

1 We are now going to proceed --

2 DR. KENT: Madam Chairman, if I could just add
3 one other thing? Kenneth Kent.

4 CHAIRPERSON DUTCHER: Okay.

5 DR. KENT: Relative to the measurements,
6 the whole science of saliva is something which has
7 been blossoming within the last 10 years and there
8 have been major changes in the quantification of the
9 salivary measurements. There currently are no hard
10 and fast gold standards. The best gold standards that
11 exist state that any patient that receives radiation
12 therapy to the salivary glands in excess of 45 Gray
13 will have extremely deleterious morbidity. The major
14 measure is a quality of life issue for these patients.
15 Quality of life issue measures are very difficult for
16 patients because they can only compare themselves to
17 their existing experience. Dr. Lo Presti presents a
18 very valid example. He perceived that he was very
19 dry. His perception. However, when he compared
20 himself to his peer group of patients who received
21 radiotherapy without the benefit of medication, he
22 realized that his morbidity was not nearly as great as

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1 anyone else. It is standard that when a patient sits
2 for an interview, they are constantly sipping water.
3 It is very unusual that a patient can get up and give
4 a 20-minute dissertation after receiving high dose
5 radiotherapy to the salivary glands without having to
6 take a single drink. I think this testifies very
7 strongly to the quality of life change that can occur
8 with this medication.

9 CHAIRPERSON DUTCHER: Thank you. Thank
10 you very much. Okay. Does anybody need anything else
11 further clarified? I would like to just go with the
12 discussion and then if there are issues that need
13 clarification, we will clarify them. Because it
14 sounds like some of us are confused and we don't want
15 to be confused. Any comments or questions? I will
16 proceed. Ready?

17 Okay. This application seeks approval for
18 ethylol to reduce the incidence of severe radiation-
19 induced xerostomia, severe being defined as greater
20 than or equal to RTOG Grade 2 acute and late
21 xerostomia. Efficacy data come from a single multi-
22 center randomized Phase III trial in patients with

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1 head and neck cancer. It compares ethyol plus standard
2 fractionated radiotherapy with radiotherapy alone in
3 303 patients. The patient characteristics were
4 generally well-balanced on the study arms.

5 The primary efficacy endpoints were acute
6 and late xerostomia, Grade 2 or higher, and acute
7 mucositis Grade 3. There was no difference between
8 the study arms and the incidence of acute Grade 3
9 mucositis. However, acute and late xerostomia, Grade
10 2 or higher, were significantly more common on the
11 radiotherapy alone arm. And there you have the tables
12 showing acute and late xerostomia.

13 Although patients on the RT plus ethyol
14 arm received a higher median dose of radiation therapy
15 than patients on the RT arm, a higher proportion of
16 patients randomized to the RT arm received higher
17 total doses of radiation greater than 6500 Centigray.
18 When patients were grouped according to radiation dose
19 received, an advantage for ethyol was apparent in each
20 group. And there is a table showing incidence of late
21 xerostomia by dose.

22 Does the trial provide substantial

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1 evidence that ethyl decreases the incidence of
2 moderate to severe xerostomia in patients undergoing
3 radiation treatment for head and neck cancer?

4 Dr. Simon?

5 DR. SIMON: I just want to make a general
6 comment. I guess not just specific to this question,
7 but I have a lot of concern about -- I think the whole
8 analysis is data-driven because the sponsor decided to
9 present this at a time prior to the stated time of
10 definitive analysis in the protocol, presumably
11 because of what they believed the study showed, even
12 though it was at a time when according to the curves
13 we see, there are lots of patients who are censored at
14 around 15 months. And I don't believe that that is
15 the way to analyze clinical trials. I don't believe
16 it leads to reliable analysis.

17 DR. WILLIAMS: Rich, I would like to make
18 a comment. That may be true for tumor data, but I
19 believe for efficacy, when the primary endpoint -- all
20 the data is collected by one year, that these data
21 wouldn't have changed.

22 DR. SIMON: We are seeing 18-month data

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1 here.

2 DR. HARWOOD: As a radiation oncologist,
3 I absolutely agree with that. You see xerostomia
4 develop in less than six months and then starts
5 improving after that. So in terms of this drug's
6 ability to protect the salivary glands from the effect
7 of radiation, you will see this at 6 months, 12
8 months, and probably see even more improvement as the
9 time goes out. So I think in terms of this drug
10 having an effect, and it certainly seems to me that it
11 is having a beneficial effect on xerostomia and acute
12 mucositis, then I think we will have seen it by the
13 time that these patients have been followed. As I
14 have indicated earlier, I think there is somewhat of
15 a concern about tumor protection, but I think that
16 that is less of a concern in the patients that are
17 receiving post-operative radiation, as has been
18 demonstrated from the data from the RTOG. But I have
19 residual concerns about tumor protection in definitive
20 radiotherapy patients. But I really do think that the
21 evidence that has been presented -- and anybody who
22 has ever done quality of life studies in head and neck

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1 cancer know how difficult it is. I started doing this
2 20 years ago, and I had difficulty demonstrating
3 differences in quality of life between patients who
4 had had their larynxes preserved by radiation and
5 those that had had laryngectomies, believe it or not.
6 So quality of life studies are very hard.

