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**NUCLEAR REGULATORY COMMISSION**

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                              Uses of Isotopes

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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TELECONFERENCE

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WEDNESDAY,

DECEMBER 12, 2007

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The meeting was convened via teleconference at 12:00 noon, LEON S. MALMUD, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

- LEON S. MALMUD, M.D. Chairman
- DARRELL FISHER, Ph.D. Member
- RALPH P. LIETO Member
- STEVE MATTMULLER, R.Ph. Member
- SUBIR NAG, M.D. Member
- SALLY WAGNER SCHWARZ, R.Ph. Member
- BRUCE THOMADSEN, Ph.D. Member
- WILLIAM VAN DECKER, M.D. Member
- RICHARD J. VETTER, Ph.D. Member
- JAMES S. WELSH, M.D. Member

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1        NRC STAFF PRESENT :

2                    CYNTHIA M. FLANNERY (ALT DFO)

3                    DONNA-BETH HOWE, Ph.D.

4                    ANTHONY HUFFERT

5                    DORIS LEWIS

6                    ASHLEY TULL

7                    SANDRA WASTLER (DFO)

8                    DUANE E. WHITE

9

10        ALSO PRESENT :

11                    LYNNE FAIROBENT, AAPM

12                    CHRIS GALLAGHER, ASNC

13                    EMILY GARDNER, ASNC

14                    DEBBIE GILLEY, FL/OAS/CRCPD

15                    EUGENIA KRIMER, ACR (FOR GLORIA ROMANELLI, ACR)

16                    RICHARD MARTIN, ASTRO

17                    MIKE PETERS, SNM

18                    DOUGLAS PFEIFFER, AAPM

19

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

(12:04 p.m.)

MS. WASTLER: Welcome.

CHAIRMAN MALMUD: Good morning. Good afternoon.

MS. WASTLER: Well, I guess we are in the afternoon. Okay. We have everyone now with the exception of Dr. Eggli and Dr. Suleiman, who we knew were not going to be there. So we have a quorum. So I am going to go ahead with the remarks as the designated federal officer. And then I will turn the meeting over to you, sir.

CHAIRMAN MALMUD: Thank you.

MS. WASTLER: All right. As the designated federal officer for this meeting, I am pleased to welcome you to the telephone, I guess I should say, -- I am in Rockville -- for this meeting of ACMUI.

I am Sandra Wastler, the Chief of the Medical Safety and Events Assessment Branch. I have been designated as the federal officer for this Advisory Committee in accordance with 10 CFR part 7.11.

Present today is the alternative designated federal officer, Cindy Flannery. This is

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1 a --

2 (Interruption.)

3 MS. WASTLER: Somebody put us on hold.

4 CHAIRMAN MALMUD: Someone has us on hold.

5 MS. WASTLER: Yes. This is an announced  
6 meeting of the Committee. It is being held in  
7 accordance with the rules and regulations of the  
8 Federal Advisory Committee Act and the Nuclear  
9 Regulatory Commission.

10 CHAIRMAN MALMUD: Someone just joined us.  
11 Hello?

12 MEMBER MATTMULLER: This is Steve  
13 Mattmuller listening in.

14 MS. WASTLER: All right. Thank you, Mr.  
15 Mattmuller.

16 This meeting was announced in the Federal  
17 Register notice on -- what was the date, Ashley? I  
18 have forgotten. I forgot the --

19 MS. TULL: November 26th.

20 MS. WASTLER: November 26th. The function  
21 of the Committee is to advise the staff on issues and  
22 questions that arise on the medical use of byproduct  
23 materials.

24 The Committee provides counsel to the  
25 staff but does not determine or direct the action or

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1 decisions of the staff or the Commission. The NRC  
2 solicits the reviews of the Committee, and it values  
3 their opinions.

4 I request, whenever possible, we try to  
5 reach consensus on the procedural issue we will be  
6 discussing today and would recognize there may be  
7 minority or dissenting opinions. If you have such an  
8 opinion, please allow them to be read into the record.

9 At this point I have already gone through  
10 and recognized the individuals in attendance at the  
11 meeting today. With that, Dr. Leon Malmud will chair  
12 today's meeting, and I will turn that meeting over to  
13 him.

14 CHAIRMAN MALMUD: Thank you.

15 MS. WASTLER: Before we do that, I would  
16 just like to point out that there are several people  
17 with me here in the room. And I am going to ask them  
18 to go around and introduce themselves.

