

Official Transcript of Proceedings
NUCLEAR REGULATORY COMMISSION

Title: Advisory Committee On the
 Medical Uses of Isotopes

Docket Number: n/a

Location: Teleconference

Date: July 9, 2012

Work Order No.: NRC-1725

Pages 1-44

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

+ + + + +

TELECONFERENCE

MONDAY, JULY 9, 2012

+ + + + +

The meeting convened telephonically at
11:00 a.m., Leon S. Malmud, M.D., ACMUI Chairman,
presiding.

MEMBERS PRESENT:

LEON S. MALMUD, M.D., Chairman

BRUCE R. THOMADSEN, Ph.D., Vice Chairman

DARICE BAILEY

MILTON J. GUIBERTEAU, M.D.

SUSAN M. LANGHORST, Ph.D.

STEVEN MATTMULLER

CHRISTOPHER PALESTRO, M.D.

JOHN SUH, M.D.

WILLIAM VAN DECKER, M.D.

LAURA WEIL

JAMES WELSH, M.D.

PAT ZANZONICO, Ph.D.

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2 NRC HEADQUARTERS STAFF PRESENT:

3

BRIAN MCDERMOTT, Director, Division of

4

Materials Safety and State Agreements

5

CHRIS EINBERG, Acting Deputy Director,

6

Division of Materials Safety and State

7

Agreements

8

JANINE KATANIC, Acting Branch Chief

9

Radioactive Materials Safety Branch

10

MICHAEL FULLER, Designated Federal Official

11

ASHLEY COCKERHAM, Alternate Designated Federal

12

Official

13

SUSAN CHIDAKEL, Office of General Counsel

14

DONNA BETH HOWE, Medical Radiation Safety Team

15

RONALD ZELAC, Medical Radiation Safety Team

16

NRC REGION I:

17

SANDY GABRIEL

18

PENNY LANZISERA

19

NRC REGION III:

20

CASSANDRA FRAZIER

21

SARA FORSTER

22

PUBLIC PARTICIPANTS:

23

SCOTT BERTETTI, Bayer

24

DR. COLIN BIGGIN, Algeta

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1 JEFFREY BOVA, Bayer
2 ROBERT DANSEREAU, NY State Dept of Health
3 WILLIAM DAVIDSON, University of Pennsylvania
4 DR. LOTHAR EVERZ, Bayer
5 LYNNE FAIROBENT, Am Assoc of Physicists in Medicine
6 DR. JOSE GARCIA-VARGAS, Bayer
7 MARIA GARRIGAN, Bayer
8 DR. JOSEPH GERMINO, Bayer
9 ALAN JACKSON, Henry Ford Hospital
10 JOHN JACOBUS, National Institutes of Health
11 DR. DEEPIKA JALOTA, Bayer
12 Dr. JANAKI KRISHNAMOORTHY, NY State Dept of Health
13 KAREN LANGLEY, University of Utah
14 RALPH LIETO, St. Joseph Mercy Hospital
15 DR. PETER LUEHRS, Bayer
16 GARY LUNGER, Bayer
17 KHALID MAMLOUK, Algeta
18 DR. PIERRE MAPOUYAT, Bayer
19 JANETTE MERRILL, Society of Nuclear Medicine
20 DR. ERIK MERTEN, Bayer
21 MICHAEL PETERS, American College of Radiology
22 DR. JEFFRY SIEGEL, Nuclear Physics Enterprises
23 MICHAEL SHEETZ, University of Pittsburgh
24 DR. MICHAEL TOMBLYN, Moffitt Cancer Center &

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Research Institute

CINDY TOMLINSON, American Society for Radiation

Oncology

DR. DIMITRIS VOLIOTIS, Bayer

DR. MONA WAHBA, Bayer

GARY WILLIAMS, Veterans Health Administration

MATT WILLIAMSON, Memorial Sloan-Kettering

Cancer Center

NANCY YOUNG, Xcenda

JESSIE ZHOU - Bayer

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P R O C E E D I N G S

11:01 a.m.

1
2
3 MR. FULLER: Okay. This is Mike Fuller
4 at NRC headquarters. We're going to go ahead and get
5 started.

6 MALE PARTICIPANT: Good morning, Mike.

7 MR. FULLER: Okay. As the Designated
8 Federal Official for this meeting, I am pleased to
9 welcome you to this public meeting of the Advisory
10 Committee on the Medical Uses of Isotopes or ACMUI.

11 My name is Mike Fuller. I am the team
12 leader of the Medical Radiation Safety Team, in the
13 Radioactive Materials Safety Branch, and I have been
14 designated as the federal official for this Advisory
15 Committee in accordance with Title 10, Code of
16 Federal Regulations Part 7.

17 Present today as the Alternate
18 Designated Federal Official is Ashley Cockerham, the
19 ACMUI coordinator. This is an announced meeting of
20 the Committee. It is being held in accordance with
21 the rules and regulations of the Federal Advisory
22 Committee Act and the Nuclear Regulatory Commission.

23 The meeting was announced in the June
24 21st, 2012 edition of the *Federal Register*. This

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1 meeting is being transcribed by the NRC in accordance
2 with the Federal Advisory Committee Act, and in
3 addition, I also want to make everyone aware that
4 this meeting may also be transcribed or recorded by
5 others.

6 The function of the Committee is to
7 advise the staff on issues and questions that arise
8 on the medical use of radioactive material. The
9 Committee provides counsel to the NRC staff, but does
10 not determine or direct the actual decisions of the
11 NRC staff or the Commission.

12 The NRC solicits the views of the
13 Committee and values their opinions. I request that
14 whenever possible, the Committee try to reach a
15 consensus on the procedural issues that will be
16 discussed today, but I also recognize that there may
17 be minority or dissenting opinions.

18 If you have such opinions, please allow
19 them to be read into the record at the appropriate
20 time. At this point, I would like to perform a roll
21 call of the ACMUI members participating today. Dr.
22 Leon Malmud, Chairman.

23 (No response.)

24 MR. FULLER: Dr. Bruce Thomadsen, Vice

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1 Chairman.

