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Patient Release Information Collection

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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PUBLIC MEETING

SODIUM IODINE I-131

PATIENT RELEASE INFORMATION COLLECTION

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THURSDAY

JANUARY 21, 2016

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ROCKVILLE, MARYLAND

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The meeting was convened in room T-2B3
of Two White Flint North, 11545 Rockville Pike, at
9:00 a.m., Donna-Beth Howe, Ph.D., presiding.

STAFF PRESENT:

DONNA-BETH HOWE, Ph.D., Senior Health
Physicist, Medical Radiation Safety Team
GENE CARPENTER, NMSS, Facilitator

ALSO PRESENT:

GARY BLOOM, Thyroid Cancer Survivors'
Association
SUE BUNNING, Society of Nuclear Medicine and
Molecular Imaging
MUNIR GHESANI, M.D., Mount Sinai St. Luke's
and Mount Sinai West
CAITLIN KUBLER, Society of Nuclear Medicine
and Molecular Imaging
MIKE LICHTY, *unaffiliated*

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P R O C E E D I N G S

9:07 a.m.

MR. CARPENTER: Good morning.

My name is Gene Carpenter. I am an NRC Meeting Facilitator.

Thank you for standing by with us. For those of you who are not in the Washington, D.C. area, we had a significant snowfall amount, almost an entire inch, last night. So, that made everything a little crazy around here, and we are just trying to get started a little bit today.

This is the Workshop for Sodium Iodine, I-131, Patient Release Information Collection, public workshop. We have an agenda on the NRC website. I do recommend that you take a look at that.

The presentation will be made today by Dr. Donna-Beth Howe, and it will be in several parts. We're going through the introduction phase right now. In just a moment, we will start with the website information. We have at 10:30 the Patient/Licensee Acknowledgment Form and Best Practices in Making Informed Decisions on Releasing Patients Treated with I-131 Based on Radiation Exposure Considerations.

Beth, you couldn't make that a little longer? Never mind.

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1 (Laughter.)

2 DR. HOWE: I tried.

3 MR. CARPENTER: And then, at noon we will
4 break for lunch. And at one o'clock we will come
5 back and start with Guidance for Released Patients,
6 and at 2:30, the Brochure for Nationwide Use, and
7 Conclusion.

8 We have set out these times. So, we will
9 try to stick to those times. If any one session ends
10 a little bit early, in case there is somebody who
11 wants to specifically check on that one session, the
12 10:30, the one o'clock, the 2:30 one, we will start
13 approximately at that time for those. So, we may put
14 you back on hold for a time period from there.

15 For the people in the room, if there is
16 an emergency of any kind, we have to evacuate the
17 building, please follow an NRC staff member.

18 We do have restrooms right outside door.
19 You do not need to be escorted to those, and they are
20 through the door, into the hall, left and right,
21 male/female.

22 As we continue through this, as I said,
23 we will be going through this, the meeting is being
24 transcribed. That will be available later, once
25 transcription is complete and we have had a chance to

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1 take a look at it.

2 Dr. Howe will be giving the presentation.
3 What we will be doing is setting up, once she gives
4 her presentation, we will go for the comments or the
5 questions. What I would like to do is, for this
6 first round, for the website information, once she
7 completes that, we will go around the room, see if
8 there's any questions or comments. And then, I will
9 ask the operator, Christine, to open the lines for
10 anyone who would like to participate from the
11 telephone. At that time, she will tell you to do *1
12 to request to speak.

13 As we mentioned, there is the option for
14 anonymity. If you don't wish to give your name, you
15 do not have to. If you do wish to give your name,
16 certainly feel free to do so.

17 At this time, I would like to turn this
18 over to Dr. Howe and go into the presentation.

19 DR. HOWE: Thank you, Gene.

20 The first thing I would like to cover is
21 NRC is collecting information on patient release and
22 what sodium iodide treatments. And what treatments
23 are we hoping to collection information on?

24 Well, it is both the treatments for
25 hyperthyroidism and for thyroid cancer patients. We

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1 have had some responses from the public that thought
2 that it was only for thyroid cancer patients, but we
3 are also looking for the hyperthyroid information,
4 too.

5 Who do we hope is going to provide the
6 information? Because we are focusing on patient
7 information, patient instructions, and patient and
8 physician decisions, we really want to hear from
9 patients; we want to hear from patient advocacy
10 groups; we want to hear from individual physicians on
11 their experience; we want to hear from licensees;
12 different professional organizations; agreement
13 states; our Advisory Committee on Medical Isotopes,
14 and any other interested individuals that have an
15 interest in I-131 patient release issues.

16 Now we are not talking about rulemaking
17 changes. We are collecting information that we hope
18 to use to improve our guidance to the medical
19 community and to patients.

20 What are we asking for? We are asking
21 for existing information. We are asking for those
22 that respond to us to give their experience. In some
23 cases we have asked for information in four different
24 categories. One is on websites, procedures and
25 processes that you, either as a physician or as a

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1 patient, might recommend.

2 And we want responses based on your
3 personal experience. So, we are not asking anybody
4 to generate new information. We are not asking any
5 groups to go out and develop any new information for
6 us. This is really what are people doing; how are
7 they doing it, so that we better understand how we
8 can make sure information is clear and concise.

9 Specifically, I have four topics. This
10 information collection is described in a Federal
11 Register notice. If you are part of our medical list
12 server or you have looked at our public meeting site,
13 we have tried in all cases to make sure that the
14 Federal Register notice that really outlines the
15 information we are collecting and the depth that we
16 want is available to you. If it is not, if you don't
17 have it and you would like a copy, then I have got
18 information on later slides that tell you how to get
19 in touch with me and I will send The Federal Register
20 notice out to you.

21 It is not long. It is only four pages.
22 We are hoping it is in a level of language that
23 everyone can understand. So, we tried not to make
24 it too technical.

25 Okay. We have four topics. The first

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1 one is information responsive to patient concerns
2 about medical treatment involving the use of I-131.

3 Where do patients go to get information?
4 What do patients think are really good sites? And
5 most of this information we are expecting will be
6 website locations.

7 We are looking for information that
8 physicians use to make decisions on when it is safe
9 to release I-131 patients. We are assuming that is
10 a dialog between physicians or other members of the
11 licensee's staff with patients to determine that it
12 would be reasonable to release patients. And that
13 release can be immediate or it can be delayed. We
14 are not making any distinction.

15 The third topic is the radiation safety
16 information to be used by patients once they are
17 released. So, you will see a theme. One is the
18 information patients want to know before they get the
19 treatment; the other is the information that the
20 patient and the licensee share to make a good decision
21 on when to give the treatment and, also, when to
22 release the patient. The third one is, what
23 information will help the patient make sure that doses
24 to other members of the public are as low as
25 reasonably achievable.

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1 And the fourth topic is a brochure that
2 people think can be distribution on a nationwide basis
3 that will help provide some clarity on these issues.

4 This is an information collect effort,
5 and you have two different methods to submit
6 information on this information collection. One is
7 electronically, and I have got the information on
8 this particular slide, where you go into
9 www.regulations.gov. You search for the docket
10 number NRC-2015-0020, and provide an electronic copy
11 of what you want to submit to the NRC.

12 Now our public meeting today, we
13 certainly will be available to answer questions if
14 you are not sure what we are looking for. We are
15 looking for more of a dialog between the different
16 groups, so that we can hear on a real-time basis what
17 people are doing.

18 But I must emphasize that, in order for
19 us to process the information, we are going to have
20 to have you submit it to us officially, either
21 electronically or in mail form, to Cindy Bladey in
22 the Office of Administration and to the Nuclear
23 Regulatory Commission. And that information is on
24 the slides. They are also on our meeting notice
25 website.

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1 So, if you end up with any questions about
2 electronic submissions, we have a point of contact,
3 and that is Carol Gallagher. You can email her at
4 carol.gallagher@nrc.gov or you can call her at
5 301-415-3463. If you have any technical questions
6 or clarifications, then you can certainly call me.
7 My phone number is 301-415-7848 and my email is
8 donna-beth.howe@nrc.gov.

9 All of this information is located in The
10 Federal Register notice. So, if you didn't get a
11 chance to copy it and you need a copy of The Federal
12 Register notice, you will find the information is in
13 there also.

14 So, our first topic of the day is the
15 website. For the website information collection, we
16 would like for members of the public to identify
17 websites that provide potential patients with
18 information on radioactive iodine treatment
19 procedures, so the patient will understand their
20 medical condition, the reason for the I-131
21 procedures, the process, how to reduce radiation
22 exposure to others.

23 If you look at our Federal Register
24 notice, you will see that we have put a number of
25 bullets or subtopics in each topic. We do not

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1 consider those to be all-encompassing. We have
2 always put a statement in there that says, if you
3 think there is something else that should be
4 addressed, let us know. If you think we have
5 something in here that is not really that important,
6 let us know and let us know why not.

7 So, we are really asking open-ended
8 questions because we are trying to collect
9 information. This is not the normal type of
10 information collection that you see from the NRC where
11 we ask for a survey, we ask for simple yes/no or
12 multiple choices. We are really looking for
13 information that you have and information from your
14 personal experience.

15 So, what do we want you to submit for the
16 website? We would like for you to identify the
17 website. We would like for you to indicate the topic
18 that it addresses, and we would like to have you
19 provide us with a link to that specific information.
20 We know there are some general websites out there
21 that have a lot of information, but you really have
22 to do a lot of navigating to get down to specific
23 information.

24 I could use an example of the NRC website.
25 We think it is very clear to us how to navigate it,

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1 but we know, when we talk to the members of the
2 public, we have to provide a lot more information.

3 So, in this case if there is a specific
4 topic on, say, the medical use of I-131, then
5 reference that topic, give us a specific link to that
6 website that you think provides good information
7 there. We are trying to make it as clear and as
8 simple as possible for people to respond.

9 So, I think we can now open it up.

10 MR. CARPENTER: Okay. Thank you very
11 much, Donna-Beth.

12 DR. HOWE: Yes.

13 MR. CARPENTER: As mentioned before, we
14 will go around the room and, then, we will go to the
15 telephones. So, anybody in the room have any
16 comments they would like to make?

17 MR. BLOOM: Good morning.

18 Do I need to say my name?

19 MR. CARPENTER: You can, but you don't
20 have to.

21 MR. BLOOM: I'm Gary Bloom. I'm the
22 Executive Director of ThyCa, Thyroid Cancer
23 Survivors' Association and I am a 20-year papillary
24 thyroid cancer survivor.

25 As far as identifying a website, ThyCa

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1 has a very extensive website. It is WWW. T, as in
2 Thomas, H-Y-C-A.-O-R-G. We believe that it follows
3 the entire patient journey from diagnosis through
4 treatments, including radioactive iodine, testing and
5 ablation, if and when necessary; also, discussing
6 precautions that should be utilized.

7 Our materials are all medically reviewed
8 by a very large medical advisory council. And so,
9 wherever there is medical-related information, it has
10 all been medically reviewed. It is not people like
11 me, patients, who are just laypeople giving medical
12 opinions, because we are not suited to do so.

13 So, we encourage use of our website.
14 And, yes, as really Donna-Beth said, there is a lot
15 of material to go through. So, people will have to
16 spend some time, but it is meant as, it is a resource,
17 so people can come and go as different parts of their
18 journey become more relevant.

19 And then, also, we have support groups
20 that we identify on our website, both face-to-face
21 and electronic, where people can go to speak to people
22 about their own experiences. Again, that is not
23 medical advice. It is meant to share experience, to
24 try to help people either create clarification in
25 their journey or to help them coalesce ideas for

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1 questions to ask their medical practitioners when the
2 opportunity presents itself.

3 Thank you.

4 DR. HOWE: Thank you, Gary.

5 I think one point I need to make is NRC
6 is thinking about setting up a website where we have,
7 essentially, topics or high-level items and, then, we
8 would reference over to other websites for that
9 particular item. So, it might be think of our website
10 as kind of an index and, then, over to other websites.

11 So, members of the public should think in
12 those terms and look at our list of topics and see if
13 the topics are adequate or they are too much or they
14 are too little, and specific links to pieces of that
15 information.

16 The other point is NRC normally does not
17 get into the practice of medicine and we normally
18 stay away from really medical issues, other than our
19 regulatory. But, in this particular case, our
20 Commissioners have asked us to try to make a place
21 where people can find clear and consistent
22 information. So, your sites would be a part.

23 MS. KUBLER: Excuse me. Hi. I am
24 Caitlin Kubler. I am with the Society of Nuclear
25 Medicine and Molecular Imaging.