7 One might suggest that we should initiate
8 the bagel test. Because I agree with the patient
9 advocate that this is one of the most significant
10 effects of radiation in the inability to eat dry
11 bread. This has been amply demonstrated that
12 amifostine in his particular case has improved his
13 quality of life. So forgive me for being a simple man,
14 but I would have understood it better if they had
15 asked the patients randomized into the trial, can you
16 eat a bagel or a piece of toast in the morning or can
17 you not? And I kind of suspect the evidence would
18 have been strongly in favor of amifostine.

19 DR. WILLIAMS: I'd like to go back to
20 Rich's question, which I believe if we are addressing
21 question number one, as the protocol defined it and as
22 we analyzed it, it was the months 9 through 12 data

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1 that we used to determine late xerostomia, and that
2 was the primary endpoint in the protocol. So for the
3 purposes of that endpoint, additional follow-up would
4 not be helpful.

5 However, I believe there was an amendment
6 to the protocol changing analysis to later and the
7 purpose of that was to collect more tumor data. But
8 for the purposes of question one, I don't know that
9 that applies.

10 DR. HARWOOD: I completely agree. You have
11 to look at all the data together. There is a lot of
12 data been produced on this, including the information.
13 The reason that the salivary gland was chosen was that
14 that was protected the most, I think, in the original
15 U.S. Department of Defense data from 25 years ago, and
16 I am sure that is what has led to this trial being
17 done.

18 DR MARGOLIN: I realize we are not
19 supposed to talk about the package insert before we
20 vote, but I think it is important because the question
21 has been raised by the FDA and by Dr. Harwood and some
22 of us are also concerned about the inability or the

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1 underpowered state of the current data to really
2 reassure us that tumor protection is not being
3 afforded. And if this gets out, obviously with all of
4 the other kinds of things that are being done in head
5 and neck cancer, and the use of platinum which is a
6 drug for which this protector is already approved, one
7 can just imagine all the other situations that it will
8 be used for very different than the patients that were
9 in this study. So the question is whether that
10 package insert will say something specific about
11 postoperative resected head and neck patients
12 undergoing radiation alone, for example, as opposed to
13 chemoradiotherapy or as opposed to patients with
14 primary definitive therapy being given for an
15 unresectable tumor.

16 DR. HARWOOD: I was actually -- I actually
17 prepared a few comments and you have kind of hit the
18 nail on the head. I think that this -- it is my
19 opinion that the drug is protecting salivary function.
20 It is also my opinion that there is enough data in the
21 trial to support its use in patients who are receiving
22 postoperative radiation. I personally would be

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1 hesitant to recommend it at this point in time in
2 definitive radiotherapy patients because I don't think
3 that we have enough patients entered into the trial to
4 permit us to be absolutely confident that there is no
5 tumor protection, even though I think it is very
6 unlikely to be the case.

7 One interesting piece of information is
8 that this drug has been approved in renal protection
9 and ovarian cancer for cisplatin, and there is five-
10 year data on that to suggest that there is no tumor
11 protection. Interestingly in head and neck cancer,
12 increasingly cisplatin plus or minus 5FU is used as a
13 predictor of radiation responsiveness, in that in the
14 VA laryngeal cancer study patients who are given up-
15 front chemo, primarily cisplatin, and if they
16 responded they went on to radiation and had laryngeal
17 preservation, and if they didn't, they went on to
18 surgery. So I regard the ovarian cancer study as very
19 significant in that we have five-year data to support
20 the fact that amifostine is not protecting and
21 producing a lower responsiveness in the ovarian cancer
22 patients. But I personally would be hesitant to

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1 recommend it right now until more data is accumulated
2 in the definitive radiotherapy patients.

3 This drug, I think, also becomes more
4 important because more and more patients are now
5 receiving hyperfractionated radiotherapy and
6 chemotherapy and radiation, which all of us know
7 produces significantly increased mucosal toxicity.
8 There has been some discussion here about toxicity of
9 amifostine, but the toxicity and morbidity of
10 amifostine is vastly less than what one sees in
11 patients getting simultaneous chemo and radiation for
12 head and neck cancer.

13 I remember an early study in chemo and
14 radiation in head and neck cancer, and one would start
15 off with 150 patients and due to the lifestyle of
16 these patients, of which we are all aware, only 25
17 completed the study. So I find it absolutely
18 extraordinary that in fact the sponsor has in fact
19 been able to get as many patients through this study
20 as in fact they have.

