1 DR. NERENSTONE: I guess I am confused.
2 Explain to me why we can't use a more generic, yes,
3 this technology looks to be acceptable and have the
4 devices group figure out which technology, from a
5 technologic point of view, is acceptable. Why
6 should we be in the position of branding the test?
7 DR. GUTMAN: Yes, I don't think you should
8 be in the position of branding the test. The
9 individual device, with it is the device on the
10 table today or whether it would be an alternative
11 device, in order to make specific claims is going
12 to be knocking at our door. I was actually going
13 to respond to Tim by saying the truth is that for
14 the device at hand the questions have been laid to
15 rest, analytical questions. This device actually
16 is essentially ready to go and the discussion of
17 this committee in terms of how to label the drug
18 may have some corollary impact on how we want to
19 label the device since we like to maintain
20 consistency across centers when possible. It is
21 not always possible.
22 I suppose you can do anything you want,
23 but it would be awkward to endorse, except in a
24 general sense technology. With home brew they can
25 do whatever they want. They can offer this test

1 for brain cancer if they want. But the truth of
2 the matter is that for a commercial company to
3 market this for this purpose, whether they decide
4 to incorporate themselves into the biological
5 labeling or whether they decide not to, have to
6 come knocking on our door in a separately equal or
7 separate but different manner.
8 DR. NERENSTONE: Dr. Redman?
9 DR. REDMAN: My concern is maybe unfounded
10 but looking into the future is that if you start
11 putting into a product insert, not necessarily
12 advocating specific tests but referring to specific
13 tests, it is going to make it much more difficult
14 for future companies looking at future assays and
15 tests if, in order to get into a product insert
16 which everybody is going to be read and nobody is
17 going to care if the device committee approves us
18 or not --
19 DR. NERENSTONE: I care.
20 DR. REDMAN: I know you care but in the
21 real world it is setting a precedent, and I think
22 it is going to make it much more difficult for
23 somebody who comes up with a better test because
24 they are not going to have access anymore -- I am
25 assuming all the slides have been used. So, even

1 if they show, using some other technique, that it
2 is at least equivalent to IHC or equivalent to
3 FISH, they won't have the clinical outcome data
4 and, therefore, they won't be included in the
5 product label and, therefore, why should we go
6 after it because if it is not in the product label
7 nobody is going to use us.
8 DR. KEEGAN: I think the only response I
9 can really make is if we have data that is derived
10 from a particular set of studies and sources using
11 a particular device, I think it would be
12 appropriate to identify that device in the label.
13 I don't think we have the kind of information that
14 Dr. O'Leary sort of alluded to, that if you have
15 data from 15 different devices and it all pretty
16 much showed the same thing you could amalgamate the
17 information somehow and not list every single
18 device. In fact, we have data from one FISH
19 manufacturer that has provided us information. We
20 have heard that FISH assays even come in direct and
21 indirect forms. So, I think it would be an extreme
22 leap of faith to go from this single FISH assay
23 with this relatively preliminary concordance
24 information to making a broad and sweeping
25 statement about technology in the absence of any

1 data. The types of data that would be necessary to
2 get additional labeling, I think that is what the
3 purpose of this morning's discussion was about, how
4 the companies begin to approach this, and it is
5 difficult but I think at this point it would not be
6 prudent to make a sweeping technology statement
7 that all assays are created equal, nor to fail to
8 identify where the source of the data was.
9 DR. REDMAN: So, if the FDA, through the
10 device mechanism, approves a new test will it be
11 automatically enrolled into the package insert of
12 the drug?
13 DR. GUTMAN: This is a peculiar link
14 because we do this all the time. We are approving
15 new products to be used in support of drugs all the
16 time. Generally, when we approve a new product to
17 be used to support anything -- use of a drug,
18 changing doses of a drug -- what is unusual about
19 this is that it usually actually doesn't feed back
20 into the product labeling. Usually we approve
21 products with new claims to support changes in drug
22 or biologic use but it doesn't come knocking at
23 this committee's door, and I think it may be the
24 unusual way in which the diagnostic and the
25 therapeutic have been linked in this case that has