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1 We submitted comments on the website
2 reviews during the last collection information period
3 that NRC had open. We actually reviewed about 15
4 different websites and we provided the linking. We
5 will be happy to submit that information again.

6 But one of the things that we did, in
7 addition to submitting the topic and the website link,
8 was to rate the website on a scale of 1 to 5, 1 being
9 the least helpful and 5 being the most helpful. And
10 then, we also clarified which audience it would be
11 good for.

12 I noticed two kinds of themes we are
13 looking at, patient information and, then, we also
14 reviewed guidelines that physicians would give to
15 patients. So, that area was also addressed.

16 And so, we do believe that the specific
17 brochure that we have developed would still be
18 beneficial to the NRC to consider. We will be happy
19 to submit that again.

20 As well, we believe that the ATA
21 guidelines are good. They might be a little
22 outdated, but I want to go ahead and mention that.

23 We do have a member representative, Munir
24 Ghesani, who is, unfortunately, running a little bit
25 late. But he will be here and he will talk about

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1 some of the patient experiences.

2 We actually formed a work group, and we
3 are hoping to address some of the areas that Donna-
4 Beth had mentioned in the past. I know we have a lot
5 of urban and city information, but how are some of
6 the rural facilities handling things and the
7 information specifically given the patients? You
8 know, you need to consider the specific patient
9 circumstances. Hopefully, when Munir gets here, he
10 can talk a little more about that and some of the
11 experiences that we addressed in our work group.

12 I don't know if, Sue, you want to mention
13 anything else?

14 MS. BUNNING: Hi. Sue Bunning.

15 MR. CARPENTER: Sorry, if you will come
16 up to the microphone, please?

17 MS. BUNNING: The only other thing is,
18 if you go to the SNMMI website, I think that there is
19 a lot of information on both the physician guidance
20 side as well as the patient side. And in reviewing
21 it, it is a lot of information and it is sometimes
22 very hard to find.

23 So, we over the last year have upgraded
24 some of the search capabilities for our website. But
25 one of the tasks we have is to go back and see if

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1 there is a better way to package all of the
2 information because I think we want to be sure online
3 we have all of that. So, we are working on that
4 internally, and we are hoping to get some more
5 information out of this meeting and what is coming,
6 to see how we might package a little bit more neatly
7 for when the patients and physicians go to our site.

8 DR. HOWE: Thank you.

9 MR. CARPENTER: Okay. No other comments
10 in the room?

11 (No response.)

12 In that case, Christine?

13 OPERATOR: Thank you.

14 MR. CARPENTER: If you can go ahead and
15 open up the lines, please?

16 OPERATOR: Yes, sir.

17 At this time, if you would like to ask a
18 question, please press *, then 1. If you are asking
19 anonymously, you will receive an identification
20 number prior to asking your question. Once again,
21 to ask a question at this time, press *, then 1. And
22 if you would like to withdraw the question, press *,
23 then 2.

24 One moment, please.

25 MR. CARPENTER: Thank you.

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1 OPERATOR: The first question comes from
2 No. 1. You may ask your question.

3 ANONYMOUS: Yes, thank you for the
4 opportunity.

5 I just would like to point out to NRC
6 staff that the webcast is about 15 to 20 seconds
7 delayed from what is coming over the telephone bridge.
8 In fact, the last speaker cut out several times. So,
9 it was pretty, very difficult to understand exactly
10 what her point was. So, I just kind of want to point
11 this out to staff, so maybe somebody can kind of tweak
12 this, so that the webcast portal and the bridge line
13 are in sync.

14 Thank you.

15 DR. HOWE: Okay. We just got information
16 from my technical person. You have to look at the
17 bridge line and, then, use the telephone line for
18 communication because the telephone line is how we
19 assure that we have an orderly meeting.

20 (Off-the-record comments.)

21 MR. CARPENTER: Theron, I believe he is
22 saying that the slides themselves are a few seconds
23 behind what he is hearing. So, we will take that.
24 Thank you very much. We appreciate that heads-up.
25 This may be a technical problem that we are going to

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1 have to address, unfortunately, in future ones, but
2 we will try to be mind of that as we go forward.

3 DR. HOWE: And I think a point that we
4 want to make is that, in order for you to communicate
5 with us, you need to use the phone lines.

6 Theron was saying that, if you want the
7 verbal to match the slides exactly, you listen to the
8 webcast. But, in order to communicate with us, you
9 need to use the telephone line. Hopefully, that is
10 clear to everybody.

11 MR. CARPENTER: Thank you very much, sir.

12 Next question?

13 OPERATOR: At this time, sir, I'm showing
14 no further questions.

15 MR. CARPENTER: Okay. We will go around
16 the room one more time.

17 (No response.)

18 Nothing Further?

19 DR. HOWE: Okay.

20 MR. CARPENTER: Anything else from the
21 telephones, Christine?

22 OPERATOR: At this time, I'm showing no
23 questions.

24 MR. CARPENTER: All right. Again,
25 apologies to those who are listening-in from home.

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1 We will try to make sure that we take into account
2 the delay, and we will deal with that.

3 I'm showing the time as 9:30. So, we
4 have approximately one hour until our next topic. As
5 mentioned earlier, we were trying to maintain that
6 schedule. So that, if people dialed-in to listen to
7 one particular topic, that we would do that.
8 Otherwise, we would go through the entire
9 presentation at this rate very quickly, and anybody
10 who dialed-in later would not get the advantage of
11 that.

12 So, at this time, I'm going to ask that
13 we take a break and that we will continue at 10:30.
14 All right?

15 Christine, we will be back to you in
16 approximately 50 minutes.

17 Thank you.

18 (Whereupon, the foregoing matter went off
19 the record at 9:32 a.m. and went back on the record
20 at 10:29 a.m.)

21 MR. CARPENTER: Yes, this is Gene
22 Carpenter with the Nuclear Regulatory Commission
23 again. Thank you for your patience.

24 As mentioned earlier, we were going to go
25 right in accordance with the agenda. So, we are now

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1 at the 10:30, Patient/Licensee Acknowledgment Form
2 portion.

3 We have had a couple of more people join
4 us in the room. I don't know how many people are
5 online.

6 But we will going forward with this, so
7 we don't have such a long break after we get through
8 and break for lunch, in the afternoon we will start
9 again at approximately one o'clock for the Guidance
10 for Released Patients. And then, once that session
11 is done, instead of waiting until 2:30, if we get
12 done early, we will go ahead and roll through to the
13 Brochure for Nationwide Use, and Conclusion. That
14 way, hopefully, if need be or it supports it, we will
15 get done a little earlier today.

16 But, of course, if anyone on the phone
17 does need to get some more information, please contact
18 either Donna-Beth Howe or any of the other folks that
19 are listed on the session.

20 As I said, we are going to go into the
21 Patient/Licensee Acknowledgment Form. Dr. Howe will
22 give the presentation. This time, instead of
23 starting in the room, we will start on the telephone.
24 And once we have gotten through the telephone, we
25 will go to the people in the room.

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1 Dr. Howe?

2 DR. HOWE: Thank you, Gene.

3 So now, we have moved to the second topic
4 that we are collecting information on. This is the
5 part where the patient and the licensee or the
6 physician are interacting and really talking about
7 the disease and finding out information that helps
8 the licensee decide when to safely release the
9 patient. So, we are looking at the best practices
10 that are used by individual physicians and licensees
11 that focus on enhancing the ability to make informed
12 radiation safety decisions on their release.

13 And this release could be immediate or
14 this release could be hospitalization or this release
15 could be somewhere between the two. We are not making
16 any value judgments on this. We believe that in this
17 best practices there will be a dialog between
18 physicians and licensees and patients.

19 So, we are also looking to see if
20 physicians and licensees have acknowledgment forms.
21 We are looking for licensees to describe any policy
22 that provides a procedure that gives him confidence
23 that the patient is released at the appropriate time,
24 providing an acknowledgment form that both the
25 patient and the licensee may sign, that the dialog

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1 has occurred.

2 We are looking for responses from
3 patients and from physicians on what is the best
4 timing to have this dialog between the patients and
5 the licensee and when is the best time between the
6 dialog and the release. We are looking for patients
7 and other interested individuals' perspective on this
8 timeframe and on the interaction and the information
9 that is transmitted.

10 So, that essentially tells you what we
11 are looking for. All of this is talked about in more
12 detail in The Federal Register notice. You will see
13 a number of topics that we believe are probably key
14 topics in this discussion. Once again, we want to
15 reiterate that won't believe that they are all the
16 topics, nor necessarily are they the best topics.
17 So, we are looking for feedback from the general
18 public on if there are other topics they think are
19 more relevant or if they think that some of the topics
20 that we have listed are not really appropriate, to
21 give us that feedback and tell us why.

22 Once again, we are also looking for
23 experience. We know that there are some general
24 guidance documents that maybe the professional
25 societies put out, but maybe a physician has to modify

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1 that for their individual practice. That is the kind
2 of information we are looking for.

3 Now we have had a few public comments
4 received. The one thing I will say is that we are
5 looking for putting those procedures in perspective.
6 How do you use those procedures? How do you make the
7 decision? At what point do you make the decision?
8 And we are not looking for a long dissertation on
9 this. We are looking at maybe a sentence or two that
10 the puts the policy or the procedure into the right
11 perspective for how the decisions are being made.

12 So, at this point, I think we can open it
13 up for discussion and questions.

14 MR. CARPENTER: Thank you very much, Dr.
15 Howe.

16 All right. As I mentioned before, at
17 this time we are going to go to the telephones and
18 ask the folks that are on the telephone to *1, and
19 the operator will, then, key you in, so that you can
20 give your comments.

21 I do also recognize from earlier that
22 there is a delay on the webcast. So, there may be
23 some difficulties between syncing-up what is on the
24 screen and, also, the phone lines. We do appreciate
25 that challenge, and thank you for bearing with us on

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1 that.

2 As before, if you do not wish to give
3 your name, you can remain anonymous.

4 So, at this time, Operator, we would like
5 to go ahead and open for any questions or comments
6 from the line.

7 OPERATOR: Thank you.

8 Once again, if you would like to ask a
9 question or you have a comment, please press *, then
10 1. And to withdraw, you may press *, then 2.

11 One moment.

12 (Pause.)

13 At this time, sir, there are no
14 questions.

15 MR. CARPENTER: Thank you very much. We
16 will come back to the lines in a moment.

17 We will go around the room now. Any
18 comments in the room?

19 Yes? Please press the microphone.

20 Thank you.

21 DR. GHESANI: Hi. I'm Munir Ghesani from
22 SNMMI.

23 As a Society, we have polled a large
24 number of our end-users and trying to get the idea
25 about the best practices and how they manage. I can

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1 give you some insight into what our local practice
2 parameters are as well.

3 We, overall, work very closely between
4 the physicians, the technologists, and the radiation
5 safety department to plan out each and every patient's
6 treatment accordingly.

7 In terms of choosing the right approach,
8 in fact, back in the late nineties, we published an
9 article in Health Physics looking at, is there a way
10 you can quantify the exposure and see how you can use
11 that information in providing more customized
12 recommendations to the patients? If you want, I will
13 give you the reference later on about the article.

14 But one of the things we found was very
15 interesting was that sometimes the contact
16 restrictions and the impact of exposure to the family
17 and friends is very counterintuitive. You may have
18 a hyperthyroid patient with 70-80 percent uptake and
19 treated with 12- or 15-millicurie dose on one hand,
20 and you may have a thyroid cancer patient with a
21 really good surgery done, less than 1 percent uptake
22 in the neck on diagnostic scan and you are giving a
23 200-millicurie dose.

24 And when you look at the output of the
25 software in terms of what the restrictions are going

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1 to be, very interestingly, the one with the
2 hyperthyroidism ends up getting more long-term
3 contact restrictions than the one with the thyroid
4 cancer because the residual of remnant of less than
5 1 percent is the one that is going to hold on very
6 minimal activity as opposed to more than 99 percent
7 of the dose washes out very quickly.

8 So, we use that kind of data, that kind
9 of information in customizing the recommendations for
10 the patients and we make sure that we verify it with
11 our radiation safety. They look at the data and they
12 agree that that is the way to address the treatment
13 of the patients.

14 In fact, if at any point we find an
15 outlier in terms of the patient not being able to
16 follow the instructions or some kind of family or
17 social situations that can prevent them from getting
18 treated as an outpatient, we do not hesitate to
19 recommend that those patients should be treated as an
20 inpatient.