21 So I also would think that it probably
22 could be approved in the chemoradiation advanced head

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1 and neck patients, because those patients get profound
2 mucositis. And in the two supporting studies, I think
3 they showed a significant reduction in mucositis in
4 them. So I really am personally in favor of some kind
5 of limited approval, but not blanket approval such as
6 they gave in the United Kingdom.

7 DR. WILLIAMS: It is quite possible to go
8 ahead and answer this question number one just for the
9 efficacy and then have some other answers for others
10 such as tumor control.

11 CHAIRPERSON DUTCHER: I think we have to
12 remember that the question is asking only about
13 xerostomia. Only about salivary production, not about
14 mucositis. So does this trial provide substantial
15 evidence that ethyl decreases the incidence of
16 moderate to severe xerostomia in patients undergoing
17 radiation treatment for head and neck cancer, and I
18 guess through endpoints months 9 through 12. All
19 those who would vote yes? 11 yes. Voting no? Okay,
20 one no. Carolyn Beaman voted no. So two no. Okay.

21 The next issue is salivary measurements.
22 Clinically meaningful levels of saliva production in

1 time categories for saliva collection analysis were
2 defined retrospectively. In the analysis of
3 unstimulated saliva collection, the applicant used
4 greater than .1 gram of saliva as the cutoff for
5 adequate function. They used the time window of one
6 year's follow-up defined as 6 to 15 months after
7 treatment, and noted a significant difference in favor
8 of the ethyol arm. 63 patients with adequate function
9 on the ethyol arm versus 43 patients in the RT arm
10 with a P value of .003. The analysis of stimulated
11 saliva collections by the applicant and longitudinal
12 analysis of unstimulated saliva collections by the FDA
13 did not show statistically significant differences
14 between study arms.

15 Do the results of the salivary
16 measurements provide supportive evidence that ethyol
17 reduces the incidence and severity of late xerostomia?
18 Dr. Margolin?

19 DR MARGOLIN: I am sorry, I must either be
20 misinterpreting this slide or these numbers may be
21 wrong. But on page 19, again these bars suggest that
22 the total number studied was only 63 in the amifostine

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1 arm and the number studied was 43 in the RT alone arm,
2 and that these are the percentages of --

3 CHAIRPERSON DUTCHER: I think those are
4 the n's.

5 DR MARGOLIN: Can those be clarified?

6 CHAIRPERSON DUTCHER: Those are the n's,
7 I believe, on the slides, correct?

8 DR. WILLIAMS: I believe you are looking
9 at a different analysis. This was the sponsor's
10 analysis, not the one done by Gani.

11 DR MARGOLIN: But the numbers were
12 identical. That is why I was querying that.

13 CHAIRPERSON DUTCHER: Those are the n's.

14 DR MARGOLIN: So in the question, what do
15 63 and 43 --

16 DR. RUSSELL: Let her comment on the slide
17 first.

18 DR. RUSSELL: The n's are actually the
19 numbers of patients who had more than .1 gram. So it
20 is 72 percent of those patients who were actually
21 analyzed for this endpoint and 49 percent of those
22 patients analyzed for this endpoint respectively.

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1 CHAIRPERSON DUTCHER: And what are those
2 denominators?

3 DR MARGOLIN: Is 63 the denominator or the
4 numerator?

5 DR. RUSSELL: The numerator.

6 DR MARGOLIN: So the 22 percent is the
7 previous number that the patients -- the 97 and the
8 106 is the denominator?

9 DR. RUSSELL: The level -- approximately
10 those numbers. They are slightly less in both
11 treatment arms.

12 CHAIRPERSON DUTCHER: It says late
13 xerostomia -- on page 15, late xerostomia at one year
14 patients available data, n equals 97 for amifostine
15 and n equals 106 for RT. And then here we have
16 unstimulated saliva at one year, 63 had the number
17 that was .1 gram or greater. So that 63 is 72 percent
18 of the 97 roughly speaking. Close enough. Is that
19 right? That is right. Okay. So, a comment, Dr.
20 Lippman?

21 DR. LIPPMAN: I do think the salivary
22 measurements are supportive. I was concerned initially

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1 when I saw the .1 cutoff and it was defined
2 unfortunately later on. But I think when -- listening
3 to the presentation and seeing the median saliva
4 levels, it looks as though -- this data looked at from
5 several angles seems to be supportive. So I do feel
6 that the salivary data is supportive and that there is
7 no accepted standard.

8 DR. SIMON: Well, I think it is difficult
9 to make a judgment here. When two different analyses
10 give what appears to be two totally different answers,
11 I think there needs to be some assessment as to why
12 they are giving different answers. And what it is
13 about the data that is -- does doing things from
14 baseline just add a lot of variability to data? I
15 think there needs to be a more in-depth analysis
16 myself before I could make a judgment. I think it is
17 difficult. There is a lot of missing data, which is
18 very understandable. But for myself, I think that
19 really when you -- I don't like the use of cutoffs
20 like that. I would have rather just seen sort of a
21 more straight forward analysis without introducing
22 thresholds, particularly when you haven't defined the

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1 thresholds prospectively in the protocol. So I am
2 just left with concern one way or the other.