19 MS. HOWE: Donna-Beth Howe.

20 MS. FLANNERY: Cindy Flannery.

21 MS. LEWIS: Doris Lewis.

22 MR. WHITE: Duane White.

23 MR. HUFFERT: Tony Huffert.

24 MS. WASTLER: All right.

25 MS. TULL: This is Ashley Tull. I would

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1 also remind anyone who speaks to identify themselves  
2 for the court reporter.

3 CHAIRMAN MALMUD: Thank you.

4 MS. WASTLER: Are there any members of the  
5 public on the line?

6 MS. KRIMER: Eugenia Krimer is sitting in  
7 for Gloria Romanelli.

8 MS. FAIROBENT: Lynne Fairobent, AAPM.

9 MR. PFEIFFER: Doug Pfeiffer, AAPM.

10 MR. MARTIN: Richard Martin with ASTRO.

11 MS. GARDNER: Emily Gardner and Chris  
12 Gallagher with ASNC.

13 MR. PETERS: This is Mike Peters from SNM.

14 MS. WASTLER: All right. Thank you very  
15 much.

16 Dr. Malmud, I will turn the meeting over  
17 to you.

18 CHAIRMAN MALMUD: Thank you. This is Leon  
19 Malmud.

20 The past several years the National  
21 Academies has been conducting a study of industrial  
22 kind of research and commercial uses for radiation  
23 sources.

24 In response to this, this is actually in  
25 response to congressional concerns that radiation

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1 sources could be purchased or stolen for terrorists by  
2 use in dirty bomb attacks on the United States.

3 Does someone want to say something? Okay.  
4 I'm picking up an echo. All right.

5 The goal of the study was to identify  
6 industrial or other processes that could be replaced  
7 with economically and technically equivalent or  
8 perhaps even improved process that did not require the  
9 use of radiation sources or perhaps using a radiation  
10 source that would pose a lower risk in the event of an  
11 accident or an intentional attack involving a  
12 radiation source. The Energy Policy Act of 2005  
13 actually directed the NRC to enter into an arrangement  
14 with the National Academies to conduct that study.

15 Once the results of that study are issued,  
16 the NRC will have only a few days to review the report  
17 and to provide comments. The NRC's comments will be  
18 focused on the NRC's mission, which is safety and  
19 security of radioactive material. The NRC believes  
20 that it's vital for Congress to also understand any  
21 potential impacts on the practice of medicine, which  
22 would result from the report and the recommendations.

23 In other words, the NRC, quite simply,  
24 wants Congress to be aware that any restrictions on  
25 existing uses of radioactive material could impact the

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1 actual practice of medicine.

2 So, in order to provide the NRC with  
3 ACMUI's comments in the time frame necessary, we  
4 really had to do this, which is a slight change in  
5 ACMUI's normal procedure.

6 Given our own professional schedules, the  
7 requirements of a notice of a meeting for the full  
8 Committee, meaning the full ACMUI, which requires ten  
9 days' notice prior to the meeting, did not really give  
10 us time to have a meeting in Rockville, but we could  
11 schedule this teleconference.

12 We need to give the NRC our impressions  
13 about what needs to be done in order to assure that  
14 whatever changes are made in the availability or  
15 restrictions on use of radioactive material do not  
16 negatively impact the practice of medicine and the  
17 delivery of patient care within the United States.

18 So, as the Chair of the Committee, I  
19 thought that Drs. Vetter and Nag by virtue of their  
20 technical expertise would adequately represent the  
21 views of the full ACMUI in this particular issue.

22 It is also, I believe, our opportunity to  
23 voice any "practice of medicine" issues directly to  
24 Congress. Therefore, we wanted to brief the full  
25 Committee regarding the issue. And this needs to be

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1 done in a timely fashion so that when we are asked for  
2 our opinion, we can respond with the opportunity to  
3 have given it prior thought.

4 So, basically, the purpose of the meeting  
5 is to voice our concern on behalf of patients  
6 regarding the practice of medicine and possible  
7 restrictions that might occur to the practice of  
8 medicine with tightening of the availability or the  
9 use of certain radioactive materials.

10 Is what I have said clear?

11 PARTICIPANT: Yes.

12 MS. WASTLER: Dr. Malmud, this is Sandra  
13 Wastler. Could I clarify a couple of points?

14 CHAIRMAN MALMUD: Please do.

15 MS. WASTLER: I think what we want to make  
16 clear is that because of schedule requirements by FACA  
17 with regards to setting up a meeting of the full  
18 Committee and to getting it in the Federal Register  
19 notice, that it takes like three weeks to schedule a  
20 full Committee meeting if everybody happens to be  
21 available.

22 What we're faced with is that when this  
23 report comes out -- and in a minute, I'm going to ask  
24 Tony Huffert, who is with Research, to give you just  
25 an overview of, you know, the requirements or the

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1 contractual requirements with regards to this  
2 document.

