 considerations?

12 DR. FAIRCLOUGH: Wouldn't some of those
13 considerations be similar to unblinded evaluation of
14 toxicity, looking for certain symptoms?

15 DR. JUSTICE: Well, I mean, it depends. The
16 typical toxicity is assessed by the physician, but if
17 you're talking about health-related quality of life
18 assessment of toxicity by the patient, sure, I think the
19 same -- things like asthenia or fatigue, as we said before
20 could be disease toxicity.

21 DR. FAIRCLOUGH: Yes. I mean, if the physician
22 doesn't ask, he doesn't know. There's an assessment bias
23 that could be conditional on the physician's knowing the
24 particular drug, and so it's the same issue in some ways.

25 DR. PAZDUR: Correct.

1 DR. CELLA: If I suggested that we next time
2 focus in, not necessarily completely at the exclusion of
3 other items, but focus in on timing of assessment,
4 acceptability or minimum standards of questionnaires, and
5 kind of how to develop a pre-submission package that tells
6 a coherent story, sort of along the lines of what Rich was
7 saying, would those seem like a reasonable three? It sets
8 aside for the moment issues like blinding, reporting and
9 labeling, anything post-marketing, and any other ancillary
10 studies or study design issues that aren't covered by
11 those.

12 Does it seem like a reasonable course to
13 pursue? I don't think we can even imagine adding more than
14 three items, and that may be too much. We may have to trim
15 that because we still have to review the first three.

16 How about only two? Timing and acceptability
17 and the prestudy stuff hopefully can flow right from that
18 along with issues like blinding. Sound good? Okay.

19 Creating a pre-submission story.

20 Yes, Kay.

21 DR. DICKERSIN: When you talk about blinding,
22 it's not quite related but it's kind of related. At lunch
23 some people were mentioning to me, who have been on trials,
24 about the patient being so afraid of being kicked out of a
25 trial, that they don't give the true story about their

1 | quality of life experience or that they make things sound
2 | better than they are. It kind of fits in with validity.
3 | It's not a blinding issue because even if they're on
4 | placebo, they're going to say everything is great.

5 | I don't know where that fits in, but it fits in
6 | somewhere in what you're talking about. And I don't know
7 | how to get at it, but maybe part of assessing quality of
8 | life, if we mean it to be meaningful, we have to reassure
9 | the patient that it will not affect their participation in
10 | the study and that that would need to be part of what we're
11 | talking about too.

12 | DR. CELLA: In measurement terms, you're
13 | referring to a concern about response characteristics,
14 | things that influence the way in --

15 | DR. DICKERSIN: Systematic misclassification
16 | problems.

17 | DR. MOINPOUR: Social desirability and
18 | affecting the response that's related to that.

19 | DR. CELLA: And hope.

20 | DR. SLOAN: I don't know if, along those lines,
21 | you want to talk about providing QOL data as part of the
22 | eligibility. I know that has been an issue that the
23 | cooperative groups have dealt with, and I'm not sure we've
24 | got a final answer yet per se. We've got guidelines. But
25 | that kind of comes around that as well.

1 DR. CELLA: Well, we need to close up now. I
2 want to thank everyone for coming very much. We were all
3 engaged in interesting and active discussion. There's a
4 lot of work to be done. I think we set a good course.
5 You'll be hearing from us in the mail and on the Internet
6 to clarify the summary of this meeting and the agenda for
7 the next meeting very soon. Thanks.

8 (Whereupon, at 3:55 p.m., the subcommittee was
9 adjourned.)

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