3 DR. HARWOOD: I hate to come back to this,
4 but you have to understand the patient population that
5 you are dealing with. And I think -- and one has to
6 look at the lifestyle of the patients that we are
7 studying. And this is different. And it is very
8 difficult, let me tell you, to have the follow-up
9 levels. As a clinician that has treated hundreds and
10 hundreds of these patients, it is very hard to get
11 these patients to come back for follow-up, and it is
12 very hard to get them to do these various studies of
13 saliva functions. So I personally think the numbers
14 of patients that they have got to measure the saliva
15 is extraordinarily high given the patient population
16 that you are dealing with. I really do.

17 DR. SIMON: I meant to imply that. That
18 it was not a criticism of the study. That for this
19 patient population, I think that was good. But still
20 you do not want to be left with doing the analysis two
21 ways and getting two totally different answers.

22 DR. LIPPMAN: But at least in terms of the

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1 unstimulated saliva, on page 18, the medians are
2 different as well. So the cutoff issue I have the
3 same concern, but it does look as though when you look
4 at the data in different ways, at least the
5 unstimulated data seems to be consistently supportive.

6 DR. SIMON: As long as the pre-treatment
7 medians wouldn't be different also.

8 CHAIRPERSON DUTCHER: Dr. Schilsky?

9 DR. SCHILSKY: Just one other comment
10 about that. I mean I guess looking at it from the
11 clinical perspective, there doesn't seem to me to be
12 any particular rationale to have chosen the FDA's
13 analysis method of looking at change from baseline.
14 I personally actually was quite persuaded by the
15 comments from the sponsor that what is important is
16 where you end up at the end of the treatment. Because
17 the bottom line is is your mouth wet or dry when you
18 have completed all the treatment. And who cares how
19 wet it was when you started.

20 DR. HARWOOD: Exactly right. And it comes
21 down to can you eat a bagel or can you not.

22 CHAIRPERSON DUTCHER: So the Phase IV

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1 study is going to be bagels. Other comments? All
2 right. Do the results of the salivary measurements
3 provide supportive evidence that ethyol reduces the
4 incidence and severity of late xerostomia. All those
5 who would vote yes? 12 yes and one no. Carolyn votes
6 no. Okay.

7 Patient benefit questionnaire. As
8 described in the presentations, analytical plans for
9 this parameter were submitted retrospectively.
10 Consequently, the applicant and the agency chose
11 different methods of analysis. The applicant
12 evaluated the overall mean of the 7 subscales of the
13 PVQ and found a statistically significant difference
14 in favor of ethyol 7 months and one year after
15 completion of therapy. The longitudinal analyses by
16 the FDA looked at three discrete areas identified by
17 the reviewers as most clinically significant --
18 functional well-being, global assessment of dryness
19 and use of external aids and found trends in favor of
20 ethyol.

21 Do the results of the patient benefit
22 questionnaire provide support to this application?

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1 Dr. Sledge?

2 DR. SLEDGE: This kind of gets back to the
3 methodologic question I was asking earlier. If this
4 scale has been used previously and has been used in
5 the way that the sponsor used it previously, then I
6 don't see any particular reason why we should take the
7 FDA as opposed to the sponsor way of analyzing this.
8 If it hasn't, then it is a flip of the coin as to
9 which one to accept. But my understanding from what
10 I heard was that it has indeed been used before and it
11 has been used in head and neck cancer.

12 DR. WILLIAMS: We certainly had no
13 evidence submitted to us that it had been used in
14 another trial and that it had been connected up to a
15 particular clinical event. I mean our tendency to
16 frown upon lumping of a bunch of different subscales
17 is we don't know what it means when you get through.
18 I mean, what does it change on the scale versus a
19 particular subscale may ask a question and you can at
20 least calibrate it to that question. There is a 2
21 point change on this question dealing with a specific
22 name. So that is where our philosophy came from. But

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1 we had nothing submitted to us to indicate it had been
2 used in other trials in support of it.

3 CHAIRPERSON DUTCHER: I want to make one
4 comment from the sponsor.

5 DR. MACKOWIAK: Sorry, just to clarify.
6 The instrument had been used in other studies,
7 pilocarpine studies. However, non-significant
8 findings, of course, are rarely published. And we
9 talked about the difficulty of finding a difference.
10 So when we looked to the literature to find
11 publications of instruments, we are not going to see
12 it there. So it has been used.