21 DR. HOWE: Thank you.

22 And I think that brings back the point
23 that, hopefully, I made early on, that we are not
24 just looking for experience from thyroid carcinoma
25 patients and practices, but we are also looking for

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1 experience from hyperthyroid patients and practices.

2 DR. GHESANI: Correct.

3 DR. HOWE: So that we can cover the whole
4 gamut.

5 MR. CARPENTER: Thank you.

6 Any other comments in the room?

7 MR. LICHTY: Hi. My name is Mike Lichty.
8 I was a thyroid cancer patient diagnosed late 1997,
9 had the surgery in 1997 and, then, radioactive iodine
10 treatment in January of 1998. So, that is 18 years
11 ago this month.

12 My experience with the radioactive iodine
13 treatment was fine. I had no real complaints. I was
14 treated at Washington Hospital Center and came in and
15 took the capsule -- it was several capsules -- and
16 was not allowed to be released, I think based on
17 Washington, D.C., radiation exposure regulations,
18 until my radiation levels being emitted, as measured
19 by some kind of little mini-Geiger counter, for lack
20 of a better term for it, until it met a certain level,
21 which turned out to be a little more than 24 hours,
22 maybe 26 to 28 hours. And then, I was supposed to
23 stay about 3 feet away minimum from people for 48 to
24 72 hours afterwards.

25 That was the protocol then. I don't know

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1 what it is exactly now. But I had no real problems
2 with it.

3 Beyond that, though, I do have -- one of
4 my younger brothers was diagnosed, probably about two
5 or three years ago, with his thyroid just wasn't
6 functioning properly. And his endocrinologist, of
7 course, the treatment was to have radioactive iodine,
8 a smaller dose than what I had, to just cease the
9 function of the thyroid and be put on Synthroid or a
10 thyroid replacement from then on.

11 I recall that my initial reaction was I
12 didn't think that was the right way to go about it.
13 So, I talked to my endocrinologist as well as his,
14 and they said it was. So, when he had the treatment,
15 it was a lower dosage, but he was able to do it as an
16 outpatient-type thing and go home and just maintain
17 safe distance, I think for 48 to 72 hours.

18 So, I have direct knowledge, and my
19 experience was fine, and indirect knowledge with my
20 brother, and everything went fine through that. That
21 is what I have to contribute to this discussion.

22 DR. HOWE: Thank you.

23 Any other comments?

24 MR. BLOOM: Do you want my name again?

25 DR. HOWE: If you want to.

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1 MR. BLOOM: Gary Bloom with ThyCa,
2 Thyroid Cancer Survivors Association.

3 As I had mentioned earlier, I am a thyroid
4 cancer survivor as well as Executive Director of an
5 association for thyroid cancer survivors. We, as a
6 population, have a perspective that what knowledge is
7 shared with the patient is very important, and it
8 gets to a few points that I made notes about.

9 The first factor is, is the patient
10 hypothyroid? Because people are still being treated
11 in a hypothyroid state versus using Thyrogen as a
12 part of the therapy. If a patient is hypothyroid,
13 oftentimes, their level of comprehension is
14 diminished. That means that it is very important
15 that the message from the medical professional has to
16 account for that, because, otherwise, it is like
17 talking to a bobblehead. There will be a head
18 nodding, but there is not always the digesting of
19 specialty information.

20 This is an experience, whether it is the
21 ablative dose or just a small testing dose. Being
22 treated with I-131 is a different experience than
23 most people experience. And so, there has to be a
24 message delivered, but there has to be the ability to
25 digest it. So, I think the dosing facility people

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1 need to know the health condition of the patient they
2 are working with, for one.

3 I would encourage in any circumstance,
4 but especially if a person is hypothyroid, that it
5 would be great to have a second set of ears in the
6 room, meaning a loved one or friend to the patient,
7 so there is the opportunity for better receipt of
8 instructions.

9 I am not here to question that facilities
10 give good instructions because, first of all, I have
11 very limited perspective. I have been treated at two
12 different facilities, and I can only speak from my
13 own experience. But I do believe most, if not all,
14 professionals are sharing good information, but that
15 doesn't mean it is being heard well or received well
16 or understood well.

17 And I feel like that is part of the
18 message out of this meeting, what do we do to improve
19 the receipt of information as much as what do we do
20 about the delivery of the information. So, having
21 more than one person hearing the information would be
22 good.

23 Also, the timing. In my life as an
24 advocate, I'm amazed how many people I have met who
25 have said their sequence of events was, "Here take

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1 this I-131. Now we're going to talk to you about
2 what precautions to take." Bad sequence. I don't
3 think that happens very often, but if it happened
4 once or twice, it is too many times.

5 So, it is very important that the
6 sequence be proper. It could be revisited after the
7 dosing, but there has to be a conversation in advance
8 of being treated, so that there is a good dialog.
9 What is the home situation? Is there somewhere for
10 the person to go to once they have received the I-131.

11 I'm sorry, I didn't get your name.

12 DR. GHESANI: Munir Ghesani.

13 MR. BLOOM: Dr. Ghesani?

14 DR. GHESANI: Yes.

15 MR. BLOOM: As Dr. Ghesani said, people
16 are being treated with I-131. What are we going to
17 do with them? There is a period of timeline we are
18 hot; we are radioactive. And so, the patient needs
19 to have a plan. Again, better to make that plan
20 before being treated than after.

21 So, to me, the messages are: are there
22 enough ears in the room for the patient to walk out
23 with good information? Does the patient actually
24 have mental acuity, hypothyroid versus Thyrogen?
25 Does the patient actually have mental acuity,

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1 regardless of hypothyroid or Thyrogen?

2 Again, I can only speak to a cancer
3 scenario. So, I am not discounting the hyperthyroid
4 patient being treated. But when a person is told
5 they have cancer, some people suddenly stop walking
6 on the planet earth in the same way. They are
7 anxious, and their ability to hear instruction, which
8 is specialty instruction because it is about their
9 health, is diminished. So, we always are encouraging
10 that that person have multiple set of ears with them.

11 But, also, just what is their ability to
12 digest this special information? This is not here
13 is how you walk to the grocery store or how you find
14 a loaf of bread. This is special information that
15 we are only going to hear for most of us once or twice
16 in our lifetime, and it is just out of the norm.

17 So, the person giving this instruction
18 has to be aware that the person receiving it is a
19 little off-balance potentially and that the
20 information being addressed is unique. We talk about
21 level of understanding in terms of just a general
22 educational perspective. We encourage lowering the
23 message down to a lower level of education, using
24 more routine words, less big technical terms, and
25 accounting for a language factor. We live in a

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1 melting pot.

2 I am reminded, when I lived in California
3 years ago, at the time you could take your driver's
4 test in 38 languages, which I thought was pretty
5 remarkable. Now most facilities can't handle that,
6 and I am not asking them to, but they need to make
7 sure that the patient can hear the message.

8 And what happens when the patient is not
9 a native English speaker and the doctor is an English
10 speaker or the technician is an English speaker? We
11 need to have a pathway to making sure that the message
12 is delivered and heard, again, not so much that the
13 message is delivered; how is it heard?

14 So, those are some of the points that in
15 my experience are very important to consider, and I
16 just wanted to share that.

17 Thank you.

18 DR. HOWE: Thank you.

19 DR. GHESANI: Can I make some followup
20 comments?

21 DR. HOWE: Yes, please do.

22 DR. GHESANI: I liked your points very
23 much. In fact, what we have done is that it is not
24 just hyperthyroidism that you can state, well, you
25 can't remember. All of us have information overload.

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1 Even as a patient when I go to my primary care, I am
2 mindful of the fact that I may not remember everything
3 and I am usually writing little notes on anything
4 that I need to take care of.

5 So, what we do is, in fact, we had
6 handouts for the patients and we encouraged them to
7 bring the family members with them. The other thing
8 which is very important is it is not just simply
9 giving the handout and saying, "Follow it." What we
10 do is, while they are waiting in the waiting room, we
11 give them the handouts. So, it gives them a chance
12 to review it and ask specific questions about the
13 contents that they are about to receive.

14 This way, when the consult takes place,
15 we can ask them to write specific customized questions
16 that they may have that they need to have additional
17 information about the points that we are writing in
18 the handout. So, that helps them.

19 The other important thing you mentioned
20 about giving the instructions before, not after,
21 actually, what we have found a number of times is
22 that, especially in New York, when people have their
23 parents living with them, sharing a bathroom, and
24 having a situation where they may have a pregnant
25 woman that cannot go anywhere -- so, in fact, the

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1 opportunity to have all of that resolved is, in fact,
2 well before you even plan the treatment.

3 Nowadays, since we use Thyrogen, there is
4 another complicating factor, which is that you have
5 to inject the Thyrogen two days before you even
6 administer the iodine. So, it is not about
7 discussion on the day of treatment. You have to
8 actually provide them at least three to five days
9 before you even order and administer Thyrogen
10 because, otherwise, you are going to waste that dose.
11 If, suddenly, there is some important patient
12 situation that precludes you from treating, then it
13 causes, more importantly, the patient inconvenience
14 of having to reschedule the entire treatment at the
15 last minute.

16 So, from all that standpoint, we go
17 several weeks before. That also gives us the
18 opportunity to give them the instructions on low
19 iodine diet. Because if you suddenly plan your
20 treatment a few days before, you have not prepared
21 the patient appropriately.

22 In my opinion, I think the ideal time is
23 about two weeks before, where you can discuss all of
24 the matters that may be more complicated in terms of
25 them being able to follow the contact restrictions;

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1 plus, it gives you all the opportunity to give them
2 proper instructions on preparations, low iodine diet,
3 and anything else they may need. So, you are
4 absolutely right.

5 DR. HOWE: Can you expand a little bit
6 on -- Mr. Bloom raised some questions about the
7 ability to take the information in. Can you expand
8 on how you try to comprehend what is being taken in?

9 DR. GHESANI: Yes. So, in terms of
10 addressing that, we almost always require that the
11 patients bring somebody with them who is their close
12 caretaker. If that does not happen, sometimes we
13 have actually arranged a phone call while in the room
14 while we are discussing with the patient, as long as,
15 you know, first, we clear it with the patient that
16 that is okay with them.

17 While that discussion takes place, you
18 don't want to rush that discussion. So, what we do
19 is our treatment plan, we have a technologist who is
20 working for 40 years in the same department. She has
21 been promoted to be the point person for all thyroid
22 patients. Now that includes whether it is a
23 hyperthyroid, whether it is a multinodular goiter
24 patient coming for just a simple scan, or a
25 complicated thyroid cancer patient who needs multiple

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1 visits.

2 She has a spreadsheet that she maintains.
3 So, every time we have a phone call from a clinician,
4 we know where we will find information if the patient
5 is already being worked-up for potential treatment.

6 So, we go to her. We work very closely
7 with her. She spaces out the treatments such that
8 it is never rushed where you treat one patient at one
9 o'clock and, then, suddenly, at 1:15, the next patient
10 is waiting.

11 This is precisely the reason why.
12 Because when you go in the room and you need to have
13 enough time for discussions, you can never
14 underestimate the time it will need for you to have
15 that consult. So, that is another important point.

16 You have to re-enter it sometimes. You
17 have to make sure in the notes you put a little marker
18 and put a note in there saying this is exactly what
19 you need to follow for the instructions, especially
20 when there are more complicated contact restrictions
21 for pregnant patients or young children.

22 We have had several instances where a
23 mother of four, and the oldest one is seven years
24 old, and she needs to be treated. There have been
25 instances where we had to treat them as an inpatient.

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1 It is very interesting when we give them the
2 instructions and say, "Oh, you cannot be in contact
3 with your children and you cannot cook." And then,
4 suddenly, the light goes on and says, "This is heaven.
5 I haven't had that kind of situation for years." And
6 they just are looking forward to that break.

7 (Laughter.)

8 And we just laugh it off. You know, this
9 is their opportunity to have -- and they will bring
10 their iPads or their magazines and they are just
11 reading and making sure that they are protecting their
12 close family members, especially young children.

13 So, every situation is very different.
14 You have to take it early on, well before we plan the
15 treatment. Even at the treatment time, there are
16 very unanticipated questions that come up that you
17 have to be prepared to address, too.