1 made this unusual bridge. Maybe it will be
2 occurring more frequently in the future. We
3 certainly work very interactively and closely with
4 CBER both in the original device and in this
5 device.
6 It would seem to me that although we may
7 be running out of samples on this clinical trial
8 set, you certainly don't preclude additional
9 sponsors who are clever from finding design methods
10 to try and bridge themselves -- you know, this
11 product in our house is a PMA so it is free-
12 standing and you can't necessarily link to it but,
13 in fact, you can build bridges. It might be
14 inconvenient. You might have lots of trips to
15 Washington if we continue to add products one by
16 one and we might at some point decide that it is or
17 is not worthwhile doing. But putting the truth,
18 which is the data set on which this rests, and
19 linking it to that company doesn't bother me at all
20 and certainly doesn't preclude future companies --
21 I mean, this is a free marketplace and other
22 companies may decide -- they may have trouble
23 finding samples but they won't have trouble finding
24 ideas.
25 DR. NERENSTONE: Dr. Lippman?

1 DR. LIPPMAN: I think if a trial was
2 designed as a pivotal trial with a certain assay --
3 I mean, this is linked to a pivotal trial like the
4 CTA here, then I think that ought to be featured
5 fairly prominently. Right now, based on what was
6 presented, it was a very nice study; there is a
7 template now to do this. It is retrospective. You
8 could have 14 FISH companies now go up and show
9 this, and I think if we do put it in the package we
10 need to be consistent about putting all these in.
11 In other words, this is a retrospective study. It
12 wasn't part of the trial. They went back and they
13 looked at survival, and I think they did a great
14 job, but this kind of thing could be done with a
15 lot of different assays now, and I think if we set
16 a precedent that that trade goes in the package
17 insert we need to be consistent, and maybe even go
18 back to all the package inserts where that has
19 happened in the past and put the trade in it.
20 DR. GUTMAN: You have to realize, and
21 maybe I am confused, but, although you may not
22 realize it, there are actually two package inserts
23 at this table. There is the package insert
24 relating to drug labeling, which is the issue on
25 the table today. Whether this committee met or

1 didn't meet, there is the issue of the device's
2 labeling. This device has actually already been
3 approved and is already commercially available with
4 labeling and we are negotiating possible changes in
5 that label based on information that has been
6 shared with you today.
7 It is possible to add all kinds of devices
8 to the market without ever returning to this
9 committee, frankly, with claims to be used to
10 support the use of this biologic.
11 DR. LIPPMAN: I understand, but if we are
12 talking about the drug label, we are talking about
13 putting this on the Herceptin drug label, that is
14 what people will read, if anything. I don't know
15 how many people will read the other label. So, if
16 we are going to feature it in the drug label, we
17 need to be consistent I think, particularly because
18 this is going back and doing the best you can, and
19 I think they did a great job, but going back
20 retrospectively now with what has been done, and
21 these kinds of differences could be done with a lot
22 of other assays.
23 DR. NERENSTONE: And, to top it off, there
24 is a 32 percent discordance rate. So, this is not
25 a home run linkage. Dr. O'Leary?

1 DR. O'LEARY: I think the basic message is
2 one that I am sure the lawyers would send through
3 anyway, which is not to do anything in the drug
4 package insert that would create an undue
5 commercial advantage by featuring some folks who
6 were approved for this indication and not featuring
7 other folks who were approved for this indication,
8 and just making sure that we keep everything
9 coordinated and up to date, as I am sure you are
10 planning to do.
11 DR. NERENSTONE: Dr. Gutman?
12 DR. GUTMAN: Yes, I want to clarify this.
13 I do realize this is potentially interesting and
14 precedent setting, and that there is a potential to
15 keep adding and adding to this labeling and making
16 it longer and longer. I guess as new assays come
17 in we will have to grapple with that. Once you
18 have established a course of action, you have done
19 studies and you have publicly aired them, it makes
20 it easier for the agency to do that on its own
21 without input. So, one of the issues to be weighed
22 in this whole thing is what is the benefit -- I
23 mean, I presume we brought this here because we
24 actually think there is some benefit to having this
25 information appearing in the drug labeling that is

1 special because of the nature of the product. So,
2 if you disagree with that maybe you want to torpedo
3 the whole idea of making the link with the drug
4 labeling, although we have already set the
5 precedent by putting the other drug in, and we
6 thought we were doing public health good by doing
7 that.
8 DR. NERENSTONE: Dr. Watson?
9 DR. WATSON: It is actually an interesting
10 problem to have to sort out. I think you have to
11 acknowledge those that came in for the trial.
12 However, those things that discriminate this FISH
13 assay from others that are in existence there is no
14 data really to support, which is indirect versus
15 direct and the availability of this chromosome 17
16 tag for which there was no data -- sort of
17 standardizing around that within the cell,
18 contributed anything. But they did come in first
19 with the proposal, and it is the data. It may
20 contribute. We don't know that, which is why you
21 get hooked into dealing with that which is before
22 you.
23 DR. NERENSTONE: Why don't we have the
24 vote, which is what you need?
25 DR. KEEGAN: Yes.