13 CHAIRPERSON DUTCHER: Thank you. Dr.
14 Nerenstone?

15 DR. NERENSTONE: I think even the FDA said
16 that their analysis was trending in favor of it. It
17 is descriptive. I think that is all you can say. Does
18 it tend to support the application? Yes, it does. In
19 a statistical hard-nosed way, no it doesn't. Next
20 question.

21 CHAIRPERSON DUTCHER: She has to get out
22 of here.

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1 DR. HARWOOD: Amen to that.

2 CHAIRPERSON DUTCHER: Okay. We are
3 voting. Do the results of the patient benefit
4 questionnaire provide support for this application?
5 Those who would vote yes? 11 yes. I am abstaining.
6 And the patient rep voted no.

7 Tumor control. In the evaluation of
8 cytoprotective agents such as ethyol, one must
9 consider the adequacy of evidence demonstrating that
10 the cytoprotective agent is not protecting the tumor
11 from anticancer treatment. In this case, the FDA
12 determined that relatively large trials in patients
13 with head and neck cancer would be needed to rule out
14 such a tumor protective effect relative to radiation
15 therapy. The most relevant data submitted is from the
16 randomized control study discussed above. In this
17 trial, no difference was noted between the arms in
18 time to local/regional recurrence, disease-free
19 survival and overall survival. The lower bound of the
20 95 percent confidence intervals cannot exclude the
21 possibility that ethyol is 36 percent, 31 percent, and
22 13 percent inferior respectively.

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1 The sponsor also cites data from a 100
2 patient randomized study of radiation therapy
3 plus/minus ethyl in rectal cancer, and data from a
4 randomized trial of chemotherapy plus/minus ethyl in
5 ovarian cancer.

6 Is there adequate evidence that ethyl
7 does not protect tumors during treatment of head and
8 neck cancer with radiation therapy?

9 DR. HARWOOD: This is where I have
10 expressed concerns already. I think that the problem
11 with the trial to some degree was the large number of
12 patients who were postoperative patients who have been
13 resected for cure, albeit though they have a fairly
14 high frequency of recurrence. And the relatively
15 small number, one-third I think, of definitive
16 radiotherapy patients entered into the trial. I have
17 already talked about this. So I believe that there is
18 enough data to say this drug is not tumor protective
19 in the post-operative patients. But I personally
20 would prefer to see more definitive radiotherapy
21 patients treated and followed for a longer period of
22 time. Because it is those patients who I think

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1 conceivably could be at risk from three to five years
2 out of having a 5 to 10 percent difference in
3 survival. I don't know that that is the case, and
4 there is no evidence that that will be the case. But
5 I think that there has just not been enough follow-up
6 on that group of patients for me personally to
7 recommend its use in that area.

8 So I would think that we do have enough
9 information on the postoperative patients, because
10 that is the large group in the trial. And those
11 patients do, as has been discussed, tend to recur
12 early. But in the definitive group of patients, I
13 would be somewhat more hesitant because there are just
14 not that many patients that have been entered. And
15 the supporting studies, the rectal cancer study, I
16 think, is really irrelevant. These are patients being
17 treated palliatively with radiation for rectal cancer.
18 There are two other supporting studies which are
19 chemoradiation studies, but the follow-up in those
20 patients is short and the number of events and
21 recurrences are less than 5, I do believe.

22 So I think that we have enough patients

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1 followed for long enough who are postoperative, but in
2 the definitive radiotherapy patients, I would
3 personally prefer to see larger numbers of patients
4 followed for longer periods of time to be absolutely
5 certain on that issue. And I think that is a very
6 important issue.

7 CHAIRPERSON DUTCHER: Dr. Williams?

8 DR. WILLIAMS: Could you clarify what you
9 mean by -- I mean wording you might use in labeling by
10 a postoperative patient? Which patients who are going
11 to have surgery and radiation do you think this might
12 be indicated for?

13 DR. HARWOOD: These are patients that have
14 had a curative resection and had all gross tumor
15 removed but have positive margins or extracapsular
16 extension and things like that. The definitive
17 patients are patients who have never had surgery and
18 who are receiving radiation for cure, of course. So
19 the postoperative patients, both the high and low risk
20 -- and I think they had a good definition of the --
21 the sponsor had a good definition of this.

22 CHAIRPERSON DUTCHER: Dr. Margolin?

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1 DR MARGOLIN: Yes. I would like to
2 strongly agree with that and support that. And I
3 think it would be very, very unwise for us to take any
4 -- to put any faith in the data against tumor
5 protection in other histologies for which other
6 treatments are given. We have many examples in
7 oncology where things that would appear to be
8 interchangeable are not.