3 But we have only a day or two essentially  
4 to turn these comments around. So what Dr. Malmud and  
5 what we were trying to come up with was a mechanism by  
6 which ACMUI as a body could provide their comments.

7 And the only way we could figure to do  
8 this was to, as Dr. Malmud said, appoint a  
9 subcommittee and get the full Committee to give the  
10 subcommittee authorization to speak for them so that  
11 when the subcommittee would comment on this report,  
12 those comments would be basically the full ACMUI's  
13 comment. And then after the fact, the full Committee  
14 would be briefed on the report and its  
15 recommendations.

16 So that is basically the direction that we  
17 are trying to go. You know, we want to provide the  
18 members with an opportunity to have their voice heard  
19 along with ours to Congress essentially on this topic.  
20 And we're just trying to figure out a procedural way  
21 of doing so. And this was the approach that we had  
22 come up with that was really, we felt, the only viable  
23 way to proceed.

24 And, with that, I will ask Tony if he  
25 could give you just a very quick overview of the I

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1 guess contractual side of the NAS report. And maybe  
2 he can tell us what the latest is on when the report  
3 will be issued.

4 MR. HUFFERT: Thank you, Sandi. I'm Tony  
5 Huffert. I work in the Office of Nuclear Regulatory  
6 Research at the U.S. NRC here in Rockville. And one  
7 thing that the Office of Research does with the  
8 National Academies is enter into these types of  
9 contractual arrangements with a study.

10 Now, this study was directed by Congress.  
11 And the NRC was directed to work with the National  
12 Academies on this topic. That direction, as Dr.  
13 Malmud said, was from August 2005, the Energy Policy  
14 Act. And since that time, I have been working very  
15 closely with the National Academies in providing them  
16 technical information so they could write a report.

17 They have about a dozen experts, including  
18 someone from the medical community, working on this  
19 report. And they are looking at a wide variety of  
20 source applications. But these are typically the very  
21 high-activity sources, not the lower-activity sources.

22 What we do with the National Academies is  
23 we provide them with as much technical information as  
24 they need. And then they go off by themselves and  
25 write a report.

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1           After the report is prepared, the NRC is  
2 offered an opportunity to review it very quickly for  
3 information security purposes. Basically we want to  
4 make sure that the report does not contain any  
5 information that could be useful to a terrorist  
6 organization.

7           After we conduct that review, the NRC has  
8 completed its job of supplying information to the  
9 National Academies. And it's up to them to resolve  
10 any comments on the report or come up with a  
11 publications schedule.

12           So where we are right now in the process  
13 is it's up to the National Academies to prepare a  
14 final report and issue it. When they issue it, they  
15 would brief the NRC and Congress within 24 hours, and  
16 it would be available on their Web site almost  
17 immediately.

18           As far as schedule is concerned, I think  
19 the National Academies might be rolling out the report  
20 in the next several weeks. I don't think that this  
21 will happen before the holidays, but with the National  
22 Academies, you never know. They only have to give the  
23 NRC a very short time before they go forth with their  
24 own independent process.

25           MS. WASTLER: We only have a very short

1 time to effect any comments on that document to the  
2 National Academy and to Congress after they make the  
3 report public. And that is the issue that we are  
4 trying to deal with.

5 MR. HUFFERT: And, again, the National  
6 Academies is an independent organization. It is not  
7 part of the federal government. They report directly  
8 to Congress. And they have their own independent  
9 process, and they are very careful not to release  
10 information about the report prior to briefing the  
11 study sponsor, which is the NRC, and Congress.

12 MS. WASTLER: I just wanted to clarify the  
13 points from Dr. Malmud and provide you with background  
14 as to why we have requested this full ACMUI meeting  
15 and why Dr. Malmud is proposing a motion, I believe,  
16 or will be that the ACMUI give the subcommittee  
17 authority to speak on his behalf on this issue so that  
18 we can in the appropriate timely manner provide both  
19 ours and your comments on this document when it is  
20 released.

21 MEMBER NAG: This is Dr. Nag. May I just  
22 interject one comment?

23 CHAIRMAN MALMUD: Please do, Dr. Nag.  
24 This is Malmud.

25 MEMBER NAG: Yes. Basically this is for

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1 my fellow ACMUI members. There are two options. In  
2 that short time of one or two days, the whole  
3 Committee cannot provide the input because we cannot  
4 meet in one or two days.

5 So the options are either for the ACMUI  
6 not to have any voice or to have one or two select  
7 members of ACMUI be the subcommittee members and talk  
8 on behalf of the whole ACMUI. And basically the ACMUI  
9 members would have selected the one or two members to  
10 be its voice. I think that is my summary for the rest  
11 of the ACMUI members.