2 VICE CHAIRMAN THOMADSEN: Present.

3 MR. FULLER: Ms. Darice Bailey,
4 Agreement State representative.

5 MEMBER BAILEY: Present.

6 MR. FULLER: Dr. Milton Guiberteau,
7 Diagnostic Radiologist.

8 MEMBER GUIBERTEAU: Present.

9 MR. FULLER: Dr. Sue Langhorst,
10 Radiation Safety Officer.

11 MEMBER LANGHORST: Present.

12 MR. FULLER: Mr. Steve Mattmuller,
13 Nuclear Pharmacist.

14 MEMBER MATTMULLER: Present.

15 MR. FULLER: Dr. Christopher Palestro,
16 Nuclear Medicine.

17 MEMBER PALESTRO: Present.

18 MR. FULLER: Dr. John Suh, Radiation
19 Oncologist.

20 MEMBER SUH: Present.

21 MR. FULLER: Dr. William Van Decker,
22 Nuclear Cardiologist.

23 MEMBER VAN DECKER: Present.

24 MR. FULLER: Ms. Laura Weil, Patients'

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1 Rights Advocate.

2 MEMBER WEIL: Present.

3 MR. FULLER: Dr. James Welsh, Radiation
4 Oncologist.

5 MEMBER WELSH: Present.

6 MR. FULLER: Dr. Pat Zanzonico, Nuclear
7 Medicine Physicist.

8 MEMBER ZANZONICO: Present.

9 MR. FULLER: Okay. I would like to
10 state for the record that since we have at least
11 seven members in attendance, a quorum has been
12 established.

13 I will now ask NRC staff members who are
14 present here in headquarters to identify themselves,
15 and then after that we'll go out to the phones for
16 other NRC staff.

17 MS. CHIDAKEL: Susan Chidakel, Office of
18 General Counsel.

19 DR. HOWE: Donna Beth Howe, Medical
20 Radiation Safety Team.

21 DR. KATANIC: Jeanine Katanic, Acting
22 Branch Chief for the Radioactive Materials Safety
23 Branch.

24 MR. EINBERG: Chris Einberg, Acting

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1 Deputy Division Director for the Materials Safety and
2 State Agreements Program.

3 MR. FULLER: Okay. Other headquarters
4 NRC staff that are on the phone please?

5 MS. COCKERHAM: This is Ashley
6 Cockerham.

7 MR. McDERMOTT: Brian McDermott,
8 Division of Materials Safety and State Agreements.

9 MR. FULLER: Brian, could you go ahead
10 and repeat? We had two folks at once.

11 MR. McDERMOTT: Sorry. Brian McDermott,
12 Director, Division of Materials Safety and State
13 Agreements.

14 MR. FULLER: And did I hear Ron?

15 MR. ZELAC: Yes. Ronald Zelac, Medical
16 Radiation Safety Team.

17 MR. FULLER: Okay. Any other NRC
18 headquarters folks who are on the phone?

19 (No response.)

20 MR. FULLER: Okay. I'd like now go to
21 the NRC regions, and ask folks who are participating
22 from the regions. Region I?

23 MS. GABRIEL: Sandy Gabriel.

24 MS. LANZISERA: And Penny Lanzisera.

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1 MR. FULLER: Region III?

2 MS. FRAZIER: Sandy Frazier.

3 MS. FORSTER: Sara Forster.

4 MR. FULLER: Region IV?

5 (No response.)

6 MR. FULLER: Okay. Do we have anyone
7 else from the Nuclear Regulatory Commission who is
8 participating by phone?

9 (No response.)

10 MR. FULLER: Okay. At this point in
11 time, I would like to do a bit of a roll call on
12 folks, individual members of the public who have
13 notified us that they plan to participate.

14 For some of these names, I want to
15 apologize up front if I do not pronounce them
16 correctly, and for the transcriptionist and for the
17 record, if I do pronounce your name incorrectly, if
18 you will please pronounce it correctly for the
19 record.

20 First, Brian Abraham, Medical Imaging
21 and Technology Alliance.

22 (No response.)

23 MR. FULLER: Scott Bertetti, Bayer.

24 MR. BERTETTI: Present.

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1 MR. FULLER: Dr. Colin Biggin, Algeta.

2 DR. BIGGIN: Present.

3 MR. FULLER: Jeffrey Bova, Bayer.

4 MR. BOVA: Present.

5 MR. FULLER: Denise Cannaday, SMT,
6 Incorporated.

7 (No response.)

8 MR. FULLER: Peter Currie, Bayer.

9 (No response.)

10 MR. FULLER: Robert Dansereau, New York
11 State Department of Health.

12 MR. DANSEREAU: Present.

13 MR. FULLER: William Davidson,
14 University of Pennsylvania.

15 DR. DAVIDSON: Here.

16 MR. FULLER: Casey Deitrich, CQ
17 Transcriptions.

18 (No response.)

19 MR. FULLER: Dr. Lothar Everz, Bayer.

20 DR. EVERZ: Present.

21 MR. FULLER: Lynn Fairobent, American
22 Association of Physicists in Medicine.

23 MS. FAIROBENT: Present.

24 MR. FULLER: Dr. Jose Garcia-Vargas,

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1 Bayer.

2 DR. GARCIA-VARGAS: Present.

3 MR. FULLER: Maria Garrigan, Bayer.

4 MS. GARRIGAN: Present.

5 MR. FULLER: Dr. Joseph Germino, Bayer.

6 DR. GERMINO: Present.

7 MR. FULLER: Alan Jackson, Henry Ford

8 Hospital.

9 MR. JACKSON: Present.

10 MR. FULLER: John Jacobus, National

11 Institutes of Health.

12 MR. JACOBUS: Present, and the
13 pronunciation is Jacobus.

14 MR. FULLER: Thank you. Dr. Deepika
15 Jalota, Bayer.

16 DR. JALOTA: Present.

17 MR. FULLER: Dr. Janaki Krishnamoorthy,
18 New York State Department of Health.

19 DR. KRISHNAMOORTHY: Present.

20 MR. FULLER: Karen Langley, University
21 of Utah.

22 DR. LANGLEY: Present.

23 MR. FULLER: Ralph Lieto, St. Joseph
24 Mercy Hospital.

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1 MR. LIETO: Present.