9 CHAIRPERSON DUTCHER: Mr. Gruett?

10 MR. GRUETT: I think the key word here is
11 adequate, and I don't think that has been
12 demonstrated.

13 CHAIRPERSON DUTCHER: Dr. Schilsky?

14 DR. SCHILSKY: I think we all have the
15 same concerns. And I guess one thing I am unclear
16 about is I suspect that the design of this trial was
17 based upon the total number of patients entered with
18 respect to ability to look at non-inferiority. So
19 once you start to break-out these subsets, I don't
20 know that we have any sufficient power in any subset
21 to be able to conclude with a reasonable level of
22 confidence that there is not an inferior outcome for

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1 the amifostine-treated patients. Maybe somebody could
2 comment further on that. But I am just -- I mean I
3 think that the concerns are completely valid about we
4 don't have enough events yet to determine that there
5 is not actual tumor protection. But I don't know that
6 the solution to that problem is to start to break it
7 out into subsets. Because I have a feeling then that
8 the patient numbers are going to be too small to be
9 able to draw any conclusion with confidence.

10 DR. HARWOOD: Well, I think that we have
11 200 patients, I believe, give or take that are the
12 postoperative patients. And as has been discussed and
13 I completely agree with that 90 percent of these
14 recurrences occur within the time frame of these
15 patients that have been followed. And I think the
16 additional supplemental RTOG data that was presented
17 is very supportive of that. So I really do think that
18 we have enough patients followed for long enough in
19 that group. And there is absolutely -- I would add
20 that there is absolutely no hint of tumor protection
21 in any of this data, nor in any of the other data that
22 has been accumulated through the years. So I kind of

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1 have a feeling that my worries about the definitive
2 radiotherapy group are kind of theoretical, and in the
3 fullness of time will not prove to be correct. But I
4 really think that it will be prudent to do that.

5 But I really strongly believe, as a
6 radiation oncologist treating many head and neck
7 cancer patients, that I would be comfortable treating
8 the postoperative patients with amifostine.

9 CHAIRPERSON DUTCHER: Dr. Lippman?

10 DR. LIPPMAN: I have a real concern
11 similar to Dr. Schilsky about taking out subsets from
12 this trial to make recommendations. I mean, this was
13 a very well-designed, well-powered large trial for
14 this disease, and I would just be very concerned to
15 make recommendations from subset analyses within this
16 trial. And that was why I made the comment, because
17 you addressed this earlier about the chemoradiation.
18 I don't think we can make any comments about that. I
19 think that needs to be clarified in the
20 recommendation. But in this case, to subset based on
21 any of these stratification factors I think is going
22 to be problematic.

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1 CHAIRPERSON DUTCHER: Dr. Margolin?

2 DR MARGOLIN: I think you are absolutely
3 right about that. Because this is -- what we were
4 talking about was actually a subset and not the
5 complete patient population here. But I think what
6 you end up having to do in the package insert is not
7 to put it in the first sentence of the indication that
8 it is only for post-op NED patients, but rather to go
9 into extensive detail in the package insert that
10 certain populations of patients were not studied in
11 sufficient detail to allow this indication to apply to
12 them or to recommend it, such as chemoradiation or
13 definitive radiation patients.

14 CHAIRPERSON DUTCHER: Dr. Ozols?

15 DR. OZOLS: Dr. Chico, you concluded that
16 it was premature. But since most of the events have
17 taken place, do you think there will be more data
18 coming from this trial with longer follow-up?

19 DR. CHICO: I would think there would be,
20 although the cutoff point that was determined was up
21 to 18 months, and that was the extent they provided to
22 the agency.

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1 DR. WILLIAMS: It sort of depends on what
2 kind of patients were entered and how long -- I am not
3 sure -- maybe the sponsor might have a comment.

4 DR. BRIZEL: Thank you very much. I think
5 we are getting to the crux of the issue here which is
6 what is the natural history of this disease. And in
7 other diseases -- prostate cancer and breast cancer,
8 for example -- the natural history of the disease may
9 be 15 or 20 years. And certainly within that context,
10 absolutely with longer follow-up, you would expect to
11 see more events. But in head and neck cancer, not
12 just through the RTOG data base, but if you look at
13 the article that I published in the New England
14 Journal. If you look at articles or institutional
15 experiences and cooperative group experiences just
16 about anywhere, you see that 80 to 90 percent of all
17 of the events that are going to occur do so within
18 this 12 to 18 month framework. So with all due
19 respect, I think that the likelihood of seeing more
20 events with longer follow-up is probably pretty small.
21 And again, the events that we have seen have been
22 local/regional events. And so when I look at this, I

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1 see the natural history of the disease again. The
2 problem with not having "enough events" is that
3 compared with ovarian cancer or the Liu study, which
4 was unresectable rectal cancer, a much greater
5 proportion of these patients are cured of their
6 disease. So there aren't as many events to occur.
7 And in order -- I am no statistician and I don't
8 pretend to be, but if we want to look at the number of
9 events that we are talking about to prove non-
10 inferiority, we are looking at a very minimum of
11 doubling the size of the study population, if not a
12 tripling or a quadrupling. And to put that in the
13 proper perspective for this group of patients, the
14 largest study randomized trial in head and neck cancer
15 was an RTOG forearm randomized trial that accrued
16 1,100 patients on it. Only 1,100 and took six years
17 to get there. The next largest was the British chart
18 study, which again took many, many years and only had
19 900 patients. So I think it is very important to keep
20 these issues to frame the context of the discussion.
21 Thank you.