18 DR. HOWE: Thank you.

19 MR. BLOOM: I am sure many of the
20 questions are things that you have already covered
21 with them, and that is just another reminder of the
22 acuity issues or the imbalance in people's lives at
23 this critical time, when, again, what you think is
24 routine -- and I don't say that blithely -- but dosing
25 with radiation is something that you do

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1 professionally and you understand it. To us as a
2 layperson, the consumer -- I say that in two ways, I
3 guess; we are buying it and we are ingesting it -- to
4 us, as a consumer, this is a really anxious time.
5 I'm taking radiation. We have all seen these scary
6 pictures.

7 For me, I am saying that doctors need
8 to -- and likely they are, so forgive me -- they need
9 to be sensitive to the anxiety of the person who is
10 ingesting that radiation because it is not routine.
11 It is not something you just go to the supermarket
12 and buy. So, it is a scary circumstance.

13 My other question I wanted to quickly ask
14 you is -- I love what you do. I mean, that process
15 is just wondering. So, is that you, as a New York
16 physician, or is that you, as leadership of the SNMMI,
17 speaking and saying this is what the Society is trying
18 to get all of its members to do?

19 DR. GHESANI: That is a good question.
20 The anecdotes that I gave you were my personal
21 anecdotes in my own practice, but on a broad scale I
22 represent the Society. In fact, in preparation for
23 this meeting -- and there was another one in the
24 summer -- where we, in fact, have created a
25 subcommittee of our Society that meets on a regular

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1 basis and mostly phone calls, but in person when we
2 have our annual meetings or semi-annual meetings. We
3 get together, and we, actually, then, each individual
4 goes out and inquires about the practices in their
5 own geographic area.

6 So, what you see and what we have
7 provided, and in large part what I mentioned about
8 the ideal way of treating and being sensitive to the
9 patient's understanding and the patient's personal
10 situation and anxiety, it all reflects the Society
11 work. Because, in preparation for this, we actually
12 have been working on it for several months to gather
13 that information.

14 MR. BLOOM: That is fantastic. I love
15 it, and keep it up. Thank you.

16 MR. CARPENTER: Any other
17 questions/comments in the room?

18 MR. BLOOM: I will ask one more, if you
19 don't mind. Do you have a written checklist that the
20 professional follows, whether it is your or someone
21 on your staff? The reason I ask that is you are
22 human. As you can tell, I love to talk. So, when I
23 go to see my doctor, as an example, and the doctor
24 gets to step two out of ten and I interrupt and take
25 it off on a tangent, with my wife slapping my knee

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1 saying, "Okay. Shut up, so the doctor can get back
2 to his message," are you able to resume at No. 3 or
3 have I take you off in this meandering path and it is
4 like, okay, now I am on No. 7? And three through six
5 have gotten overlooked? Again, that is more out of
6 being human than questioning your abilities.

7 DR. GHESANI: Yes. So, the best way -- I
8 don't know if it is by design or by just practice
9 pattern -- the way it works out in our day-to-day is
10 that we have documents. What we do is they are
11 created in duplicate. So, the patients can send for
12 them, the instructions, everything.

13 The reason for that is that one of the
14 sets gets scanned in and goes into our electronic
15 medical record, and the second set the patient takes
16 with him or her. It turns out that we have one copy
17 each.

18 So, while we go over the discussion, you
19 know, we are going through step-by-step. We talk
20 about potential literature, you know, reports of
21 carcinogenesis for a larger dose, then the salivary
22 gland, and all the other instructions. So, we go
23 step-by-step.

24 As I said, it probably is by design, but
25 it has been rooted in our system for so long that

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1 they are used to following it in a way that the
2 patient has a list and we have a list. So, we go
3 through that one at a time, but we don't necessarily
4 check it off. But, at least in the back of our mind,
5 we have the template and a layout of what we need to
6 discuss. So, that helps.

7 MR. BLOOM: Perfect. Thank you for
8 explaining that.

9 DR. GHESANI: Sure.

10 MR. CARPENTER: Yes. I am going to go
11 to the telephones.

12 Operator?

13 OPERATOR: We do have questions. The
14 first question comes from the anonymous No. 2.

15 You may ask your question.

16 ANONYMOUS: Hi. Can you hear me clearly?

17 MR. CARPENTER: Thank you. Yes.

18 ANONYMOUS: Hi. My name is Deborah
19 Graves. I am a trained scientist and, also, a thyroid
20 cancer patient.

21 I want to actually thank the previous
22 speakers -- they made some really good remarks -- and,
23 also, thank the NRC for doing this project. Because,
24 as a patient in the modern age of social media, I am
25 in communication with a lot of other patients. It

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1 is no surprise we share information.

2 One of the things we know is that
3 different people get different instructions, and it
4 is very frustrating to know, gee, I got the same dose
5 as another person, but they were told to isolate for
6 three days and I was told to isolate for seven days.
7 Or I was told I can put my trash out at the street
8 right away, and they are told they have to hold it
9 for 90 days. These kinds of discussions happen
10 amongst patients all the time.

11 I did receive an acknowledgment form from
12 my nuclear medicine department, and we signed off
13 that we had had a discussion and that their evaluation
14 was that I was competent to follow the instructions
15 they gave me to protect my family members and the
16 public.

17 My thought on timing is the patient needs
18 to know this information beforehand, partly because
19 it takes time to absorb it. And also, if you are
20 isolating at home, which seems to be the norm in the
21 U.S. nowadays, you need time to prepare your home, to
22 make arrangements for pets and children, to make
23 arrangements for sleeping, so that you are not
24 exposing your family.

25 So, in my particular case, nothing was

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1 done in a big rush. After surgery, my
2 endocrinologist referred me to nuclear medicine, and
3 they immediately mailed me their instruction
4 paperwork for home isolation and followup to
5 radioactive iodine treatment. So, I have probably
6 read that paper 20 times by now.

7 So, I am definitely an advocate of
8 getting that information to people sooner, so that
9 they have time to absorb it and prepare. I have
10 heard instances of people, through social media, who
11 took their radioactive iodine pill and thought they
12 were doing isolation in the hospital and, then, were
13 immediately sent home. And that is a very awkward
14 situation for the patient's comfort as well as for
15 them to protect their family, since they were not
16 prepared.

17 I had a meeting with the radiologist in
18 nuclear medicine as well as the physicist in which we
19 went over that information and in which they
20 interviewed me. And I know they were assessing my
21 home situation. You know, did I have children? Did
22 I have a separate bathroom, that kind of thing? My
23 nuclear medicine department was definitely evaluating
24 those things about me in the opportunity to make sure
25 that I was going to be safe to the public.

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1 Something that frustrated me, as a
2 patient, was the guidelines I got were the guidelines
3 that everyone getting treated at this facility got.
4 I know they were written before they even met me.
5 So, there was nothing specific to my thyroid remnant
6 size, my dosage, my kidney function, any of that.

7 As a scientist, I like to quantitate
8 things, and I wish I could have known, you know, if
9 I measure at 1 meter with a Geiger counter from
10 myself, at what level is it safe for me to be around
11 my husband or my pet or to go ride on the subway? I
12 don't think that information -- certainly, it is not
13 available to me and the general public. Patients
14 would like to know.

15 You know, this stuff is invisible. I was
16 told it was there; I can't see it. A lot of times
17 you can't feel it. And how do I know it is safe to
18 sort of go back out there, safe to fix dinner for my
19 family?

20 I will probably, through the internet,
21 send in a recommendation for thyroid cancer patients
22 to be aware of an internet community in Facebook, the
23 LID Life Community. That was started by thyroid
24 cancer patients to help each other figure out how
25 they are going to eat for those few weeks they are

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1 doing low iodine diet in advance of their treatment.

2 And it is also a forum for people to share
3 how they have prepared their home for isolation and
4 ask questions about their symptoms. Is this normal?
5 Did other people have this?

6 It has been a really helpful group for me
7 and a lot of other people. I will try to get that
8 information to Donna-Beth through the internet forum
9 for the comments.

10 Thank you.

11 DR. HOWE: Thank you.

12 MR. CARPENTER: Thank you very much. And
13 thank you, also, for thanking us. It is not often
14 that we at the NRC get members of the public saying
15 thank you to us. So, I appreciate that whenever I
16 hear it.

17 Operator, is there anyone else?

18 OPERATOR: The next question comes from
19 anonymous No. 3.

20 You may ask your question.

21 ANONYMOUS: Yes. My name is Cherry
22 Wunderlich. I am a thyroid cancer survivor since
23 1999.

24 I, too, really appreciate this meeting,
25 that it is webcast, phone, as well as for the people

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1 who are able to come. This is really a terrific
2 forum, and thank you very much.

3 I was treated successfully in 1999. What
4 I would like to emphasize is that this was a very
5 scary time for me, to suddenly out of the blue hear
6 that I had cancer and, then, that two months later,
7 I was going to have radioactive iodine. So, I just
8 had lots and lots of questions.

9 I have very patient, wonderful doctors,
10 both the endocrinology and surgery and nuclear med,
11 as well as there was like a support group locally.
12 So, there were people to talk to in person as well as
13 online, which the previous caller alluded to, how
14 helpful the online communities are.

15 But, having lots and lots of questions,
16 at that time I called my providers. The
17 professionals really used model procedures. I did
18 receive written instructions. I know now they give
19 patients much more extensive information and it is
20 all in writing, and they get mailed in advance.

21 But, to suddenly have to absorb being a
22 cancer patient and having to go -- I had never heard
23 of a millicurie; I had never heard of radioactive
24 iodine. I do a lot of writing and editing, including
25 medical, and this was just a field I knew absolutely

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1 nothing about. So, it was incredibly confusing.

2 So, the written instructions and having
3 them at a very, very basic level, I can't emphasize
4 that enough in terms of how helpful that is, and the
5 opportunity to talk back and forth and have a family
6 member present, which I also did.

7 I was kept in the hospital overnight.
8 For me, that was a huge relief because just the
9 dosing, of having the people around me very heavily
10 protected in their garb and the special container,
11 all of that, again, it was very unfamiliar.

12 My doctor did come by, so I could ask
13 questions in person, and there were nurses and people
14 around for that. So, that was just very, very
15 reassuring.

16 I would suggest that you look to the
17 facilities that are giving lots of instruction and
18 taking lots of time with the patients, both in advance
19 and during the time of the dosing, to develop some
20 models that people in less-specialized centers or in
21 areas that don't have as much specialty practitioners
22 as the major urban areas do, so that can be a
23 leadership role to really help, so that every patient
24 receives the kind of information that I received and
25 that I understand patients at the same facility are

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1 still receiving.

2 Thank you very much. That is all I have
3 to say.

4 MR. CARPENTER: Thank you for comments.
5 We appreciate those insights.

6 Before we go to the next caller, I would
7 like to reiterate, for those callers who self-
8 identified themselves, thank you for that. Again,
9 it is not necessary that you do so. If you wish to
10 remain anonymous, that is certainly acceptable.

11 Operator, next caller?

12 OPERATOR: At this time, sir, there are
13 no further questions.

14 MR. CARPENTER: Very good.

15 Let me go back around the room. Were
16 there any other comments based on this?

17 Go ahead.

18 DR. GHESANI: So, after hearing the two
19 comments over the phone, I can give you a little more
20 insight into the points that you raised.

21 You mentioned getting, one of you
22 mentioned about getting treatment as an inpatient
23 versus outpatient. We heard of some people who were
24 treated in the nineties were treated in a hospital.
25 So, it may be important to know the background

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1 information.

2 I don't know the exact dates, but I know
3 there was a transition that occurred where we used to
4 measure the radiation and decide, based on the
5 radiation level, whether the patient can or cannot go
6 home. Instead, we have shifted to a different
7 approach where it is about what is the maximum amount
8 of radiation; anybody in close contact, whether that
9 is a family member or a working colleague in a very
10 close working environment? That ends up getting
11 determination of whether the patient will be treated
12 as an inpatient in the hospital or as an outpatient.

13 So, that may be, you know, if you find
14 differences in the way you and one of your colleagues
15 or family members were treated, that is one thing to
16 keep in mind. There has been that transition point
17 somewhere in the mid- to late nineties.

18 The second point, about getting different
19 instructions, I am aware, and we, in fact, in our
20 work that we did, we did find differences. So, there
21 is no doubt that there are variations in the way the
22 patients get information from one institution to the
23 other.

24 In part, though, that has to be taken
25 into account, that ever patient's situation is very

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1 unique and very different. You had to take into
2 account many factors, including the height and
3 weight, the amount of thyroid iodine that you are
4 able to hold onto your thyroid gland, the amount of
5 iodine pool that individuals have.

6 With the way, for the last several
7 decades, the way we are supplementing the iodine in
8 our diet, the iodine overall is higher now than it
9 was before. So, that is one point.