2 MR. FULLER: Dr. Peter Luehrs, Bayer.

3 DR. LUEHRS: Present.

4 MR. FULLER: Gary Lunger, Bayer.

5 MR. LUNGER: Present.

6 MR. FULLER: Ragnhild Loberg, Algeta.

7 (No response.)

8 MR. FULLER: Dr. Pierre Mapouyat, Bayer.

9 DR. MAPOUYAT: Present.

10 MR. FULLER: Andrew McKinley, American
11 Society of Nuclear Cardiology.

12 (No response.)

13 MR. FULLER: Ruby Meredith, University
14 of Alabama at Birmingham.

15 (No response.)

16 MR. FULLER: Janette Merrill, Society of
17 Nuclear Medicine.

18 MS. MERRILL: Present.

19 MR. FULLER: Dr. Erik Merten, Bayer.

20 DR. MERTEN: Present.

21 MR. FULLER: Vigdis Reinton, Algeta.

22 (No response.)

23 MR. FULLER: Dr. Maria Rivas, Bayer.

24 (No response.)

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1 MR. FULLER: Joseph Rodgers, Theragenics
2 Corporation.

3 (No response.)

4 MR. FULLER: Dr. Gerhard Schlueter,
5 Bayer.

6 (No response.)

7 MR. FULLER: Dr. Jeffrey Siegel, Nuclear
8 Physics Enterprises.

9 DR. SIEGEL: Present.

10 MR. FULLER: Michael Sheetz, University
11 of Pittsburgh.

12 DR. SHEETZ: Present.

13 MR. FULLER: Rose Talarico, Bayer.

14 (No response.)

15 MR. FULLER: Dr. John Talian, Bayer.

16 (No response.)

17 MR. FULLER: Dr. Michael Tomblyn,
18 Moffitt Cancer Center and Research Institute.

19 DR. TOMBLYN: Present.

20 MR. FULLER: Cindy Tomlinson, American
21 Society for Radiation Oncology.

22 MS. TOMLINSON: Present.

23 MR. FULLER: Dr. Dimitris Voliotis,
24 Bayer.

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1 DR. VOLIOTIS: Yes, present.

2 MR. FULLER: Dr. Mona Wahba, Bayer.

3 DR. WAHBA: Present.

4 MR. FULLER: Gary Williams, Veterans
5 Health Administration.

6 MR. WILLIAMS: Present.

7 MR. FULLER: Matt Williamson, Memorial
8 Sloan Kettering Cancer Center.

9 MR. WILLIAMSON: Present.

10 MR. FULLER: Okay. That's all the folks
11 that I'm aware that have notified us that they plan
12 to participate. Are there other members of the
13 public who are on the call?

14 CHAIRMAN MALMUD: This is a member of
15 the Committee, Dr. Malmud, who joined you while you
16 were taking roll, but I did not wish to interrupt
17 you.

18 MR. FULLER: Okay, yeah. I was hoping
19 that you had joined us, Dr. Malmud.

20 CHAIRMAN MALMUD: Yes, I had.

21 MR. FULLER: Okay. Are there other
22 members of the public who would like to announce
23 themselves?

24 MR. PETERS: This is Michael Peters,

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1 American College of Radiology.

2 MS. VOUGLIS: This Jessie Zhou from Bayer.

3 MR. FULLER: I'm sorry, could you repeat
4 that name?

5 MS. VOUGLIS: Jessie Zhou from Bayer.

6 MR. FULLER: Could you please spell your
7 last name?

8 MS. VOUGLIS: Z-H-O-U.

9 DR. MAMLOUK: This is Khalid Mamlouk
10 from Algeta. You need me to spell my last name?

11 MR. FULLER: Could you please?

12 DR. MAMLOUK: M as in Mary, A as in
13 Apple, M as in Mary, L-O-U-K.

14 MR. FULLER: Okay, thank you. Anyone
15 else?

16 (No response.)

17 MR. FULLER: Okay. Individuals who
18 would like to ask a question or make a comment
19 regarding a specific issue the Committee has
20 discussed should request permission to be recognized
21 by the ACMUI Chairperson, Dr. Leon Malmud. Dr.
22 Malmud at his option may entertain comments or
23 questions from members of the public who are
24 participating with us today. Comments and questions

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1 are usually addressed by the Committee near the end
2 of the meeting, after the Committee has fully
3 discussed the topic.

4 I would also like to add that the
5 handouts and agenda for this meeting are available on
6 the NRC's public website. As a courtesy to all who
7 are listening to this meeting, and because the
8 meeting is being transcribed, I would also like to
9 ask for all participants to put the phone, put your
10 phone on mute unless you are speaking.

11 If you do not have a mute button, you
12 may press *6 to mute and unmute the line as needed.
13 Also please remember to note place your phones on
14 hold, as the meeting may be disrupted by background
15 music, if your phone system defaults to music.

16 Okay. I would like to point -- at this
17 point, I would like to turn the meeting over to Mr.
18 Chris Einberg. He is our Deputy Director for the
19 Division of Materials Safety and State Agreements,
20 and he would like to make a few opening comments.

21 MEMBER EINBERG: Okay, well thank you
22 Mike. Just a few brief comments. First, I'd like to
23 thank the ACMUI subcommittee for the work and their
24 recommendations for licensing of radium-223 chloride.

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1 Radium-223 chloride represents a first in class
2 alpha-emitting therapeutic radiopharmaceutical and is
3 being considered for use in treatment of skeletal
4 metastases.

5 Staff will consider the recommendations
6 and make a decision on how radium-223 chloride will
7 be licensed, and at this point, I'd like to turn it
8 back to Mike here.

9 MR. FULLER: Thank you, Chris. Okay.
10 At this point, I'd like to turn the meeting over to
11 Dr. Leon Malmud, who's the chairman of the ACMUI, and
12 so that the ACMUI can begin. Dr. Malmud.