22 CHAIRPERSON DUTCHER: Yes, Mr. Gruett?

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1 MR. GRUETT: I am a cancer survivor. I
2 had throat cancer. My entire throat has been removed.
3 And I worry about this drug. My doctor has told me
4 that my chances now -- I am in recovery for two years
5 -- are very good. I am probably 98 percent cancer
6 free. But if I was on this drug, I would worry
7 because we don't have information that goes beyond two
8 years, and I am a patient. And for my own self, the
9 benefits I don't think overcome the gamble that takes
10 place in this unknown period of time between the two
11 and five year period that I was explained that cancer
12 could reoccur. So my feelings are I am afraid of it.
13 Because we don't have enough information. I guess
14 fear is the unknown and we are lying in an unknown
15 area right here. Because maybe it has suppressed the
16 cancer, but it didn't remove it. So I don't think
17 there is enough info yet.

18 CHAIRPERSON DUTCHER: Dr. Simon?

19 DR. SIMON: I think the issues are
20 difficult. Dr. Chico quoted a figure before of 190 or
21 200 events needed for an equivalence trial, and that
22 is the kind of thing you might calculate ahead of time

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1 once you actually have data that power doesn't really
2 become the definitive issue because you have some of
3 the data already. On the other hand, I personally
4 always like to see two studies, just because one study
5 can and has been sometimes a fluke. And in this
6 particular case, the study looks pretty convincing.
7 But in terms of -- I looked at what was shown for the
8 RTOG data and it was not true that 80 or 90 percent of
9 the events occurred by 12 to 15 months. Once you got
10 to 2 years, yes, the curves plateaued then. But
11 certainly not at 12 months. So I think some points
12 are being stretched here. I think there was sort of
13 a rush to present this at a time when we could have
14 had a little bit more follow-up, although probably not
15 enough to make a difference.

16 Personally I am torn between the fact that
17 I really like to see two studies, because I think one
18 can be misleading, and on the other hand I know that
19 studies in this population are very difficult to do
20 and this is a drug that looks like it has some real
21 advantages to offer to the patient. So I think it is
22 a difficult judgment.

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1 I think with regard to the issue that was
2 raised in terms of subset analysis, I don't -- a lot
3 of times we say we want to stay away from subset
4 analysis, and that is in a situation where we see
5 ineffectiveness sort of across the board except
6 possibly for a subset. And there, I think it is very
7 compelling to sort of stay away from subset analysis
8 and then recommend some approval for some subset which
9 may just be a random finding. Here I think we have
10 reason to believe that some subset of patients really
11 warrant longer follow-up and that they were not well
12 represented in this trial. I think the cautious thing
13 -- it may be appropriately cautious to not recommend
14 approval of the drug for that subset. And also that
15 may lead to then another study in that group of
16 patients, which I think would really be good to me for
17 a drug that really offers something to cancer patients
18 where most drugs don't. I think it is appalling that
19 we should not be able -- for a common disease, we
20 should not be able to have two good studies.

21 CHAIRPERSON DUTCHER: Dr. Wasserman?

22 DR. WASSERMAN: Yes. Todd Wasserman,

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1 again, radiation oncologist from NSU. Gail Broder
2 eluded to the fact this morning that there was an ASCO
3 panel which has deliberated over the last roughly year
4 and a half and whose report has gone through the board
5 and is pending publication. And we wrestled with the
6 issue -- I was on the panel too and we wrestled with
7 the issue of tumor protection. And one, we recognized
8 that tumor protection was a theoretical risk only. I
9 mean, there was really never any data to suggest that
10 tumor protection would occur. There was always a
11 worry that it could occur. And so you had to prove
12 the null effect essentially, the lack of any effect on
13 the tumor. And it was concluded that this was
14 something that would just take forever, number one,
15 and has been part of the baggage that this drug has
16 carried around all this time. So I can tell you that
17 the writing in the ASCO report, for whatever it is
18 worth, is that it is a theoretical risk only.

19 DR. LIPPMAN: I'd just like to address the
20 issue of two studies. This is the area that I work in
21 and I would like to sort of highlight what Dr. Brizel
22 just said. In head and neck cancer, this would be

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1 considered a very large, well-done definitive trial.
2 The trials that usually come out are like the ones
3 mentioned with 40 patients randomized and things of
4 this sort. And the VA cooperative study program
5 larynx preservation trial, which was really a landmark
6 trial, had 330 patients. So personally I would go
7 with a well-designed large randomized trial as opposed
8 to two or three studies of 50 patients, which is
9 common in the head and neck literature. It doesn't
10 address the issue we are talking about in terms of
11 tumor control, but in terms of definitive studies in
12 this area.