10 Secondly, many people take different
11 types of supplements. Sometimes you don't realize
12 what you have in the supplements, and sometimes there
13 are even more iodine-rich supplements that you can
14 take that can actually overload your system with the
15 iodine. All of those factors have to be taken into
16 account when you give the instructions.

17 We can't get full details, but we do
18 several uptake measurements. Those measurements can
19 allow us to understand what percentage of iodine that
20 we are giving it in a pill that ends up in the target
21 area, which is typically the neck in the thyroid
22 gland.

23 So, part of the instructions, the
24 variations that you see are we are aware of it, that
25 there is a variability from site to site. But there

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1 is also a fact that you have to take into account
2 that everybody is very unique and very different, and
3 there will be some variations, based on what we know
4 about individuals, that you need to give the
5 instructions to.

6 MR. CARPENTER: Thank you.

7 Yes, sir?

8 MR. LICHTY: Yes, I have a followup to
9 that. I have heard that there are different
10 regulations in different states and the District of
11 Columbia for how much radiation you can before you
12 can be released. Like I think Johns Hopkins, for
13 example, does not require you to stay overnight, but
14 I was treated in D.C. and they did. I have heard
15 that that is based on different regulations or
16 radioactive emissions. I want to know if that is
17 still the case.

18 DR. HOWE: The situation you are talking
19 about is that the regulations that are followed for
20 the District of Columbia are the regulations that are
21 promulgated by the Nuclear Regulatory Commission.
22 The regulations at Johns Hopkins comes under, are
23 promulgated by the State of Maryland.

24 Now there is a level of compatibility and
25 agreement. We have what we call Agreement States.

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1 In the Agreement States, NRC has relinquished its
2 authority to regulate radioactive materials in those
3 states. But there are certain levels of regulatory
4 responsibility for the state to maintain something
5 equivalent, not equivalent, but something that will
6 protect the public health and safety the same way the
7 NRC regulations do.

8 So, we have something called
9 compatibility. Sometimes the compatibility has to
10 be identical. In other cases, the major elements
11 have to be there. In other cases, it is for health
12 and safety. So, you have to have kind of the same
13 objectives.

14 For release of patients, it is the same
15 basic objectives have to be in place. And so, most
16 states have over time adopted a similar type of
17 release criteria as NRC puts out.

18 What happens is NRC will change its
19 regulations and, then, the Agreement States have
20 three years to work on whether regulations up to ours
21 and it depends on the level of compatibility. So,
22 that is why you are seeing a little bit of a change,
23 especially in the timeframe from 1997 until 1980,
24 because there was a three-year timeframe which the
25 Agreement States need to kind of come into somewhat

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1 agreement with the NRC. So, that is one reason for
2 the lag and the lack.

3 And then, also, as the medical community
4 gets more experience, then it tends to maybe accept
5 a new process better. So, a lot of our NRC licensees
6 wanted to stay with the old type of system and more
7 hospitalization, and gradually that has moved.

8 Hopefully, that clarifies it a little
9 bit.

10 MR. CARPENTER: Good.

11 MR. BLOOM: Okay. One more comment.
12 So, you had mentioned the variability of the
13 individuals, which is very important. Obviously,
14 certainly as a layperson, I am deferring to you as a
15 medical professional on that.

16 But the thought that came to my mind as
17 you were explaining that was more the thoroughness
18 factor, meaning, as an example, every facility that
19 treats people with I-131 should have to ask a very
20 basic questions: how are you going to get home from
21 here? In a car? On a bus? Oh, wait a minute.

22 So, that kind of thoroughness, and that
23 is an example, and it is a very basic one. It may
24 be too basic to make the point. But that kind of a
25 question should be uniform. I don't feel like there

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1 is any debate about that. Every patient who is in
2 that position in advance should be asked: how are
3 you going to get home after you are given this
4 radioactive material? Because the person sitting in
5 the next seat could be newly-pregnant woman who
6 doesn't show it. So, why would you assume that that
7 lady is pregnant? Are we exposing people
8 unnecessarily? So, that is what I think of when I
9 think of thoroughness.

10 DR. GHESANI: That is a very important
11 point to make because, if you are following the ALARA
12 principle, which is, as we call it, as low as
13 reasonably achievable, it is a fundamental basic
14 under which we work on every single case.

15 And your point about a woman who may not
16 show, in fact, the most significant load of any
17 potential radiation effect is in the earlier stage as
18 opposed to the later stage of pregnancy. So, you
19 always have to operate as if like you are going to be
20 in the worst given situation.

21 From that standpoint, we have very
22 much -- our coordinator that I referred to earlier,
23 she, in fact, well before even the first Thyrogen
24 injection is done, is going through the logistics of
25 how far they live, how they are going to take the

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1 transportation back home, and how they will make sure
2 that, when they get home, that children and any other
3 young adults or family members are already prepared.

4 Many times it turns out, which is good
5 for the families and the patients, that they are able
6 to work out the details where the patients are usually
7 by themselves, as long as they are healthy enough to
8 take care of themselves. And then, the family
9 members find a way of making a short trip or going to
10 another family for a few days.

11 All of that discussion, although as it
12 was earlier mentioned over the phone as well, is that
13 there are so many important points that impact
14 individual's lives and their family's lives. So,
15 they have to be addressed well in advance before you
16 even have the patient come in for treatment.

17 MR. CARPENTER: Okay. Thank you.

18 Let me go back to the telephones.

19 Operator, do we have anybody?

20 OPERATOR: We do. The next question
21 comes from the No. 4.

22 You may ask your question.

23 ANONYMOUS: Yes. Hi.

24 I have been a technologist and radiation
25 safety officer for almost 30 years now. I know that

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1 doing I-131 therapies, we have come across a lot of
2 different scenarios over the years.

3 But one thing I would like to say gets
4 overlooked frequently is when you are asking a patient
5 about their work situation to make sure that, if they
6 are doing any kind of risky behavior in their work
7 situation, that you address what they would do in
8 case of being injured.

9 Frequently, we have had -- well, I
10 wouldn't say "frequently" -- but we have had in the
11 past where patients state, "Well, I work in the
12 outdoors. I work as a firefighter," or such things.
13 If they are not working close to other individuals,
14 frequently, they are told, then, they don't have as
15 much restriction or have to wait as long before they
16 can go back to work.

17 In one case, we had an arbor who was told
18 that he had no restrictions on work because they felt
19 that he was working outside by himself. So, that
20 would be perfectly fine to go back to work. He did
21 the very next morning and was in a tree with a power
22 saw and cut into his arm, cutting his artery.

23 So, he did have all the information on
24 him when he presented at the ER to be able to state
25 that he had had this therapy and exactly what type of

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1 therapy, and the patient was amazing. So, everything
2 was contained and very well treated. Everything was
3 cleaned up properly and the patient was treated fast
4 and out again.

5 But, just so that you consider that when
6 you are writing your instructions, that patients
7 work, if they do any risky behaviors, should be
8 considered as well, and what information to give the
9 patient based on that would be appropriate.

10 MR. CARPENTER: Very good. Thank you.

11 DR. HOWE: And I hope you are going to
12 submit information to us, either electronically or in
13 writing.

14 ANONYMOUS: I'm not quite sure how to do
15 that, but I will look into that.

16 MR. CARPENTER: Yes. That was the
17 earlier part of the conversation. If you would like
18 to submit this electronically, you can go to
19 www.regulations.gov and search for the docket ID
20 NRC-2015-0020. Alternately, you can mail to Cindy,
21 C-I-N-D-Y, Bladey, B-L-A-D-E-Y, in the Office of
22 Administration. Her mail stop is 1 One Flint North,
23 OWFN-12-H, as in hotel, -8, care of the U.S. Nuclear
24 Regulatory Commission here in Washington, D.C. 20555.

25 And that information is also available in

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1 the material that Dr. Howe has previously put up onto
2 our website.

3 ANONYMOUS: Okay.

4 DR. HOWE: And it is available in The
5 Federal Register notice. So, since you know --

6 ANONYMOUS: Yes, I was on that website
7 just a minute ago.

8 DR. HOWE: -- about our meeting, then you
9 probably have a copy of that. So, it is in there
10 also.

11 MR. CARPENTER: Okay.

12 ANONYMOUS: Okay.

13 MR. CARPENTER: And the reason that we
14 want that is to make sure that we are able to
15 accurately incorporate all of your comments. You
16 know, we appreciate all the comments that we are
17 receiving today, but I have personally found that
18 people, when they start writing this stuff down, they
19 tend to expand a little bit more than what they do
20 when they are just talking. So, we greatly
21 appreciate that also.

22 Okay?

23 ANONYMOUS: All right.

24 MR. CARPENTER: Thank you.

25 Operator, any others?

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1 OPERATOR: The next question comes from
2 No. 5.

3 You may ask your question.

4 ANONYMOUS: Yes. Hi. My name is Zoubir
5 Ouhib. I'm a medical physicist.

6 First of all, let me just commend NRC for
7 taking this initiative. I think this is extremely
8 valuable.

9 I also commend some of the individuals
10 that have actually contributed to this, especially
11 the patients. I think they have provided us with
12 some extremely valuable information, which will lead
13 me to one item.

14 I think when it comes to designing this
15 pamphlet or these instructions, or whatnot, it would
16 be great to basically separate the pre-, the during,
17 and the post-treatment. It has to be simply, such
18 that all patients will be able to understand it, to
19 the point, and not like you have spoke, that it is
20 too detailed where they get lost in it.

21 But it is sent out, and there are patients
22 that might not be able to read these instructions.
23 And therefore, there has to be some sort of a video
24 or something that they can connect with and it will
25 be easy.

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1 In other words, when there is confusion,
2 they go back to it and, then, they simply say, "Oh,
3 okay. They told me not to do this and, instead, to
4 do this." I think that will be valuable.

5 I think in that pamphlet or that video I
6 think it will be valuable to address this fear factor,
7 because one of the patients actually has addressed
8 that very nicely, and then, to say this is not the
9 end of the world.

10 The reason the staff have to walk out of
11 that room are the following: it is not the end of
12 the world here. Again, to address the how, the where,
13 the when, and what to do, just like the previous
14 caller has stated, what to do in case of an unusual
15 situation. You know, there might be some points
16 already that can be addressed, but the other one could
17 be just, "Hey, you should have gotten this information
18 and there is a contact person 24 hours," whatnot.

19 This document should also be viewed by
20 all members, and that is the authorized users, the
21 medical physicists, the nurses, and certainly by the
22 patient, and see if that has addressed all their
23 points.

24 And one last comment. I think it would
25 be also valuable to use some of the past medical

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1 events that have occurred using iodine 131 and see
2 maybe there are a few points that can be added to
3 avoid some of those that have actually occurred.
4 Example: people are not taking the complete dose.
5 A patient hiding the pill under the pillow, and so on
6 and so forth.

7 And those are all my comments.

8 DR. HOWE: Thank you.

9 MR. CARPENTER: Very good. Thank you.

10 Operator?

11 OPERATOR: The next question comes from
12 No. 6.

13 You may ask your question.

14 ANONYMOUS: Hi. My name is Tim Lyle,
15 and I am a thyroid cancer survivor since 2004.

16 A couple of things that I wanted to talk
17 about today in regards to things that I haven't heard
18 discussed already going to patient incomppliance.
19 Doctors, medical specialists everywhere deal with the
20 patient incomppliance on a daily basis. And whether
21 that is from being told to exercise more, and how
22 many of us actually go out and, then, exercise more?
23 Or we are told to lose a few pounds. How many of us
24 actually go out and lose a few pounds? Or to take
25 this medication or that medication, and we don't take

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1 it exactly as we are prescribed to take it.

2 Doctors deal with that so often in the
3 healthcare community that, when we are looking at,
4 then, giving patients complex instruction on what to
5 do when they are dosed with a radioactive material,
6 that it doesn't always happen. An example of this
7 would be the receptionist at my endocrinologist's
8 office, when I was diagnosed with thyroid cancer,
9 told me a story of how she was in a restaurant. She
10 was eight months pregnant at the time and she was
11 there with her husband. And she recognized someone
12 in that restaurant as being a thyroid cancer patient
13 from her office, and she knew that person had just
14 been dosed with radioactive iodine the day prior.

15 That person walked up to her and said,
16 "Hi. How you doing? Hey, nice to see you." It made
17 her very, very uncomfortable because, like I said,
18 she was eight months pregnant at the time. So, she
19 was definitely showing. And this person was in a
20 restaurant and doing something they weren't supposed
21 to do, and coming up to her and exposing her and her
22 unborn child to this radiation. So, it happens
23 frequently.