13 CHAIRMAN MALMUD: Thank you. The
14 purpose of this meeting is to provide recommendations
15 on licensing of radium-223 chloride, and the
16 subcommittee members who prepared the report, which
17 you have read and have available to you is labeled
18 "Third Draft," dated July 3rd, 2012.

19 It was prepared by the Committee with
20 Dr. Zanzonico as chair. I would therefore open the
21 discussion by first asking Dr. Zanzonico for any
22 comments that he may have.

23 MEMBER ZANZONICO: This is Pat
24 Zanzonico. Thank you, Dr. Malmud, and good morning

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1 everyone. I think, I really have nothing to say at
2 this point, beyond what's presented in the summary
3 statement and recommendation of our draft report, and
4 but just to crystallize what we're primarily
5 recommending, and that is that physicians that are
6 already authorized, or authorized users in general,
7 already authorized to use therapeutic
8 radiopharmaceuticals under 35.390 or 35.396, already
9 have, in our opinion, have the requisite education,
10 training and experience to safely and effectively use
11 radium-223 chloride.

12 As such, licensing of authorized users
13 of radium-223 chloride under 35.390, either category
14 G-3 or G-4, or alternatively 35.396(d)(2) is
15 therefore recommended. We also included a
16 recommendation that the patient-administered
17 activities of the radiopharmaceutical and the
18 residual activity post-administration should be
19 assayed at the end user site, that is at the point of
20 service immediately prior to and after administration
21 of the radiopharmaceutical.

22 Overall, and other than that, we found
23 the biological and clinical data compelling, in terms
24 of the potential utility of this new agent in advance

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1 castrate-resistant prostate cancer. So I think I'll
2 confine my opening remarks to that, and thank you.

3 CHAIRMAN MALMUD: Thank you, Dr.
4 Zanzonico. Are there any comments that members of
5 the subcommittee wish to make, in addition to those
6 made by Dr. Zanzonico?

7 The members of the subcommittee were
8 Darice Bailey, Susan Langhorst, Steven Mattmuller,
9 Chris Palestro, Orhan Suleiman, Bruce Thomadsen and
10 James Welsh.

11 (No response.)

12 CHAIRMAN MALMUD: I hear none. Are
13 there comments from members of the public?

14 DR. JALOTA: Bayer would like to request
15 permission of Dr. Malmud to make a comment.

16 CHAIRMAN MALMUD: Please do. Please
17 just repeat your name, so that it may be included in
18 the minutes.

19 DR. JALOTA: My name is Deepika Jalota,
20 and I will be handing it over to Dr. Jeffry Siegel.

21 DR. SIEGEL: Good morning. I'd like to
22 thank the ACMUI Committee for the subcommittee
23 report, and give my best wishes and regards to Dr.
24 Malmud, Committee chair, and also to Dr. Zanzonico

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1 for the subcommittee chair.

2 The report recommends that radium-223
3 dichloride be licensed under 35.300, and asserts that
4 physicians already authorized to use 300 materials
5 pursuant to 390 or 396, have the requisite education,
6 training and experience to safely and effectively use
7 radium-223 with no additional T&E required.

8 Bayer believes that these
9 recommendations are most consistent with placing
10 radium-223 dichloride in dosage Category 3 in 35.390,
11 since all current Category 3 AUs would not require
12 additional work experience.

13 If, however, radium-223 dichloride were
14 to be placed in Category 4, additional T&E in the
15 form of at least three cases would likely be required
16 to attain AU status, and has the potential to
17 postpone patient access to treatment.

18 Therefore, Bayer would respectfully
19 request that radium-223 dichloride be considered as a
20 Category 3 radiopharmaceutical. Would the ACMUI wish
21 to comment on this recommendation?

22 CHAIRMAN MALMUD: That's a question from
23 Dr. Siegel to the subcommittee members.

24 MEMBER ZANZONICO: Well, this is Pat

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1 Zanzonico. I'll offer my opinion and other members
2 of the subcommittee certainly can voice theirs. But
3 I would tend to agree. I think that personally, I
4 think Category 3 is the most appropriate licensing
5 category for radium-223 chloride.

6 So in my opinion, we would agree with
7 that recommendation by Bayer. But again, I would
8 welcome any comments from other members of either the
9 subcommittee or the ACMUI.

10 CHAIRMAN MALMUD: Thank you, Dr.
11 Zanzonico. Are there other comments? Are there
12 comments from members of the public?

13 MEMBER LANGHORST: Dr. Malmud, this is
14 Sue Langhorst.

15 CHAIRMAN MALMUD: Yes, Dr. Langhorst.

16 MEMBER LANGHORST: Okay, thank you. To
17 me, I've always been confused by Category 3 and
18 Category 4 because of the and/or statement in between
19 the "to" and "the regulation." To me, I believe that
20 what you learn for one parenteral administration is
21 pretty close to what you learn for the other type
22 category of parenteral administration.

23 So I see no difference between the two,
24 and my understanding of the regulations has always

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1 been that you have either one of those, and
2 typically, we only have isotopes in Category 3.

3 So I voice my confusion over really
4 what's the difference between three and four, and
5 really if the regulations require that there be cases
6 in each one of those, or there's just three cases
7 needed in the parenteral administration. Thank you.

8 CHAIRMAN MALMUD: Thank you. Comments
9 regarding Dr. Langhorst's comment of Category 3
10 versus Category 4?

11 (No response.)

12 CHAIRMAN MALMUD: I hear none. Are
13 there other comments from members of the public?

14 (No response.)

15 CHAIRMAN MALMUD: So before us is a
16 document which is thorough and prepared by the
17 subcommittee chaired by Dr. Zanzonico, entitled the
18 Subcommittee report on licensing for radium-223
19 chloride. Quite simply, the proposal is that nuclear
20 physicians and other radiologic physicians who are
21 trained in administration of therapeutic
22 radiopharmaceuticals be granted permission to use
23 this particular agent in the same fashion. Is there
24 any discussion of this proposal?

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1 MEMBER GUIBERTEAU: Dr. Malmud?