12 CHAIRMAN MALMUD: Thank you, Dr. Nag.

13 Are there questions of Dr. Nag or myself  
14 regarding this process?

15 MEMBER LIETO: This is Ralph Lieto. I  
16 have two questions.

17 CHAIRMAN MALMUD: Yes, Ralph?

18 MEMBER LIETO: Is this applying to all  
19 radioactive sources or is this just Category I and II  
20 sources? That is my first question.

21 MR. HUFFERT: The answer is yes. The way  
22 the Congress set up this particular requirement was  
23 that the National Academies would only be able to look  
24 at Code of Conduct Category I and II sources.

25 MEMBER LIETO: Okay. Which narrows it

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1 down, I think, quite a bit from the medical side.

2 A second question is, was there  
3 consideration given to other members if other members  
4 were interested in viewing this and providing comments  
5 to the subcommittee?

6 CHAIRMAN MALMUD: Yes, Ralph. This is  
7 Malmud again.

8 The turnaround time for us to consider the  
9 problem was brief. And it seemed to me that given the  
10 membership of the Committee, a radiation physicist and  
11 a radiation oncologist, that we would have adequate  
12 coverage within these two disciplines to discuss the  
13 impact on clinical medicine. My own background, of  
14 course, is nuclear medicine. So we add that to it.

15 And we believed that this small  
16 subcommittee could deal with the issue on behalf of  
17 the whole Committee in the time frame allowed,  
18 recognizing that there are security issues involved.

19 No member of the Committee was chosen  
20 because of his or her security clearance, but we had  
21 to keep the number small. And we're discussing a  
22 theoretical issue.

23 Does that answer your question, Ralph?

24 MEMBER LIETO: Yes. Thank you.

25 CHAIRMAN MALMUD: Thank you.

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1           Okay. So we understand the process, which  
2           is that we're going to be asked to give a quick  
3           response to a recommendation that has not yet come  
4           forth. And we thought that by addressing it in this  
5           manner we could recognize the concerns of all of us,  
6           particularly since the radiation physicist crosses  
7           disciplines of radiology and nuclear medicine  
8           radiotherapy.

9           MS. WASTLER: Dr. Malmud, did you want to  
10          make a motion for the Committee?

11          CHAIRMAN MALMUD: Yes, I will. In this  
12          unusual circumstance, perhaps I should ask either Dr.  
13          Vetter or Dr. Nag, who are members of the  
14          subcommittee, rather than myself, to make the motion.

15          MS. WASTLER: That would be fine.

16          CHAIRMAN MALMUD: Thank you. Either Dr.  
17          Nag or Dr. Vetter?

18          MEMBER NAG: I will try. I make the  
19          motion that a subcommittee comprising of Dr. Vetter  
20          and Dr. Nag review the recommendation when it is  
21          released and immediately make its recommendation on  
22          behalf of the entire ACMUI in terms of the medical  
23          implications of the report.

24          MEMBER VETTER: This is Dick Vetter. I  
25          second the motion.

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1 CHAIRMAN MALMUD: Thank you, Drs. Nag and  
2 Vetter. Is there discussion of the motion?

3 MEMBER SCHWARZ: This is Sally Schwarz.  
4 I just wanted to clarify Dr. Nag's motion that it's  
5 the National Academy document that we're speaking in  
6 reference to.

7 MEMBER NAG: Right.

8 CHAIRMAN MALMUD: That is correct.

9 MEMBER NAG: This is the National  
10 Academies document that was endorsed by the NRC in  
11 response to the Congress.

12 MEMBER SCHWARZ: Right. I just thought  
13 that should be part of the motion, --

14 MEMBER NAG: Yes, right.

15 MEMBER SCHWARZ: -- the name of the  
16 document.

17 CHAIRMAN MALMUD: Thank you. The motion  
18 will be amended to include that phrase. Any further  
19 discussion?

20 (No response.)

21 CHAIRMAN MALMUD: If not, all in favor?  
22 I'm sorry.

23 MEMBER THOMADSEN: Yes.

24 CHAIRMAN MALMUD: Who is speaking?

25 MEMBER THOMADSEN: This is Bruce

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1 Thomadsen.

2 I do have the utmost confidence in that  
3 subcommittee. I think that this is a reasonable way  
4 to address the issue. If it is going out in the name  
5 of the entire ACMUI, I think it would be good if when  
6 you get the report that you do send it to the  
7 Committee and give them the opportunity should they  
8 have it to look at the report and make suggestions to  
9 that Committee.