1 DR. NERENSTONE: The question, to
2 paraphrase this, is whether we think -- actually,
3 Dr. Keegan, would you like to pose the specific
4 question you want answered?
5 DR. KEEGAN: Should the PathVysion assay
6 be identified in the labeling as one method which
7 would be useful in the selection of patients for
8 Herceptin therapy?
9 DR. KELSEN: One method?
10 DR. KEEGAN: Because we already have
11 HercepTest, so a method which is useful for the
12 selection of patients for whom Herceptin therapy is
13 intended? Be evaluated for Herceptin therapy,
14 something like that.
15 DR. NERENSTONE: Oh, no, you can't change
16 it.
17 [Laughter]
18 DR. KELSEN: As opposed to the more
19 generic FISH?
20 DR. KEEGAN: No, as opposed to not being
21 in the label at all.
22 DR. KELSEN: I understand that, but
23 opposed to asking your question, should the FISH
24 assay be in the label? Just to clarify for myself
25 that what FDA is asking is not just the type of

1 test but a specific FISH.

2 DR. KEEGAN: Yes.

3 DR. REDMAN: Right now it just says HER2

4 protein overexpression. So, are you then going to

5 include something about the genetic DNA level and

6 then say, gee, this assay, the PathVysion one that

7 has been used to do that?

8 DR. KEEGAN: It is likely that we will

9 need to include something in there that talks about

10 what the PathVysion assay measures, and then

11 discuss the data that show that it is likely to be

12 a surrogate for HER2 protein overexpression which

13 is, in fact, what Herceptin is indicated for,

14 tumors that overexpress to HER2 protein. So, we

15 view the concordance study as establishing a good

16 correlation between the amplification and protein

17 overexpression.

18 DR. NERENSTONE: Dr. Templeton-Somers,

19 would you please read the actual question?

20 DR. TEMPLETON-SOMERS: My first shot at

21 it, should the PathVysion assay be identified in

22 labeling -- I assume we mean of Herceptin --

23 DR. KEEGAN: Yes.

24 DR. TEMPLETON-SOMERS: -- of Herceptin as

25 one method useful for the selection of patients for

1 whom Herceptin would be beneficial?

2 DR. NERENSTONE: Discussion? Dr. Griffin?

3 DR. GRIFFIN: I would hope that we would

4 somehow put a cautionary statement in there that

5 reliance on a single method may not be adequate. I

6 worry about putting something like that in and it

7 being implied that using one or the other would be

8 okay. It seems to me that the data doesn't allow

9 you to make a final decision on that.

10 DR. NERENSTONE: Dr. Lippman?

11 DR. LIPPMAN: Since this is retrospective,

12 albeit a good retrospective study and not part of

13 the primary, why can't we put something to the

14 effect that recently FISH, which correlates so-and-

15 so with this, has been shown to be an important

16 predictor in retrospective analyses, parentheses,

17 see devices package insert?

18 [Laughter]

19 DR. NERENSTONE: Dr. Brawley?

20 DR. BRAWLEY: I am still struck by that

21 thing on page 14 of Dr. Jerian's comments where 10

22 percent, more than 10 percent actually -- 43 out of

23 349 3+ tumors were judged to be FISH negative, and

24 I am concerned that if people just use FISH, 10

25 percent of people who would benefit from Herceptin

1 would not get Herceptin. Dr. O'Leary, perhaps you
2 can explain to me for a third time what you are
3 talking about when it comes up to the various
4 assays.
5 DR. O'LEARY: Well, the problem is we are
6 comparing with the clinical trials assay, which
7 isn't what is out there. What is out there is the
8 HercepTest test, and there are also a significant
9 number of patients -- I don't remember the data
10 precisely but I remember that there were patients
11 who were 3+ on the clinical trials assay who were
12 not 3+ on the HercepTest as well. I don't recall
13 the tables well enough to know is this one better,
14 is that one better, but the fact is that in both
15 cases we are doing a surrogate, which is why this
16 morning's discussion was so important. It is much
17 better to be using the real test at the time of the
18 clinical trials so we don't have to discuss this
19 question.
20 DR. BRAWLEY: Can I just ask one more
21 question? With what you know, would it make sense
22 to do the HercepTest and if the person is
23 HercepTest positive, treat them; if they are
24 HercepTest negative, then do FISH, or vice versa?
25 DR. O'LEARY: I don't believe data has