2 CHAIRMAN MALMUD: Yes.

3 MEMBER GUIBERTEAU: This is Mickey
4 Guiberteau. I'm not a member of the subcommittee. I
5 certainly agree with the report, and I thought it was
6 very well done. I just have an editorial comment
7 which I would like to see addressed, and that is for
8 those who read this document as it will by various
9 individuals with different degrees of experience and
10 expertise with the regulatory processes, in terms of
11 the reference to radium-223 chloride as being -- its
12 status with the FDA, this is referenced a number of
13 times in the report.

14 Just as an example, in terms of approval
15 and non-approval, there are various forms of approval
16 of radiopharmaceuticals or drugs by the FDA, and I
17 remember in February, when the FDA granted approval
18 to proceed with an expanded access program, or its
19 investigational status, excuse me, there was a great
20 deal of confusion or some initial elation that
21 perhaps it had been approved.

22 So in line 70 of the report, I think it
23 states very well that it's described as routine, non-
24 investigational clinical use as the positive. But I

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1 think in other parts of the report, in fact, there is
2 reference to it being non-approved, without FDA even
3 being mentioned.

4 In some areas, it just -- it uses
5 different language. What I would like, since we have
6 an FDA representative and a chairman of the
7 subcommittee who is very familiar with this, that if
8 we could use some uniform language so that those
9 reading it will not --

10 I think we all know what we mean by
11 this, but it isn't clear necessarily to others what
12 approved and non-approved means, and generally non-
13 approved means for routine clinical use, although the
14 drug is approved for investigational use and now for
15 the expanded access program.

16 Which means that those that can't enter
17 controlled clinical trials may be treated with this
18 under certain circumstances in a clinical setting.
19 So in any case, I would just offer that as a
20 suggestion, to make this more uniform throughout the
21 document, when we talk about approved and non-
22 approved. Thank you.

23 CHAIRMAN MALMUD: Thank you, Dr.
24 Guiberteau. Dr. Suleiman is of course with the FDA.

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1 Orhan, would you care to comment on line 70, which
2 I'll quote, which says "Importantly, if approved by
3 the U.S. Food and Drug Administration, it would
4 represent the very first alpha article emitting ray
5 pharmaceutical in routine (non-investigational)
6 clinical use."

7 MR. FULLER: Dr. Malmud, this is Mike
8 Fuller. Unfortunately, Dr. Suleiman was not able to
9 be with us today.

10 CHAIRMAN MALMUD: Is there a
11 representative from the FDA with us?

12 (No response.)

13 CHAIRMAN MALMUD: If not, Dr. Zanzonico,
14 was this clarified for you any further?

15 MEMBER ZANZONICO: Pat Zanzonico. Dr.
16 Guiberteau's points are very well taken. It was at
17 Dr. Suleiman's suggestion, who is the FDA
18 representative to the ACMUI, that the status of
19 radium-223 chloride be made clear in our subcommittee
20 report, so that everyone who read it would
21 understand it is not yet approved for routine, that
22 is non-investigational clinical use.

23 But I also agreed with Dr. Guiberteau
24 that at certain points in the draft report, there's

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1 some jargony language used that may be clear to all
2 of us on the Committee on others, that may not be
3 generally clear. So what I would say at this point
4 is that I and the rest of the subcommittee members
5 will confer with Dr. Suleiman and develop some
6 uniform accurate language that would be clear to
7 anyone reading the report.

8 So the point is well-taken, and I think
9 we'll address that issue offline with Dr. Suleiman.

10 CHAIRMAN MALMUD: Thank you, Dr.
11 Zanzonico. May I ask a question just for clarity,
12 since we have a large audience on this call, and that
13 is that if there were to be a patient who fulfilled
14 the clinical requirements currently, could that
15 patient be treated at an institution with a broad
16 license in which there has been experience with
17 parenteral administration of radiopharmaceuticals for
18 therapy? Does anyone know the answer to that
19 question?

20 MEMBER GUIBERTEAU: Well Dr. Malmud,
21 this is Mickey Guiberteau. I mean I --

22 CHAIRMAN MALMUD: Please.

23 MEMBER GUIBERTEAU: Well, in February,
24 the FDA did approve to proceed with an expanded

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1 access program under investigational drugs. Now I'm
2 not an expert in this, and I wish Orhan were on the
3 phone or someone else to address this.

4 But the language that I believe FDA uses
5 for this is that under certain circumstances, in
6 certain institutions, that if you have seriously ill
7 patients that cannot participate in a controlled
8 clinical trial, that under this program they could be
9 treated. But certainly this does not mean routine
10 clinical use.

11 But I think it would be, you know,
12 attendant on the subcommittee to get Orhan's input
13 into this, because as I admit, this form of
14 regulation is not in my area of expertise.

15 CHAIRMAN MALMUD: Thank you. I think
16 that we all understand that it's not ready for
17 routine clinical use yet. My question was should a
18 nuclear physician be made aware of a patient who
19 would benefit from this therapy, though he or she is
20 not part of a protocol, could there be a special
21 "hardship" application of the radiopharmaceutical,
22 and would the radiopharmacy house be allowed to make
23 it available? This is in an interim.

24 MEMBER GUIBERTEAU: Right.

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1 CHAIRMAN MALMUD: Does anyone from the
2 manufacturer have any insight into this? This
3 question is addressed to the members of the public,
4 who represent the manufacturer, or to Dr. Siegel, who
5 I believe is familiar with the status of the product
6 at the current time.

7 DR. JALOTA: Hi. This is Bayer.
8 Permission to speak, Dr. Malmud.

9 CHAIRMAN MALMUD: Please. Introduce
10 yourself.

11 DR. JALOTA: My name is Deepika Jalota
12 and I represent Bayer. Essentially, the EAP program
13 is an ongoing trial that is under the IND, and it's
14 for investigational use only as far as treating
15 patients, and in order to expand access to patients
16 that qualify under the inclusion/exclusion criteria.

17 Right now, the drug is under
18 investigational use and can only be administered
19 under a clinical protocol for the ongoing study.