13 CHAIRPERSON DUTCHER: Okay. Is there
14 adequate evidence that ethylol does not protect tumors
15 during treatment of head and neck cancer with
16 radiation therapy?

17 DR. WILLIAMS: Janice, do you want to
18 modify the -- yes, that is what I wanted to ask.
19 There has been some talk about modifying the question.

20 CHAIRPERSON DUTCHER: All right. Are you
21 ready? Turn the page. Is there adequate evidence
22 that ethylol does not protect resected tumors? I guess

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1 it wouldn't. Would you like to make a stab at this
2 question?

3 DR. WILLIAMS: Dr. Harwood, you are on.

4 DR. HARWOOD: Is there adequate evidence
5 -- sorry, just give me the first part and I will go on
6 from there.

7 CHAIRPERSON DUTCHER: Oh, you don't have
8 the question?

9 DR. HARWOOD: Is there adequate evidence
10 that ethyol does not protect tumors during treatment
11 -- during postoperative radiation treatment of head
12 and neck cancer with radiation therapy? Now I am
13 doing a double positive there, but I think that is --
14 or is there adequate evidence that ethyol does not
15 protect tumor during postoperative radiation treatment
16 of head and neck cancer?

17 CHAIRPERSON DUTCHER: All those who would
18 vote yes? 8 yes. All those who would vote no? One --
19 and we have two from the other two members. Three,
20 no. Abstain? Did you vote? What did you vote?

21 MR. GRUETT: Yes.

22 CHAIRPERSON DUTCHER: You voted yes. So

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1 then 9 yes. 9 yes and 2 no. All right. Now to
2 safety profile. There were significantly more severe
3 adverse events, more missed radiotherapy sessions, and
4 more hospitalizations in the amifostine plus
5 radiotherapy arm. Adverse events attributed to ethyol
6 are listed in the following table. Regulations
7 require that substantial evidence of effectiveness be
8 demonstrated through adequate and well-controlled
9 investigations. In most cases, the FDA has required
10 more than a single trial. As noted in the 1998 FDA
11 guidance for industry, providing clinical evidence of
12 effectiveness for human drug and biologic products, in
13 other cases FDA has relied on only a single adequate
14 and well-controlled efficacy study to support
15 approval. Generally only in cases in which a single
16 multi-center study of excellent design provided highly
17 reliable and statistically strong evidence of an
18 important clinical benefit such as an effect on
19 survival and a confirmatory study would have been
20 difficult to conduct on ethical grounds.

21 DR. WILLIAMS: Janet, I would like to make
22 an additional comment. The comment here is from a

1 guidance on clinical effectiveness for drugs, and the
2 sponsor was very attentive to this guidance and noted
3 on page 13 that it expands a little bit on the
4 survival and also mentions irreversible morbidity as
5 a suitable endpoint. So we could add that in there if
6 you wanted.

7 CHAIRPERSON DUTCHER: That's a good term.
8 So an important clinical benefit such as an effect on
9 irreversible morbidity, et cetera. Considering the
10 efficacy evidence presented from this single
11 randomized Phase III study, considering the safety
12 data and considering the data on tumor protection,
13 should ethiol be approved to decrease the incidence of
14 moderate to severe xerostomia in patients undergoing
15 radiation treatment for head and neck cancer? All
16 those --

17 DR. WILLIAMS: You are going to amend the
18 question to be postoperative again, aren't you?

19 CHAIRPERSON DUTCHER: Postoperative.
20 Undergoing postoperative radiation treatment for head
21 and neck cancer. Is that what you were -- Dr. Simon,
22 is that what your comment was? Other comments? Dr.

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1 Lippman?

2 DR. LIPPMAN: Although it is unusual to
3 give simultaneous chemotherapy with postoperative, it
4 is occasionally done and maybe later on in the
5 description, as you pointed out, you could indicate
6 that it is for single modality radiation alone.

7 CHAIRPERSON DUTCHER: I think the FDA
8 pretty much understands that. Any other comments?
9 No. All those who would vote yes on question 5? 9
10 yes and one qualified yes and one very narrow
11 indication yes. So that was 11, I think. Any no?
12 One no. And I think the qualified yes, again, is the
13 same issues that came up and the narrow indication
14 seems to be the same issues that related to
15 postoperative. So 11 yes and one no. Thank you very
16 much.

17 (Whereupon, at 4:38 p.m., the meeting was
18 concluded.)

19

20

21

22

CERTIFICATE

This is to certify that the foregoing transcript in the
matter of: 62ND MEETING

Before: ONCOLOGIC DRUGS ADVISORY COMMITTEE

Date: JUNE 8, 1999

Place: SILVER SPRING, MARYLAND

represents the full and complete proceedings of the
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Irene Gray

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