1 been presented which allows one to answer that
2 question. I think it is professional judgment at
3 this point.
4 DR. NERENSTONE: Ms. Mayer?
5 MS. MAYER: Speaking of professional
6 judgment, I think it is crucial that if information
7 about this particular FISH test or any FISH test is
8 included, that makes insurance coverage at least a
9 possibility so that the oncologist is not
10 necessarily swayed by the fact that insurance will
11 only pay for one test and not the other. I think
12 in the clinic that is really going to make a
13 difference.
14 DR. NERENSTONE: Karen, for the record, do
15 you want to read it once more? Then we have to go
16 around the room and record the votes.
17 DR. TEMPLETON-SOMERS: One more try,
18 should the PathVysion assay be identified in the
19 labeling of Herceptin as one method useful for the
20 selection of patients for whom Herceptin would be
21 beneficial?
22 DR. NERENSTONE: We will start with Dr.
23 O'Leary.
24 DR. O'LEARY: Aye.
25 DR. WATSON: Yes.

1 DR. BARKER: Does approval constitute an
2 endorsement of this particular product?
3 DR. KEEGAN: Not in this labeling, it
4 doesn't.
5 DR. BARKER: NIST usually has to put in a
6 disclaimer saying that these are the data for this
7 particular system but NIST does not necessarily
8 endorse this particular --
9 DR. KEEGAN: Oh, it wouldn't carry
10 anything about NIST endorsement.
11 DR. BARKER: I am just trying to decide
12 whether I am allowed to vote here, that is all.
13 DR. KEEGAN: Oh, I see. No. No, it
14 wouldn't cover any statements by your agency by
15 endorsing it.
16 DR. BARKER: Okay, if I can vote, then I
17 would approve it.
18 DR. CARPENTER: Yes.
19 MS. MAYER: Yes.
20 DR. ALBAIN: Yes.
21 DR. GEORGE: Yes.
22 DR. KELSEN: Yes.
23 DR. NERENSTONE: Yes.
24 DR. BRAWLEY: Yes.
25 DR. LIPPMAN: Yes.

1 DR. BLAYNEY: Yes.

2 DR. TAYLOR: Yes.

3 DR. REDMAN: Yes.

4 DR. GRIFFIN: Yes.

5 DR. TEMPLETON-SOMERS: Sixteen yes, zero

6 no.

7 DR. NERENSTONE: Pat, you have heard all

8 of our discussion. Can we go to the second

9 question?

10 DR. KEEGAN: Sure.

11 DR. NERENSTONE: Because oncologists will

12 generally not have access to the package inserts

13 for HercepTest and PathVysion, FDA feels it would

14 be prudent to provide information regarding these

15 assay in the package insert for trastuzumab.

16 Please discuss which types of the following types

17 of information should be included in the PI for

18 trastuzumab:

19 Cautions regarding use and interpretation

20 of these assays and inter-laboratory variability;

21 information on assay validation; information on

22 assay clinical performance characteristics;

23 information on tissue handling, for instance

24 formalin fixed or frozen.

25 Have you gotten enough information from

1 us?

2 DR. KEEGAN: I think we have, yes.

3 DR. NERENSTONE: Patients whose tumors

4 test as IHC positive and FISH negative require

5 further study. I think we all agree with that.

6 Which patient subgroups should be studied,

7 IHC 2+, FISH positive; IHC 2+, FISH negative; IHC

8 0-1+, FISH positive? Does anyone want to comment?

9 I would say in the best of all possible worlds, all

10 of the above.

11 DR. KELSEN: Yes.

12 DR. NERENSTONE: Dr. Lippman?

13 DR. LIPPMAN: I think once Dr. O'Leary and

14 his colleagues work out the standardization issues

15 of all the labs doing IHC, then I think we should

16 do all of them and re-ask this question.