10 MEMBER NAG: The problem that -- I mean,  
11 that is what we would have liked also, but the problem  
12 is that we have about 24 hours. And in that 24 hours,  
13 to look at it, review it, and then get the concurrence  
14 of the entire ACMUI is not possible.

15 We looked at it at several different ways.  
16 And what you are suggesting would have been the best  
17 way, but, unfortunately, this is an unusual  
18 circumstance. So we had to find a way to circumvent  
19 this unusual circumstance.

20 This is not the way we normally would do  
21 it in ACMUI. And I'm sure the other members of ACMUI  
22 realize that this is not the way we have ever done it.

23 MEMBER THOMADSEN: This is Thomadsen  
24 again. I understand everything you have said. I  
25 understood that up to this point. And you have

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1 changed part of what I was asking.

2 I was not asking for getting any type of  
3 a concurrence from the members. I am asking that they  
4 get the report and if in the time frame allowed they  
5 have comments to send to the subcommittee that that be  
6 allowed so that we would have that opportunity to be  
7 able to have the input, whether we take it or not.

8 And the subcommittee doesn't have to wait.  
9 As a matter of fact, they can't wait.

10 MS. WASTLER: Right. Dr. Thomadsen, Dr.  
11 Nag, if I could comment?

12 MEMBER NAG: Sure.

13 MS. WASTLER: What Dr. Thomadsen is  
14 suggesting, if I am understanding him correctly, is  
15 that when the report becomes public and it goes up on  
16 the web site, the subcommittee would come in, do the  
17 review as through the motion, would review the report.

18 But it will be on their public web site.  
19 And, therefore, if a member chooses, it can read the  
20 report and could send comments to you for your  
21 consideration.

22 You would not go back to them. You know,  
23 if you decide, the subcommittee would decide whether  
24 to include those comments or not. But it would be an  
25 opportunity at least for them to look at it if they

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1 are able and provide you with some views on the issue.

2 MEMBER NAG: Yes. I think that is --

3 MS. WASTLER: That is doable, but it would  
4 still be -- you would only have two days. You know,  
5 essentially the subcommittee would, you know, be  
6 looking at the report and putting together the  
7 document we need to go back to Congress.

8 And if other members can read it and have  
9 some comments, they could provide them to you. It's  
10 just that the subcommittee would be marching on,  
11 speaking for the full Committee, and trying to take  
12 comments where and if available members want to make  
13 them. I mean, I think that's doable.

14 MEMBER THOMADSEN: This is Thomadsen  
15 again.

16 Would the NRC staff be so kind as to send  
17 out an announcement to the Committee when the report  
18 is released? Otherwise --

19 MS. WASTLER: Oh, of course.

20 MEMBER THOMADSEN: -- we're likely to miss  
21 that.

22 MS. WASTLER: That would be very easy for  
23 us to do.

24 MEMBER THOMADSEN: Thank you.

25 MS. WASTLER: When it is on the web site,

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1 we can send you an e-mail saying it's up, the  
2 subcommittee is reviewing it, and if you have  
3 comments. I mean, we can give you a single point of  
4 contact with us where we could get those comments to  
5 Dr. Vetter and Dr. Nag.

6 MEMBER THOMADSEN: Wonderful.

7 CHAIRMAN MALMUD: This is Malmud.

8 Dr. Thomadsen, does that satisfy your  
9 request?

10 MEMBER THOMADSEN: Yes.

11 CHAIRMAN MALMUD: Thank you. Any further  
12 discussion of the motion?

13 (No response.)

14 CHAIRMAN MALMUD: If not, all in favor?

15 (Whereupon, there was a chorus of

16 "Ayes.")

17 CHAIRMAN MALMUD: Any opposed?

18 (No response.)

19 CHAIRMAN MALMUD: Any abstentions?

20 (No response.)

21 CHAIRMAN MALMUD: Hearing no opposed and  
22 no abstentions, the motion is unanimous.

23 MS. TULL: This is Ashley Tull. I just  
24 wanted to thank the Committee for doing this within  
25 the 30 minutes allotted. I really appreciate it.

**NEAL R. GROSS**

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1 Those of you that I talked to, I told you it was  
2 possible.

3 CHAIRMAN MALMUD: Well, you have a  
4 Committee that has made it possible.

5 MS. TULL: Yes. Thank you very much.

6 MS. WASTLER: And I just want to thank the  
7 members very much for this. We appreciate it. Thank  
8 you, and have a good day.

9 CHAIRMAN MALMUD: We thank you all.

10 (Whereupon, the foregoing matter was  
11 concluded at 12:30 p.m.)

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