20 CHAIRMAN MALMUD: Thank you. That
21 clarifies it. Are there any further questions or
22 discussion regarding the report of the subcommittee?

23 MS. WEIL: Dr. Malmud, this is Laura
24 Weil, Patient's Rights Advocate.

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1 CHAIRMAN MALMUD: Yes.

2 MEMBER WEIL: Have a question regarding
3 the subcommittee's report at line 111, the section on
4 Radiation Safety and Logistical Considerations. I
5 wonder if, given that this is an outpatient
6 procedure, if there are any concerns -- and it's an
7 alpha-emitter, regarding internal contamination of
8 the public if patients are immediately discharged
9 post-treatment, and within the 36 minute half life
10 for the lead-211.

11 If there any concern regarding public
12 restrooms, the GI tract excretion of this particular
13 isotope, if there needs to be some regulation
14 regarding sequestering patients for the half hour
15 that would be necessary to reduce that exposure.

16 CHAIRMAN MALMUD: Thank you for bringing
17 the question forward. Would a representative from
18 Bayer who understands the protocol be able to answer
19 the question?

20 (No response.)

21 CHAIRMAN MALMUD: Is there anyone who's
22 able to address the issue.

23 DR. JALOTA: Yes, if you could please
24 clarify the question again, I'm sorry.

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1 CHAIRMAN MALMUD: The question relates
2 to the public safety, to the safety to the members of
3 the public, who might be exposed to a patient who
4 received the product, particularly in the one hour
5 period after having received the product. Radiation
6 --

7 MEMBER WEIL: If I might clarify, Dr.
8 Malmud. Specifically, the internal contamination
9 that might be caused by exposure to feces in public
10 restrooms.

11 CHAIRMAN MALMUD: This is longer than
12 one hour. Okay, go ahead.

13 MEMBER WEIL: Well no it isn't, but it's
14 the 36 minute half life of the lead-211 that concerns
15 me.

16 CHAIRMAN MALMUD: Thank you. Is there a
17 physicist with Bayer who wishes to address the
18 question?

19 MEMBER ZANZONICO: Well, this is Pat
20 Zanzonico. I might offer some comments in addition
21 to anyone from Bayer or anyone else would like to
22 offer.

23 CHAIRMAN MALMUD: Thank you.

24 MEMBER ZANZONICO: Certainly, the

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1 external or direct exposure should be minimal. For
2 example, strontium-89 or Metastron, as opposed to say
3 from I-131, where there's a more significant X and
4 gamma ray emission and a more significant external
5 hazard.

6 I think in terms of the internal hazard,
7 it's important to bear in mind that the administered
8 activities of radium-223 chloride, which are of the
9 order of 100 microcuries for a 70 kilogram standard
10 person in total, what is of magnitude less than one
11 typically is counted certainly for I-131 thyroid
12 disease, or even Metastron, where I believe the
13 standard is four doses or four millicuries or 4,000
14 microcuries.

15 So while there's a theoretical
16 contamination hazard, there's really no obvious or
17 significant internalization pathway. I think any
18 accidental trace internal contamination, and this
19 really would be a trace contamination, would be
20 insignificant.

21 Bayer, for example, provided some
22 calculations or the results of some calculations in a
23 document in response to comments at the time of our
24 last teleconference, presenting some worst case

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1 scenarios in terms of contamination and other means
2 of exposure.

3 It really would look like given the
4 amounts of activity, that contamination doses really
5 would be insignificant even in worse case scenarios.

6 CHAIRMAN MALMUD: Thank you. Does that
7 apply also to the radioactive progeny, including the
8 lead-211, which has a half life of 36.1 minutes?

9 MEMBER ZANZONICO: Yes. Yeah, I believe
10 so, that -- yeah. I would just say yes.

11 CHAIRMAN MALMUD: Thank you.

12 MEMBER ZANZONICO: In general terms, my
13 comments would apply to radium-223 and all of its
14 progeny.

15 CHAIRMAN MALMUD: Thank you. Does that
16 answer the question that was raised?

17 MEMBER WEIL: Yes, thank you it does. I
18 have just a further request for clarification. Is
19 there any concern re shielding for the gamma emitters
20 that are described as also existing?

21 CHAIRMAN MALMUD: We'll ask that
22 question to Dr. Zanzonico as well.

23 MEMBER ZANZONICO: Certainly. Again, I
24 think from a practical point of view, no. We're

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1 talking about a very low abundance in terms of the
2 total energy accompanied with the decay of radium-223
3 and its progeny, a very low abundance, a very small
4 proportion of that total energy being emitted in the
5 form of X and gamma rays.

6 And again, given the very low
7 administered activities of radium-223 chloride, which
8 are orders of magnitude below those for even
9 diagnostic radio traces, with much more abundant X
10 and gamma ray emissions, for which there really is no
11 significant shielding problem.

12 So I think -- I don't foresee any
13 practical difficulties in terms of the X and gamma
14 ray component of radium-223 decay and the decay of its
15 progeny.

16 CHAIRMAN MALMUD: Thank you, Dr.
17 Zanzonico. Does that address the concern you just
18 raised?

19 MEMBER WEIL: Yes, thank you.

20 CHAIRMAN MALMUD: Thank you.

21 MEMBER LANGHORST: Dr. Malmud, this is
22 Sue Langhorst.

23 CHAIRMAN MALMUD: Yes, Dr. Langhorst.

24 MEMBER LANGHORST: Yes. I wanted to add

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1 for Laura's education that the 30 minute half life of
2 one of the daughter products of radium-223, that
3 daughter product will be around as the radium-223
4 decays. So it doesn't just all go away within 30
5 minutes. The progeny are existing as the radium is
6 decaying. So I just wanted to let you know that,
7 Laura.