17 DR. KELSEN: I would make one comment, it

18 seems to me, as a person who doesn't deal

19 specifically with breast cancer a lot, that the

20 most pressing issue you all face is the 2+, FISH

21 negative because it sounds to me, and this is just

22 my own opinion obviously, that if it is either FISH

23 positive or 3+ immunohistochemistry that is as

24 straightforward as you are going to be currently.

25 So, what you grapple with is when you see this

1 weakly positive study and it is FISH negative and
2 do you treat them or you don't considering the
3 toxicity?
4 DR. NERENSTONE: Dr. Albain?
5 DR. ALBAIN: Yes, I think we would have a
6 hard time randomizing to any trial that is FISH
7 positive regarding Herceptin, yes or no, given the
8 current data. The only group that we face in our
9 daily practice is this 2+ group and what to do with
10 them. If a study could be done -- I am still
11 wondering if it even could be done prospectively,
12 but that would be the one.
13 DR. KEEGAN: So, it would be 2+ any FISH?
14 DR. KELSEN: Well, 2+ positive and FISH
15 negative is what I am hearing would be the issue
16 that clinicians would be most perturbed about.
17 DR. ALBAIN: You have strong survival data
18 for any FISH positive here from what we have seen
19 today, which is quite compelling, for the use of
20 Herceptin, no matter what the IHC level is. I
21 think what we have seen this afternoon is some very
22 small subsets and we got play of other prognostic
23 factors in those small subsets to explain some of
24 this strange noise that came out. But this group
25 of 2+, FISH negative is the one that we still

1 wonder about and, although we haven't seen any
2 benefit in anything you showed this afternoon, in
3 the absence of a prospective trial many would not
4 treat based on what you have shown.
5 DR. NERENSTONE: But I do think that if,
6 in fact, it looks like Herceptin is going to be
7 successful in the adjuvant setting, I think further
8 subgroup analysis has got to be done because we
9 have a paucity of information of all the subgroups,
10 including the 0, 1+, FISH positive subgroup. We
11 saw this with the taxol added to AC. The whole
12 thing was positive, but it looks like it is only
13 the ERPR negative subgroup. We were able to do
14 that because there were such big numbers that we
15 really could, with some confidence at a certain
16 point, suggest that maybe there is a difference.
17 So, I think when you start using things in the
18 adjuvant setting the more information that you can
19 get is going to be very important in terms of
20 public health implications for whom you are
21 treating.
22 DR. ALBAIN: Excuse me, I just don't think
23 the clinical trials breast cancer groups can do a
24 study randomizing, yea or nay, to Herceptin in FISH
25 positive patients. As much as you would like to

1 see that to inform adjuvant trials, I don't think
2 that that can happen.
3 DR. KELSEN: But you could answer this
4 more simply I think. If you treated a cohort of
5 women who were IHC 2+ positive, FISH negative with
6 Herceptin, which would be a standard of care and so
7 your package insert would allow you to do that, and
8 you looked for response and you really saw 0 out of
9 46, prospectively, carefully controlled, FISH
10 negative, IHC 2+ positive --
11 DR. ALBAIN: That has been done.
12 DR. KELSEN: -- that would really settle
13 it. It would settle it for me if you could do the
14 trial. I am not sure you could do the trial.
15 DR. NERENSTONE: Dr. George?
16 DR. GEORGE: Just a comment about 3(b),
17 are we onto that yet?
18 DR. NERENSTONE: No, we are on (a). I am
19 willing to go to 3(b). They are linked.
20 DR. GEORGE: They are related. What
21 clinical trial design, single arm versus randomized
22 -- well, either one could work. I think the
23 problem with the randomized one, if you are talking
24 about randomization between something containing
25 Herceptin or not would be unethical and, in fact,

1 that wouldn't work. I mean, theoretically it would
2 work but in practice it wouldn't be considered
3 ethical by most people. So, the single arm one
4 could be done and the good part about it is that
5 you control all the things you usually do in a
6 clinical trial, and your definition then would be
7 positivity based on something. Then you could have
8 a mixture of some that were different levels and
9 scores that might be negative and in that way you
10 could sort it out. So, you would have to have the
11 eligibility broad enough so you could have a lot of
12 those patients. It could work.
13 DR. NERENSTONE: Dr. Lippman?
14 DR. LIPPMAN: Since you raised this issue
15 and CTA is not on trial here but Kathy has really
16 been focusing on this 2+, and with all that I have
17 heard about the variability assay and that these
18 are retrospective, number one, I don't think we
19 should even touch the issue of any recommendation
20 in the labeling separating out that 2+ group. The
21 study that was positive included 2+ and 3+. We
22 talk about this all the time. The subgroups that
23 we pull out of those are provocative but not to the
24 point where we can make clinical recommendations.
25 So, I think that you could do a randomized study