24 There is an article I read a few years
25 back in the USA Today that I would like to talk about

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1 where a couple of scientists from a nuclear power
2 plant had to travel to apparently another nuclear
3 power plant and do whatever their business was there.
4 What ended up happening was they stayed in a hotel.
5 The next day when they went to the nuclear power plant
6 that they were supposed to visit, they set off the
7 radiation alarms as they walked into the nuclear power
8 plant. Well, that was a problem.

9 So, it became, how did this happen?
10 Where did they get exposed to radiation? And they
11 tracked it down to the hotel room that those couple
12 of scientists stayed in the night before, that that
13 same hotel room the previous night had been occupied
14 by a thyroid cancer patient who was dosed with
15 radioactive iodine.

16 Now there was enough contamination in the
17 room, not necessarily irradiating gamma rays, and
18 whatnot, but there was enough contamination in the
19 room yet of radioactive iodine particles that these
20 scientists got enough of that on them, that they were
21 able to, then, set off radiation alarms at that
22 nuclear power plant.

23 So, we talked about multiple times at the
24 Thyroid Cancer Survivors Association conferences
25 where we have had roundtables with the NRC

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1 officials -- so, some of you look familiar to me from
2 those roundtables that we have had. And I have
3 brought up some of these points before.

4 But there is the contamination issue that
5 I don't think has been properly addressed. When we
6 allow people to leave the hospital after they are
7 dosed with radioactive iodine and they are told to
8 take certain precautions, we have to deal with the
9 contamination that they might leave behind wherever
10 they go and we have to deal with the fact that some
11 are going to be in compliant.

12 Now we have already talked about people
13 who are in the hypothyroid state maybe not processing
14 the information that they are given quite
15 efficiently. But we just have to look at the general
16 populace as not being compliant. I mean, how many
17 people stop for stop signs because it is the law to
18 do so or do they just roll through a stop sign?

19 So, this isn't necessarily a law that
20 they are being given, told to do when they leave the
21 hospital after being dosed with radioactive iodine,
22 but it is something that is important to public
23 safety. When we don't account for those people who
24 aren't going to follow their instructions, then we
25 are left with other people, pregnant women, young

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1 children, all being exposed to radiation
2 unnecessarily.

3 We know that radioactive iodine can go to
4 the thyroid of a healthy person and damage a healthy
5 person's thyroid. If the healthy person has come in
6 contact with someone who has been dosed with
7 radioactive iodine and that happens, they get
8 contaminated. We know that they can develop thyroid
9 conditions later on in life.

10 How many times have we had that happen
11 where -- and this is just pure speculation; we can't
12 really put measurements on this -- but I am sure it
13 has happened many, many times where people have
14 probably developed thyroid cancer because they were
15 exposed to radioactive iodine. And that is
16 disconcerting to me.

17 We know that the rates of thyroid cancer
18 have been increasing exponentially over the last how
19 many years, and we haven't been able to find the cause
20 of it. But we do know that, since we have been
21 allowing people to leave the hospital and not be
22 required to be inpatients through their radioactive
23 iodine treatment, that that number has continued to
24 skyrocket.

25 So, I would like to petition the Nuclear

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1 Regulatory Commission here, and add my name to that
2 petition, to say that I think we should really require
3 patients to be inpatient in the hospital while they
4 have their radioactive iodine treatments.

5 When I had my two treatments of 200-
6 millicurie dose and 150-millicurie dose, they
7 required me to stay inpatient. The room was wrapped
8 in Saran Wrap. The bed I laid in was wrapped in
9 Saran Wrap. The toilet, the faucet, everything, the
10 remote control even for the TV, all wrapped in Saran
11 Wrap to prevent contamination of the room.

12 And I had to stay in there for three days,
13 according to the nuclear medicine techs as they came
14 up twice a day to check me with a Geiger counter. I
15 had to stay there for three days before they would
16 release me home on both occasions. That was so that
17 my radiation level had dropped far enough that they
18 thought that I was safe to go out into the public
19 again. But it took three days for that to happen.

20 We know the biological half-life for
21 radioactive iodine can be anywhere from two to three
22 days, and the half-life of radioactive iodine itself
23 is eight days. But it took that time for that
24 radiation level to drop far enough.

25 Well, how many people are going out of

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1 the hospital and they are walking down the hallways
2 of the hospital past people? They are getting on a
3 bus or a train to travel home because they live far
4 away from the center that is treating them. And we
5 are exposing the public again unnecessarily.

6 So, in my personal experience, after my
7 second dose of radioactive iodine -- I was in the
8 Marine Corps at the time -- I had to travel through
9 one of the bases to get to the hospital where my whole
10 body scan was going to take place. On the way through
11 the gate of the base, I was stopped by the MPs because
12 I set off radiation alarms at the gate. That was 12
13 days after I was dosed with a 150-millicurie dose of
14 radioactive iodine.

15 Now I followed the precautions to the "T"
16 as best I could. I took multiple showers a day. I
17 drank plenty of water. I tried to flush out as much
18 of the radioactive iodine as I could. But I still
19 set off radiation alarms 12 days later on that Marine
20 Corps installation.

21 That concerned me that people are walking
22 around, and more than just background radiation
23 levels, are exposing the rest of us. I think that
24 is something the Nuclear Regulatory Commission really
25 needs to consider.

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1 Is the insurance lobby that strong, that
2 we don't require people to be inpatient in the
3 hospital? Because what is the downside? If require
4 patients to be inpatient again, we are going to
5 protect the public. If we don't require them to be
6 inpatient, we are just saving a little money for the
7 insurance companies.

8 And that is why I think this is an issue
9 that needs to certainly be addressed. Thank you.

10 MR. CARPENTER: Thank you.

11 Okay. The next caller, please.

12 OPERATOR: At this time, sir, I am
13 showing no further questions.

14 MR. CARPENTER: Thank you.

15 The last time around the room.

16 (No response.)

17 No comments?

18 No one else on the telephone?

19 OPERATOR: No questions at this time,
20 sir.

21 MR. CARPENTER: Okay. Very good.

22 Well, I would like to thank everyone for
23 participating this morning. Since we have had
24 several comments and everything, we have gone around
25 the room a couple of times, I would like to go ahead

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1 and break for lunch at this time.

2 The schedule, the agenda has us breaking
3 for lunch until one o'clock p.m. this afternoon, at
4 which time we will restart with the Guidance for
5 Released Patients. As opposed to the agenda here,
6 if we finish that topic early, we will just go ahead
7 into the last topic of the day, Brochure for
8 Nationwide Use, and the Conclusion. For people who
9 need to get home here locally and deal with weather
10 conditions, et cetera, we will make sure that they
11 are able to get out.

12 Again, I do appreciate everyone on the
13 telephone for your participation. Please, if you are
14 able, rejoin us at one o'clock.

15 At this time, we are going to break.

16 Thank you very much.

17 (Whereupon, the foregoing matter went off
18 the record for lunch at 11:36 a.m. and went back on
19 the record at 1:01 p.m.)

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A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

3

1:01 p.m.

4

MR. CARPENTER: This is Gene Carpenter.

5

I am the NRC Facilitator for this workshop today.

6

Thank you for those of you who have joined

7

us from the morning and welcome to those of you who

8

are just now joining us.

9

We do have several people here in the

10

room. This morning we went through two topics of

11

significance, Website Information and, also, an

12

involved discussion on Patient/Licensee

13

Acknowledgment Forms and Best Practices on Making

14

Informed Decisions on Releasing Patients Treated with

15

I-131 Based on Radiation Exposure Considerations.

16

No, I cannot say that in one breath.

17

This afternoon we are going to be talking

18

about the Guidance for Released Patients. And then,

19

we will roll over into the Brochure for Nationwide

20

Use, and Conclusions.

21

This meeting is being transcribed. For

22

those of you on the telephone, whenever we do go to

23

asking for comments from the public and we ask for

24

anyone to *1 to speak on the conference, you have the

25

option of giving your name or being anonymous. You

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1 can do either. We don't require your name. It is
2 purely up to you.

3 At this time, I would like to turn this
4 over to Dr. Howe for the presentation on Guidance for
5 Released Patients.

6 DR. HOWE: Thank you, Gene.

7 This is Topic No. 3 of four topics that
8 we are gathering information on I-131 patient
9 release. This morning we talked about website
10 information, which is basically the kind of
11 information a patient might want to find just as they
12 are being diagnosed or find out more about the
13 disease, more medically-oriented; some oriented with
14 radiation; I-131, what is it?

15 We also talked about Topic No. 2, which
16 was, more or less, a discussion that the patient or
17 licensee have prior to the actual treatment, so that
18 different information can be exchanged.

19 And this is Topic No. 3, which is
20 essentially the guidance that is provided for
21 patients that are going to be released. Now these
22 could be patients that are released immediately after
23 receiving their I-131 or they could be patients that
24 are released after they have been held in a hospital
25 for a day or two, or possibly only delayed for a few

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1 hours before they are being released.

2 This morning I made it clear that we are
3 not only talking about thyroid carcinoma patients,
4 but we are also talking about hyperthyroid patients
5 because the hyperthyroid patients do retain more of
6 the I-131 for a longer period of time, even though
7 they get a lower dose.

8 We also talked this morning about there
9 is a delay between the sound coming through, if you
10 are listening on the telephone, versus the slides, if
11 you are watching on the webinar. So, there is a
12 disconnect there of about 20 seconds and, hopefully,
13 you will bear with us on that. That is a technical
14 thing that cannot be resolved.

15 Okay. Guidance for Released Patients.
16 What are we asking for? We understand the standard
17 guidance to reduce the variability of instructions
18 provided to patients and eliminate some of the
19 uncertainty in the type of information provided.

20 So, if one is looking at standardizing
21 guidance, one can go in one of two ways. You can be
22 very prescriptive where you say exactly what the
23 guidance is and there really is no departure or
24 deviation or you can approach it as we are approaching
25 our regulations now, and that is more performance-

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1 based.

2 In performance-based there are certain
3 goals that should be met or things that you want to
4 achieve. In order to be performance guidance for
5 releasing patients, we think that there are probably
6 certain tools that patients will need or methods that
7 they need to follow, so that the guidance objectives
8 can be met and so that patients can protect others.

9 That is kind of the main thrust of what
10 we are looking at. We are looking for people's own
11 experience. We are getting information from
12 patients, individual physicians, facilities,
13 professional societies, patient advocacy groups, our
14 Advisory Committee on Medical Isotopes, and also
15 other interested individuals.

16 We are looking for people's personal
17 experience. If you are going to send us your checkoff
18 list or you procedures, please put it into context.
19 Give us a little bit of information about how you use
20 the document. Give us maybe a sentence or two as to
21 how this document fits into your releasing patients
22 and your discussion with the patients. And that is
23 a general overview of the type of information we are
24 going to be asking for in this particular topic.

25 The other thing I should point out is

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1 that we have a number -- all of this comes from our
2 Federal Register notice where we indicate the
3 information we are looking for and where it can be
4 sent. We have different bullets or topics, and we
5 are not under the assumption that our bullets are the
6 only bullets or they are the best topics. And so,
7 we are asking open-endedly for people to tell us if
8 they think there are other things that ought to be
9 addressed in the Guidance for Released Patients or
10 whether we have addressed things that they don't
11 believe are that important.

12 And please explain why they should be in
13 there or why they shouldn't be in there. We are also
14 asking for a time element as to when this guidance
15 should be provided to patients.

16 So, that gives you a general overview.
17 Particular questions can be looked at from The Federal
18 Register notice. If you don't have it, I have
19 information later on where you can obtain it.

20 At this point -- oh, I have another slide
21 here. Okay. So, we are asking you to provide your
22 guidance documents that you believe provide clear
23 instructions. And for patient input, we want to know
24 when should you be provided these instructions? Were
25 they easy to understand and follow? What would make

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1 them better? When should the instructions be
2 provided? So, those are the general kinds of things
3 we are looking for.

4 And I believe we can open our discussion
5 now.

6 MR. CARPENTER: Very good.

7 Now, as we did this morning, what I will
8 do this afternoon is, for this topic, we will go
9 around the room, ask the participants here in the
10 room if they have any questions or comments. Once
11 we have gone around the room, I will, then, go to the
12 telephones and ask for comments from people that are
13 on the telephone.

14 Again, for those who are on the
15 telephone, you do not have to give your name. It is
16 entirely up to you whether or not you wish to remain
17 anonymous.