8 CHAIRMAN MALMUD: Thank you, Dr.
9 Langhorst.

10 DR. JALOTA: Sorry, Dr. Malmud.

11 CHAIRMAN MALMUD: Yes.

12 DR. JALOTA: This is Deepika Jalota.
13 Bayer would like to request permission to speak.

14 CHAIRMAN MALMUD: Please do.

15 DR. JALOTA: Erik Merten, would you be
16 able to state Bayer's position?

17 DR. MERTEN: Sure, thanks. So I have
18 nothing to add content-wise, but I would like to
19 thank Dr. Zanzonico for his remarks on that issue,
20 with regard to public restrooms and shielding. This
21 is exactly the position we have as well, and the only
22 thing that I should add is that the drug has already
23 been applied in a clinical setting more than 1,000
24 times without any radio safety issue. Thank you.

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1 CHAIRMAN MALMUD: Thank you, Dr. Merten.
2 Are there any other comments from members of the
3 Committee, subcommittee or members of the public?

4 MEMBER VAN DECKER: Dr. Malmud. Yes.
5 Who's speaking please?

6 MEMBER VAN DECKER: This is Bill Van
7 Decker. How are you?

8 CHAIRMAN MALMUD: Fine, thank you.

9 MEMBER VAN DECKER: I just wanted to say
10 that the subcommittee report was incredibly well
11 thought-out, and I think it is a very reasonably
12 defensible position they put forth. I guess my
13 question is from a general radiation safety
14 perspective, there will be a lot of people reading
15 this as it comes out, and it's kind of in an
16 intermediate stage.

17 At what point does the NRC see, you
18 know, communication with full stakeholders on a
19 frequently-asked question basis, or on a draft
20 guidance basis or on some information statement
21 basis, you know, through the professional societies
22 or through themselves, trying to get some more of
23 this information to a broader AU population, so that
24 people understand where we are and what this means in

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1 relation to the process and where we're going and
2 that type of stuff?

3 CHAIRMAN MALMUD: Thank you for the
4 question, Dr. Van Decker. That's addressed to a
5 member of the NRC staff.

6 MR. FULLER: Yes. This is Mike Fuller
7 with the NRC staff. Dr. Van Decker, the best way
8 that I can answer that question is that once we have
9 a recommendation from the ACMUI, I think that
10 recommendation is part of our process for making a
11 decision.

12 Once a decision is made, depending on
13 where we come out, we will communicate through the
14 appropriate means. It may be in terms of, you know,
15 posting things to our website and of course
16 communicating with the various professional societies
17 through the normal means.

18 So again, I guess the answer to your
19 question is that it sort of depends on exactly how we
20 might do it. But the fact that once a decision is
21 made, we will definitely communicate broadly with the
22 folks that would be interested.

23 CHAIRMAN MALMUD: Thank you, Mike.
24 Thank you. Now at this point, are there any other

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1 comments?

2 (No response.)

3 CHAIRMAN MALMUD: Hearing none -- oh,
4 excuse me.

5 MR. LIETO: This is Ralph. May I make a
6 comment and ask a question?

7 CHAIRMAN MALMUD: Please, Mr. Lieto.

8 MR. LIETO: One time was I think to
9 address Sue Langhorst's question earlier about the
10 difference under 300 Category 3 and 4. Probably have
11 to go back into the ACMUI minutes when this Part 35
12 section was revised, but I think the intent was that
13 four was handle anything, including alpha emitters as
14 well as gamma emitters that were over 150 keV.

15 So I think it was meant to be sort of a
16 catch-all that did not meet Category 3, and was
17 intentional on having that specific sort of future
18 application. My last comment is that I want to
19 strongly support the subcommittee in its
20 recommendations.

21 I think they're very well laid out in
22 their licensing considerations, and I really endorse
23 their recommendation on assaying the therapeutic
24 dosage prior to administration.

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1 My question has to do with if the
2 committee has had any consideration or knowledge on
3 the dose calibrator assay specifically, in that I'm
4 assuming the calibration settings are different for
5 glass in the plastic syringe. Are these settings
6 being supplied by the vendor to their knowledge, or
7 maybe Bayer might want to answer this also, or is
8 this something that each site is supposed to develop?

9 CHAIRMAN MALMUD: Thank you for the
10 question. It appears to be address to Bayer. Does
11 anyone from Bayer wish to address the issue of the
12 dose calibrator vis-a-vis plastic or glass syringes.

13 DR. JALOTA: This is Deepika Jalota on
14 behalf of Bayer. I'd like to hand it over to Jeff
15 Siegel.

16 CHAIRMAN MALMUD: Thank you. Dr.
17 Siegel.

18 DR. SIEGEL: Thank you, Dr. Malmud.
19 NIST has already published a study on dose calibrator
20 use for radium-223 chloride and found that
21 independent of volume and container, that is syringe
22 versus vial, that the dose calibrator can be
23 calibrated using a single vial setting within three
24 percent.

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1 So what Bayer intends to do is to use a
2 NIST-traceable source, so that when they send the
3 material out, this will be, as NIST has agreed,
4 considered a secondary standard, to which the sites
5 can then adjust their dial setting on their dose
6 calibrator, so that they will have a properly assayed
7 activity for radium-223 chloride.

8 CHAIRMAN MALMUD: Thank you, Dr. Siegel.
9 Did you explain that would be between two and three
10 percent variance?

11 DR. SIEGEL: Yes, that's what they
12 found. I think the highest percent variance, because
13 they used several different dose calibrator
14 manufacturers, is on the order of three and a half or
15 four percent activity difference.

16 CHAIRMAN MALMUD: Thank you. Is that
17 referenced in this document?

18 DR. SIEGEL: I believe it is, Dr.
19 Malmud. It's referenced, I think the last reference
20 in this document.

21 CHAIRMAN MALMUD: The very last
22 reference. All right. That would be on page --

23 DR. SIEGEL: That's reference 16,
24 correct.

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1 CHAIRMAN MALMUD: Very good, thank you.
2 So that reference is available for those who wish to
3 confirm that. Any other questions or comments?

4 MR. FULLER: Dr. Malmud, this is Mike
5 Fuller. Just if I may, it's becoming a little bit
6 difficult to hear everyone because someone is typing
7 very loudly, and it's coming across the entire call.
8 So if whoever's typing could please mute their
9 phones, or perhaps move your keyboard away from the
10 phone, it would be greatly appreciated. Thank you.