1 where you look at IHC or FISH. So, you are not
2 saying that you are randomizing to FISH negative or
3 taking FISH positive and not randomizing, but
4 taking patients that the eligibility is either IHC
5 positive as part of the standard study to determine
6 activity, or FISH positive.
7 DR. ALBAIN: And randomize to what?
8 DR. LIPPMAN: I don't know but I think you
9 could look at studies like were done here in terms
10 of some of the arms that were looked at. The
11 adjuvant study that is being done now, Kathy, the
12 one where they are taking either IHC or FISH --
13 DR. ALBAIN: But the randomized trials are
14 being selected for positive patients. So, it is a
15 totally different question. The question I am
16 raising is in the metastatic setting when you have
17 a 2+, that is the problematic area, and is there
18 anything that can be done prospectively to help
19 sort out that dilemma that you see every day?
20 DR. LIPPMAN: But getting to Stacy's
21 point, I think you could look at all ranges of FISH
22 and IHC if you had eligibility criteria being
23 either IHC 2 or 3+ or FISH positive and actually
24 did assays on both, you would get a range.
25 DR. ALBAIN: But in a metastatic trial, if

1 you are going to randomize and you have a FISH
2 positive patient you have to give them Herceptin
3 based on the survival data that is so compelling.
4 DR. NERENSTONE: Dr. George?
5 DR. GEORGE: I think that is some of the
6 confusion. The randomization is presumably
7 designed not to answer directly the question about
8 the FISH but it is looking at treatment effects.
9 So, it would be very difficult to randomize
10 patients to something containing Herceptin or not
11 in those patients. I would think that would be
12 impossible. But a single arm study involving
13 Herceptin would get you good answers about a cohort
14 of patients all treated in a certain way, all the
15 control measurements done and all those kinds of
16 things that are usually done in clinical trials,
17 and prospective, it would enable you to sort out
18 these groups. Do these groups do differently given
19 this common therapy on this trial? That would be a
20 very interesting study.
21 DR. ALBAIN: It would have to be very
22 large to control for multiple prognostic factors
23 that also operate and we still aren't sure how they
24 interact with this result.
25 DR. NERENSTONE: I am going to go to the

1 fourth question because I am not sure we are going
2 to come up with any definitive answers. I don't
3 know that there are any today.
4 Given the variability in performance of
5 these assay, both IHC and FISH, what data and
6 assurances do oncologists need from the pathology
7 laboratory regarding the validity of the assay
8 results?
9 I am going to tie in the second, should
10 the sponsor be required to make a postmarketing
11 commitment to provide more balanced information and
12 training to the oncology community on HER2
13 diagnostics? Dr. O'Leary, can I as you for a
14 comment?
15 DR. O'LEARY: It seems to me that the
16 answer to 4(a) may drop into two parts. It would
17 be awfully nice if you were an oncologist to know
18 that you are getting an assay that is one of the
19 assays which has been approved by FDA for this
20 indication for use. Certainly, that is a minimum
21 standard. If you are not, then it is incumbent
22 upon the laboratory to provide information that
23 demonstrates that this assay is valid for the use
24 for which you are putting it, that is to say, for
25 selecting patients for therapy as opposed to some

1 other adjunct use. That is just within the CLIA
2 requirements. That is a legal requirement now.
3 There is nothing new there, although I suspect that
4 requirement is not, in fact, being met.
5 Beyond that, if you have a laboratory that
6 is getting 50 percent 3+, then there is probably
7 something wrong there. But at a minimum, know
8 which assay you are getting so that you can go back
9 to the data that is there, given all its flaws, and
10 understand it.
11 DR. NERENSTONE: Other comments? Dr.
12 Kelsen?
13 DR. KELSEN: This is very difficult to do,
14 but it seems to me this is a real opportunity to
15 educate oncologists -- I don't know how many of us
16 aware of the tremendous variability in these
17 assays, but to educate them to ask the question.
18 But from the other side, from the people we heard
19 from this morning -- I am not sure how you do this,
20 is to begin to control, convince, require that when
21 home brew is done that you clearly label that it is
22 home brew. I don't know how much feedback you
23 would get from a laboratory that is doing a couple
24 of hundred of these a year, and move to a uniform
25 standard. That might be one of the most important

1 things to come out of this.