18 At this time, let's go and open it up for
19 the floor here in the room. Does anyone have
20 comments?

21 MR. BLOOM: Thank you again for this
22 opportunity.

23 I apologize, I feel like I am
24 oversimplifying this, but I feel like we have covered
25 a lot of good ground this morning which touches on

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1 this.

2 As Dr. Ghesani said, I think that
3 instructions should be handed out two to three weeks
4 in advance. That is when the initial
5 instruction/communication should happen about this
6 topic, and the perfect opportunity, at least, again,
7 from a thyroid cancer standpoint, is when discussion
8 will happen about the low iodine diet. So, it is a
9 perfect opportunity to say, "Here's what is in front
10 of you. And now, let's really delve into these
11 instructions about what you need to do before we get
12 to the dosing and, then, what we are going to need to
13 do during it," as the other doctor mentioned in his
14 comments, and then after. I like that sequence of
15 before, during, and after, breaking it up in that
16 fashion -- and that is at a high level -- and then,
17 getting into more of the details.

18 Again, as we mentioned earlier, any
19 instruction has to be carefully assessed from an
20 understanding level or simplicity level, but, then,
21 there has to be a comprehensiveness or a thoroughness
22 to it. These instructions can't be so simplistic
23 that they miss points that are very important.

24 You know, where are you going to stay?
25 What kind of home life do you have? Those are

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1 questions that need to be discussed in advance of
2 dosing because you may have to postpone dosing, and
3 you would rather find that out before the facility
4 has purchased the isotope and before the person has
5 gotten sort of mentally anguished over what is in
6 front of them. And now, at the last moment, it is
7 like we don't have a plan; you don't have a plan. We
8 no longer have flexibility to account for the lack of
9 planning that all of us collectively failed at.

10 So, I really like Dr. Ghesani's thought
11 process of broaching this early enough that there is
12 opportunity to work through hurdles. And that is a
13 normal, to me, that is a normal byproduct of any
14 interaction, that there are always complications, but
15 especially when you are talking about radiation. So,
16 comment again the doctor for his thoroughness this
17 morning.

18 So, that is all I wanted to share at this
19 time.

20 DR. HOWE: What is your experience from
21 being a patient advocate as to the spectrum of the
22 time on giving released instructions?

23 MR. BLOOM: Sorry, I'm laughing. The
24 spectrum goes from that very advanced notice to the
25 patients we meet after the fact who say, "Well, the

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1 first conversation we had about what was in front of
2 me was when it was behind me."

3 I am not here to question the medical
4 facilities and I don't know which ones these patients
5 were necessarily talking about. There is always room
6 for confusion. And the idealist in me will say that
7 it is hard to believe that a patient was dosed and,
8 then, talked to about precautions and pathways to
9 where they were going to go and how they were going
10 to get there. So, I hope that is not the case, but
11 I don't think people would make something like that
12 up.

13 It is this idea of the worst scenario
14 would be no conversation until after. That is the
15 definitely the one that has to be addressed most
16 proactively. But I think that all of these
17 situations should be addressed as, again, the doctor
18 was good enough to share with us, let's be as
19 preemptive as possible. Let's give as much
20 opportunity to build a plan, a roadmap, before we
21 even go into any danger points.

22 Of course, equally, there is always a
23 chance that, once we go down that path of planning
24 for radioactive iodine treatment, that the physician
25 and the patient will ultimately decide that it is not

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1 necessary. So, that also is part of that upfront
2 discussion.

3 At least in the olden days where we would
4 have a small dose of RAI to determine if there was
5 going to be uptake, it was very much more likely that
6 there would be a chance you would not go down the
7 treatment path. But I think it still is the case
8 that that can happen.

9 So, actually, for the patients, to make
10 them understand you may not ultimately have a
11 treatment, and up until the last minute, we could go
12 down that decision path as well. I think it is
13 important to make the patient understand all of the
14 circumstances. And then, of course, if you don't
15 have treatment, there is no guidance as far as how to
16 release a person because it is just, "See you later."

17 In a certain sense, that is the best we
18 could hope for as a patient, but that won't address
19 any health condition if there is a need. So, really,
20 relative to this discussion, I guess that part is too
21 optimistic.

22 I don't know; I think I sort of went
23 around your question rather than to it.

24 DR. HOWE: Thank you.

25 DR. GHESANI: So, these are important

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1 points. There is an opportunity here. Typically,
2 in a thyroid cancer surgery, after surgery the
3 recommendation is to wait for about six to eight weeks
4 before you administer the radioiodine because that is
5 where all the postoperative changes are resolving in
6 the neck and you don't want to administer it at a
7 time when it goes to the target area and, then,
8 remains near the thyroid gland and potential
9 micrometastatic lesions is not optimum.

10 So, recommendation -- and almost everyone
11 agrees on it -- if you find some variations in the
12 pattern, there is not much controversy about the time.
13 Most people will recommend that, surgeon after
14 surgeon will say, "Well, I will refer you to the
15 endocrinologist," but they will tell you that you
16 will wait for about six weeks, after which you receive
17 your radio iodine. That gives us the opportunity to
18 really work ahead of time.

19 So, instead of telling the patient now
20 six weeks, "Come back in six weeks and we will start
21 working on it," I think that is when the patient
22 should see an endocrinologist, but also potentially
23 see a nuclear medicine physician or a nuclear
24 radiologist and start having a consult that will
25 include the planning, proper planning, understanding

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1 their individual situation that may impact how they
2 will follow the contact restrictions, and start other
3 processes. You know, their supplements start going
4 in, so they are on Synthroid or Cytomel treatment.
5 They start their low iodine treatment.

6 And all of that will offer the
7 opportunity to avoid some of the unusual instances we
8 heard about where things went wrong after the
9 treatment. The instructions were very short. There
10 was not enough notice. The location or patient
11 didn't have enough knowledge to follow the
12 instructions. So, that is one part.

13 I think if we come up with a way to make
14 sure that right after surgery the treatment plan
15 starts, not six weeks after, even though eventually
16 the treatment will be given six weeks later, that
17 doesn't mean you just don't do anything for those six
18 weeks and let that opportunity slide by. So, that
19 is one part.

20 The second part, as I was hearing more
21 about this, I think the important thing here will
22 also be to make sure that our other clinical sub-
23 specialists are also on the same page. So, I have
24 heard anecdotal examples of where the patients may
25 receive one set of instructions from the clinicians

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1 and, then, those instructions, when they come to the
2 nuclear medicine physician, are quite different.

3 And there is always that difference in
4 the expertise and the experience that goes with
5 treating patient one after another and on a regular
6 basis treating many patients. There is some set of
7 experiences that the nuclear medicine physicians will
8 have and the knowledge and background of the
9 radioactivity and some of the physics of radiation
10 which is going to be much better handled by the
11 radiation physicists and nuclear medicine physicians
12 within their department, as opposed to the
13 clinicians.

14 No doubt, clinicians, many clinicians are
15 very tuned into it and they are well aware of what is
16 the impact and what kind of background information
17 they need to provide to their patients, but I think
18 it would be nice upon our imaging and treating
19 community to make sure that we partner with our
20 clinicians and provide all the necessary information,
21 not just to the patients, but also to our clinicians
22 as well.

23 And then, the third point, which was
24 already elaborated, is that the latest guidelines
25 that came out from the American Thyroid Association,

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1 over the period of time we have learned the evolution
2 of the thyroid cancers and we have learned that there
3 are instances in which the patients may not
4 necessarily need iodine treatment. That would be,
5 also, as important a consideration as giving the
6 treatment itself. That would be a very important
7 discussion that should take place between the
8 surgeon, the endocrinologist, and the nuclear
9 medicine physician.

10 And the first question, really, you know,
11 when we discuss and train the residents, we usually
12 tell them, "Before you even go to the step of" -- as
13 you know as part of the NRC, we have to do the
14 attestation. We have to show there are six
15 treatments, and they have to participate in the plan.
16 But, before we even go to the plan, we ask them the
17 question, "First, decide when you don't need to treat
18 and, then, only focus on how you will be treating
19 it." And that is very well laid out in the most recent
20 guidelines of the American Thyroid Association that
21 came out. We should be mindful of the fact that
22 there are instances where we may not need to give the
23 treatment in the first place.

24 MR. CARPENTER: Thank you.

25 Any other comments?

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1 (No response.)

2 No? Okay. Very good.

3 Let's go to the telephones. Operator?

4 OPERATOR: Thank you.

5 The first question comes from No. 7.

6 You may ask your question.

7 ANONYMOUS: Yes. Regarding the
8 educational process, you know, when should that be
9 done with a patient, obviously, that should be done
10 ahead of time for several reasons. The patient has
11 to make special arrangements, and that has to be taken
12 into consideration.

13 Also, a patient will go with all the
14 information and, then, all of a sudden, while they
15 thought they understood, while talking to the
16 authorized users, or whatnot, all of a sudden, they
17 have some sort of a confusion about something. They
18 are not quite clear about something. And therefore,
19 they might have additional questions that might
20 require some clarifications.

21 Also, things might have changed in their
22 life, whatever that might be. And all of a sudden,
23 now that could be a hurdle, and they need to sort of
24 get back with the user and say, "Oh, by the way,
25 here's what going on in my life here, and how do I

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1 deal with this with my treatment per se?"

2 Maybe the patient needs to be educated
3 about some sort of like a deadline. "Well, we
4 know you might have a question. However, here
5 is the thing: we need to wrap up this by this
6 date because we will order the source, and
7 therefore, there is a cost associated with it.
8 Therefore, after that, you really cannot change." Of
9 course, you can always change it, but there are
10 consequences associated with that as far as the
11 financial burden of the institution or patient, or
12 whatnot. And I think this has to be probably
13 addressed with the patient.

14 And that's all I have for a comment.

15 MR. CARPENTER: Good. Thank you very
16 much.

17 The next person.

18 OPERATOR: At this time, I am showing no
19 further questions.

20 MR. CARPENTER: Very good. Go around
21 the room one more time?

22 MR. BLOOM: Dr. Ghesani, you mentioned
23 how the doctors or the medical professionals have to
24 work across their areas of expertise, and I agree
25 that I think that is very important. As we try to

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1 brainstorm about ways to improve this process, one of
2 the complications that I can think of is when the
3 patient is working across medical centers or out in
4 the community, as opposed to within a center where
5 all of the specialists -- forgive me -- have coffee
6 together, you know, work together routinely.

7 So, the process is easier in that one
8 environment than in the other environment, which I
9 don't know statistically, but I am guessing is more
10 frequent, that people's doctors are not in the same
11 institutions. And I think somehow that thought
12 process has to enter in. And how do you get people
13 on the same page when they are not working together
14 as a routine?

15 DR. GHESANI: I can answer that. In
16 fact, there is some good news on this front, which is
17 that in many centers -- first of all, there is a trend
18 for what is called multidisciplinary approach. And
19 that is not just unique to thyroid concerns; it is
20 happening in almost every cancer.

21 So, on a weekly basis, we have on an
22 average about 20 to 30 multidisciplinary conferences
23 that are taking place. Within each department, we
24 come with a plan and say it is humanly impossible for
25 any one person to attend all of them. What we do is

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1 for every department we decide what are your interest
2 areas and what are your capabilities for attending
3 these conferences. On an average, it turns out maybe
4 in my case about three to four a week is what we end
5 up attending.

6 So, in those conferences any particular
7 case that is anything out of the ordinary in terms of
8 there is no super treatment and you can just treat
9 it, and if that is not the case, if any case requires
10 more input from the other departments, those cases
11 are discussed at multidisciplinary approach.

12 And national organizations actually
13 encourage, and if you have accreditation from them,
14 they actually come and audit the number. So, there
15 is a cancer registry, for example, and if you are
16 part of it, they will come and ask you how many of
17 your total number of patients you end up bringing up
18 for discussion at the multidisciplinary conferences.

19 So, that is actually good news. In fact,
20 just in the break time I was looking at my email, and
21 I got an invitation for one next week which was about
22 thyroid cancer. We usually try to arrange it at a
23 time when most people agree that that is convenient
24 for them to come and attend. So, that is the good
25 news.

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1 Now the other good news is that in this
2 changing paradigm we find that there are many, many
3 centers that are able to join in even remotely. So,
4 there are instances where you may have conferences
5 very similar to here where you have a few people in
6 presence physically, but, then, you have input from
7 others joining in remotely as well. So, we do the
8 webcast. We do the multidisciplinary conferences
9 that are attended by other hospitals remotely.