11 CHAIRMAN MALMUD: Thank you for bringing
12 that to our attention. Once again, are there any
13 additional comments?

14 MR. JACKSON: This is Alan Jackson from
15 Henry Ford Health System, Dr. Malmud, and I'd like to
16 pose a question, and I guess mainly to NRC. This
17 question relates to licensing. Typical broad scope
18 licenses list things like atomic number 3 through 83.

19 So that would preclude easy adoption of
20 radium-223 for broad scope licenses. That is, we
21 would need to do a license amendment. Has there been
22 any thought by NRC to change common licensing
23 conditions for this case?

24 CHAIRMAN MALMUD: Thank you for the

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1 question. It's addressed to NRC staff.

2 MR. FULLER: This is Mike Fuller, and
3 the answer to the question, pretty simply, is no.
4 The question from Henry Ford Hospital is correct.
5 For broad scope licensees, it is typically based upon
6 atomic number and they are typically licensed as
7 atomic number 3 through 83.

8 So this would not fall under that. So a
9 license amendment would be needed, in order to be
10 authorized for something other than if you need
11 authorization for something other than 3 through 83.

12 So not to say that at some point in the
13 time in the future we could not consider, but we have
14 received no such request, and the amendment is the
15 only means right now by which someone could be
16 authorized.

17 CHAIRMAN MALMUD: Thank you for that
18 clarification. I'm certain that the question will
19 arise, and that is for someone who already has -- for
20 an institution that already has a broad license, how
21 long would it take for it to process an amendment
22 request?

23 MR. FULLER: It should be a fairly
24 routine amendment request. So whatever the regions.

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1 Typically, you know, it would depend on workload and
2 so forth and how many they get and so forth and so
3 on. So it would be hard to say exactly. But it
4 would be a fairly straightforward amendment request.

5 CHAIRMAN MALMUD: Thank you. Any other
6 questions?

7 (No response.)

8 CHAIRMAN MALMUD: Hearing none, it
9 appears that the subcommittee report, first of all,
10 should be complimented for the effort put into it and
11 the final product, and secondly, would someone care
12 to make a motion for approval of the subcommittee
13 report?

14 MEMBER LANGHORST: This is Sue
15 Langhorst. I so move.

16 CHAIRMAN MALMUD: Thank you, Dr.
17 Langhorst. Is there a second?

18 VICE CHAIRMAN THOMADSEN: This is Bruce
19 Thomadsen. I will second.

20 CHAIRMAN MALMUD: Thank you, Dr.
21 Thomadsen. Thank you for seconding. Any further
22 discussion?

23 MEMBER MATTMULLER: Yes, Dr. Malmud.
24 This is Steve Mattmuller. Can we vote it as is, or

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1 were we going to rework the FDA approval language a
2 bit first?

3 CHAIRMAN MALMUD: Thanks for raising the
4 question, Steve. I'm not sure that we can rework the
5 FDA approval language until we have some feedback
6 from the FDA. If we approve it in its current form,
7 it would allow us to amend it with whatever
8 clarification comes forth from the FDA.

9 On the other hand, if we defer it, we
10 may be delaying forward movement. Whichever the
11 Committee, whichever approach the Committee wishes to
12 take is certainly acceptable to the chairman.

13 MEMBER GUIBERTEAU: Dr. Malmud?

14 CHAIRMAN MALMUD: Yes. Who's speaking?

15 MEMBER GUIBERTEAU: This is Mickey
16 Guiberteau.

17 CHAIRMAN MALMUD: Yes.

18 MEMBER GUIBERTEAU: Actually I consider
19 this more editorial than substantive, since it
20 doesn't directly relate to the regulation of radium-
21 223 under the NRC's rules. So you know, I would be
22 comfortable moving forward with an understanding that
23 we would make those changes at another time, when
24 there was more input from those who have expertise in

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1 this area.

2 CHAIRMAN MALMUD: Dr. Guiberteau, does
3 that mean that you would move this forward now, with
4 anticipation of the changes, or you would hold it
5 back?

6 MEMBER GUIBERTEAU: No, I'm sorry. That
7 means I think -- I feel that we could move it
8 forward.

9 CHAIRMAN MALMUD: Thank you, thank you.
10 Any further comments? We have a motion, which has
11 been seconded. All in favor?

12 (Chorus of ayes.)

13 CHAIRMAN MALMUD: Are there any opposed?

14 (No response.)

15 CHAIRMAN MALMUD: Are there any
16 abstentions?

17 (No response.)

18 CHAIRMAN MALMUD: The motion moves
19 forward with unanimity. Is there any other business
20 to be accomplished at this time in this
21 teleconference?

22 (No response.)

23 CHAIRMAN MALMUD: I hear none. May I
24 once again thank the subcommittee for a very thorough

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1 report, and particularly Dr. Zanzonico and also may I
2 in parentheses thank Dr. Thomadsen for his
3 chairmanship of the Committee in my absence. I very
4 much appreciate the effort that was put forward.

5 VICE CHAIRMAN THOMADSEN: This is Bruce
6 Thomadsen, and I'll just say that it's good to have
7 you back.

8 CHAIRMAN MALMUD: Thank you.

9 MALE PARTICIPANT: Amen.

10 CHAIRMAN MALMUD: Thank you very much.
11 It's good to be back, and once again, thank you all
12 for your participation, and we're looking forward to
13 further details from the FDA regarding the questions
14 that were raised, and perhaps the introduction of a
15 very effective therapeutic agent for patients who
16 have otherwise unresponsive metastatic disease from
17 prostate cancer. Thank you all. Is there a motion
18 for adjournment?

19 MEMBER GUIBERTEAU: So moved. This is
20 Mickey Guiberteau.

21 CHAIRMAN MALMUD: Thank you, second?

22 MEMBER ZANZONICO: Seconded, Pat
23 Zanzonico.

24 CHAIRMAN MALMUD: Thank you. The

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1 meeting is adjourned.

2 (Whereupon, at 11:54 a.m., the meeting
3 was adjourned.)

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