2 DR. GUTMAN: Actually, the ASR rule, as it

3 is now written, requires that there be specific a

4 statement that FDA has reviewed that device and

5 that the test result has been established and is a

6 responsibility of the testing entity that is

7 offering it. So, that currently exists. I think

8 Tim's point is that the enforcement of some of

9 these in the real world may be somewhat less than

10 perfect.

11 DR. KELSEN: I know the requirement

12 exists. I understand that quite clearly, but it

13 seems to me that it doesn't happen. All that does

14 to me is say that there is a little bit of a

15 warning. Now I think it is a substantial warning

16 for this particular indication at least.

17 DR. NERENSTONE: Dr. O'Leary?

18 DR. O'LEARY: Right, and I think that is

19 what becomes very, very important. If the word can

20 get out in the oncology community that there are a

21 number of legitimate uses for HER2/neu testing and

22 that an assay that tests for HER2/neu may be

23 perfectly okay for its use as an adjunctive

24 technique in diagnostic surgical pathology and not

25 be at all acceptable for selection of patients for

1 therapy, I think this is a very important message.
2 I have very little doubt that the manufacturer will
3 be happy to assist getting that message out to the
4 oncologists because there is commercial advantage
5 to them in doing so.
6 DR. KELSEN: Kathy, has there been a
7 session in ASCO in the last few years about this
8 sort of thing?
9 DR. ALBAIN: I think this data is just
10 coming out. The NSABP data was presented to the
11 intergroup a few months ago and we today, for the
12 first time, saw the intergroup trial data. I was
13 going to say that some of this that we heard this
14 morning, that is what is important to get in there.
15 There is this lack of confirmation with a lot of
16 these assays, and I don't know how you would word
17 it or how you would do it, but I think the
18 practicing oncologist isn't aware of this and it is
19 very important, especially for the breast cancer
20 survivors because that is what I am worried about,
21 that the wrong treatment in either direction is
22 being offered quite commonly in practice.
23 DR. NERENSTONE: Maybe that really is an
24 issue for ASCO to take up. Dr. Lippman?
25 DR. LIPPMAN: I had the impression that

1 you felt that the feeling in the community is that
2 FISH will dissect out this muddy group of CTA 2+.
3 So, do you feel like some comment needs to made in
4 the package insert about the fact that we don't
5 have evidence to clearly show that it does since we
6 are going to put it in the package insert?
7 DR. KEEGAN: I am a bit concerned about
8 that perception in the community and probably what
9 would state it best and most clearly is the data
10 that don't show that it does have discriminating
11 ability in any IHC 2+ individual to show that they
12 are going to do better or worse because they were
13 FISH positive or FISH negative. That is not to say
14 that it may not have that capability, but the study
15 has not been done and the data aren't here.
16 DR. ALBAIN: But then you have to state
17 the data is not there at all for IHC 2+.
18 DR. KEEGAN: It is in the label.
19 DR. ALBAIN: It is there for the time to
20 progression endpoint but it needs to be there for
21 the survival endpoint also then.
22 DR. KEEGAN: It is coming.
23 DR. NERENSTONE: Dr. O'Leary?
24 DR. O'LEARY: There is one thing I forgot.
25 The one other thing you could push on the community

1 to do is to find out whether your laboratory is
2 enrolled in a proficiency testing program, whether
3 it be for overexpression or amplification and, if
4 so, how well that laboratory is doing. Those are
5 reasonable things for an oncologist to know and
6 that will help drive laboratory performance very,
7 very quickly.
8 DR. NERENSTONE: I think we are done. I
9 want to remind the committee that tomorrow morning
10 we reconvene at eight o'clock sharp because we have
11 a full day, a full agenda. Thank you.
12 [Whereupon, at 5:57 p.m., the proceedings
13 were recessed, to reconvene on Thursday, December
14 6, 2001, at 8:00 a.m.]

CERTIFICATE

I, **PAMELA BRIGGLE,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

PAMELA BRIGGLE

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