10 And that actually is also a new paradigm
11 which I strongly support because now it actually
12 maintains the level of care across the system. It
13 is still not at its fully-mature state yet. I think
14 that would be an important part in going forward in
15 terms of management of patients, is that if there is
16 either direct or indirect access to bringing a case
17 discussion and asking the other departments before we
18 actually deliver the treatment, I think there are a
19 lot of benefits to that approach.

20 MR. BLOOM: I definitely agree with that.
21 Is that also into community caring physicians?

22 DR. GHESANI: So, as far as I know, what
23 it turns out to be is that if the community caring
24 physician or that community hospital has affiliation,
25 either direct or indirect, with the larger

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1 institution, then that often becomes available. I'm
2 not sure about what would be happening in a remote
3 area in a community center which does not have that
4 direct or indirect access. I think that there might
5 be still an action to call for a consult and ask for
6 an opinion for a case.

7 MR. BLOOM: Well, it certainly sounds
8 like that is addressing most of the concern. My
9 guess is that is not going to satisfy in all ways.

10 I think of, as an example, the patient
11 who goes to MD Anderson for their surgery but lives
12 in Nebraska and decides to work with a local
13 endocrinologist and nuclear medicine treatment
14 center. They are probably not going to have a
15 collaboration of that same measure that you are
16 speaking of. Hopefully, the two local physicians
17 will put their heads together, though, to at least
18 get on the same page between them.

19 DR. GHESANI: Right. I am glad you
20 mentioned that because that also brings up a point
21 you mentioned earlier when we were having a discussion
22 about patients being equally involved and being a
23 partner in their care.

24 MR. BLOOM: Yes.

25 DR. GHESANI: And there is a win/win

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1 benefit to that. In that example, if the patient
2 already had the care at MD Anderson and was aware,
3 and potentially may even have had a consult with the
4 nuclear medicine physician about what they feel,
5 whether this patient needs the treatment or not, if
6 the patient or the family members all together
7 coordinate that communication between the two
8 institutions, even if the treatment is delivered
9 remotely, at least whether the patient needs the
10 treatment or not, and if the patient does, what level
11 of treatment is needed, those are all the points that
12 are agreed upon, sometimes brokered by the patient or
13 their family members. There is still an improvement
14 opportunity for delivering that care as opposed to
15 delivering it in isolation. So, there is clearly
16 valuable to deliver.

17 MR. BLOOM: I agree. Thank you.

18 DR. GHESANI: Sure.

19 MR. LICHTY: Yes, I have a question that
20 might be a little bit off-topic. But as far as
21 releasing patients, is there consideration for some
22 of the other side effects of taking the radioactive
23 iodine, such as, well, one of the major ones is that
24 your salivary glands are affected? Most people, it
25 is just suck on Lemon Drops or something like that.

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1 But I think we have heard from some people
2 in our group that people have more severe reactions,
3 and I wonder if that is a consideration in whether
4 you even remain hospitalized or not.

5 DR. GHESANI: So, I can answer that. In
6 addition to the Lemon Drops, I think hydration is a
7 very, very important part that it plays. Mainly, it
8 increases the output, and the retention of iodine in
9 the salivary glands is shown to be lower in the more
10 hydrated state. It also increases the likelihood of
11 faster excretion of the iodine that does not end up
12 in the target areas.

13 The third advantage is that the urinary
14 bladder that is going to end up receiving significant
15 amount of dose, the hydration also will encourage the
16 patients to have frequent voids. That will decrease
17 the potential radiation dose to the urinary bladder,
18 too. So, there are multiple levels at which the
19 hydration really plays out its benefits.

20 In our case, what it turn out is that we
21 get to see the patients on the followup, too, when
22 they come for their post-ablation scans as well as on
23 their subsequent exams. We often make it a point to
24 ask them, you know, if you followed the instructions
25 appropriately; was the side effect a significant

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1 factor?

2 It turns out that the other good thing
3 that happens is that at multiple levels patients get
4 the reminders about this. So, the technologist will
5 tell them. The radiologist physicist will remind
6 them. The physicians will remind them.

7 As a result, it becomes very apparent to
8 the patient that they should be following those
9 guidelines. If they do, we find that really that
10 side effect is very minimal. In fact, I often hear
11 more about just the annoying taste, and I'm sure you
12 can tell me, there is a metallic taste patients
13 mention. That becomes often factor than having the
14 problems with the salivary glands.

15 And the other thing that I hear often
16 from them is that, when they stop their low iodine
17 diet, that is their first time to rejoice when they
18 go to the regular diet. And then, the second time
19 they mention is about a few weeks after the treatment
20 when that metallic annoying taste goes away. And
21 then, they feel so much better in terms of enjoying
22 their meals. So, that is what I hear from the
23 patients more often.

24 MR. BLOOM: I really like the fact that
25 you said you follow up with "Did you follow the

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1 instructions?" I like the swinging back on that
2 loop.

3 When I think of the comment made earlier
4 today about having pre-instructions, during
5 instructions, and post-instructions, to actually
6 evaluate after the fact how did we all do, and you
7 and I talked about this concept of it is a
8 collaboration. So, how did we do? Did I get my
9 message across as the instructor to the physician?
10 And did I, as the patient, follow those instructions?
11 I like that because that gives you feedback really to
12 know, if there were any problems, where did they
13 manifest from? And then, also, what do we need to
14 change within your institution, within your process,
15 and then, also, for the greater good? So, I like
16 that, the feedback loop. I think that is a really
17 excellent extra step.

18 Thank you.

19 MR. CARPENTER: Very good.

20 Personally, I started my low salt diet
21 when I left the military.

22 But let's go back to the telephones.
23 Anybody on the telephone?

24 OPERATOR: At this time, I am showing no
25 questions.

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1 MR. CARPENTER: All right.

2 DR. HOWE: Do we have anybody on the
3 telephone that is from a smaller facility or a private
4 practice that may want to make a comment?

5 OPERATOR: And once again, if you would
6 like to ask a question or you do have a comment, you
7 may press *, then 1.

8 One moment.

9 (Pause.)

10 DR. HOWE: So, just to repeat, do we have
11 anybody on the phone that is from a smaller facility
12 or a private practice that would like to make
13 comments?

14 MR. CARPENTER: We will give it a moment.

15 OPERATOR: We do have a question online
16 at this time. The question comes from No. 8.

17 You may ask your question.

18 ANONYMOUS: Hi.

19 OPERATOR: Your line is open.

20 ANONYMOUS: Hi. I'm starting my RAI
21 treatment the first week of February. And I can
22 honestly tell you that all I have been given is the
23 date to go in.

24 MR. CARPENTER: I'm sorry, you said all
25 that you have been given is the date to go in?

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1 ANONYMOUS: I have no idea that I'm
2 supposed to do anything to prepare for isolation. I
3 don't know of any restrictions, what I should do with
4 my family, what I should do with anything in my home.

5 MR. CARPENTER: You are hearing feedback
6 from the session. Go ahead.

7 ANONYMOUS: Can you hear me?

8 MR. CARPENTER: Yes. Thank you.

9 ANONYMOUS: Okay. Basically, what I was
10 given is the date to go in to start my RAI treatment,
11 and I know nothing until I go in that first day. And
12 that is really not enough time for me to prep. I
13 have four children in my home. I have three pets.
14 I have a husband who works 70 hours a week. I have
15 no idea of anything, and I don't understand why. And
16 I am in northern Kentucky and this is UC Radiology
17 Nuclear Medicine Department I am going to in
18 Cincinnati.

19 And it just seems not feasible to me that
20 I would be sent in, that I am going to be starting
21 treatments, and I have no idea how to prep.

22 MR. CARPENTER: Okay. Thank you.

23 Anybody in the room like to make a comment
24 on that?

25 DR. GHESANI: So, I mean, I just want to

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1 be sensitive to your personal health information.
2 From that standpoint, I will just make a comment.
3 You don't need to answer me.

4 But my comment would be that in many ways,
5 well before your treatment there are different
6 settings in which you have to visit the nuclear
7 medicine department, including getting your setup for
8 the Thyrogen injections and all of that. So, I am
9 not sure if that applies to you or not or whether you
10 were on withdrawal.

11 But, as I mentioned, you don't need to
12 give more details, especially if you are not
13 comfortable describing it, because I understand it is
14 your own personal health matter. But I would
15 recommend you go back and you call them and ask for
16 an appointment to see a nuclear medicine physician.
17 And then, also, you should inquire regarding your
18 schedule for the Thyrogen injections because,
19 typically, at least for two days in a row before you
20 actually will receive your treatment, you will be
21 visiting the department for the Thyrogen injections.
22 So, I recommend that you should make a phone call and
23 ask them to even meet with you even before you receive
24 your first Thyrogen injection.

25 ANONYMOUS: I am scheduled for the

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1 Thyrogen injections. However, my point is my
2 endocrinologist told me there is no isolation
3 necessary, from his understanding. He said that
4 medicine has evolved and we have moved on; it is not
5 the same RAI treatments as in the past.

6 Yet, when I called the Radiology
7 Department to ask what time I come in for my Thyrogen
8 injection and asked about isolation, they said I
9 wouldn't know that until my dose on Thursday. That
10 gives me no time to prepare. Is that normal?

11 DR. GHESANI: Actually, you are correct,
12 especially given your family situation you described.
13 I would recommend -- you still have about 11-12 days.
14 I would recommend that you insist on making an
15 appointment and wanting to see the physician in
16 advance of actually receiving the treatment.

17 MR. CARPENTER: Okay. Thank you, ma'am.
18 We appreciate that.

19 Anything else that you would like to
20 share?

21 (No response.)

22 Okay. Thank you.

23 Operator, do we have anybody else on the
24 line?

25 (No response.)

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1 Hello? Christine?

2 OPERATOR: Thank you. We do.

3 No. 9, you may ask your question.

4 MR. CARPENTER: Thank you.

5 ANONYMOUS: My name is Ralph Lieto. I'm
6 a medical physicist, and I have been involved in
7 nuclear medicine for over 30 years.

8 I wanted to address Dr. Howe's inquiry
9 about smaller settings in terms of how they handle
10 iodine therapies. I have worked both in a large
11 urban medical center that was a broad-scope licensed
12 as well as in a community setting. I think the
13 experience that your patient advocate was talking
14 about earlier and somewhat the patient before I got
15 on the line is typical of what happens.

16 Usually, the nuclear medicine department
17 will not know much about the patient's history until
18 they are referred by the endocrinologist. That can
19 be just a matter of a few days or a week, and they
20 aren't going to know anything until they do an uptake.

21 So, even though Dr. Ghesani makes some
22 very good suggestions as to what should be done as a
23 long-term preparation, and so forth, very often in a
24 community setting you don't have those kinds of
25 handoffs. Most of these settings do not have a

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1 medical physicist on staff. All the interactions are
2 done between the patient and the nuclear medicine
3 technologist.

4 And so, the long-term or, in fact, two-
5 week preparation that he was kind of suggesting might
6 be ideal, but I think as you get farther out of the
7 urban setting where you don't have the sort of close
8 collaboration between your endocrinologist and your
9 nuclear medicine and radiology staffs, those handoffs
10 and the timeframes between the patient presenting to
11 the nuclear medicine department to begin their
12 assessment and treatment become quite short.

13 In some settings, because of patient
14 preference and travel and other things, they will do
15 the uptake. And then, in a matter of a day or even
16 sometimes the same day, administer the radioactive
17 iodine based on the uptake that was done earlier in
18 the day, simply to minimize patient inconvenience.

19 So, it is a little bit different, and I
20 think that is the more common scenario as you get
21 into the strictly urban -- or excuse me -- community
22 settings where you don't have dedicated nuclear
23 medicine physicians that just do nuclear medicine.
24 There may be a radiologist who is also doing radiology
25 combined with his nuclear medicine practice, and you

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1 don't have medical physics on staff.

2 Thank you.

3 MR. CARPENTER: Thank you for those
4 comments.

5 Do we have anyone else on the line?

6 OPERATOR: We do. The next question
7 comes from No. 10.

8 You may ask your question.

9 ANONYMOUS: Yes. We talked so much so
10 far about a one-way street in a way. At least that
11 is my perception. I think the patient that just
12 called in, and she brought up her case, makes a very
13 important reason for us to talk about what are the
14 expectations from the patient.

15 What I mean about that is that there
16 should be some information available to them in terms
17 of what to expect going into this type of treatment.
18 And when you go to the institution, request the
19 educational material, the radiation precautions, the
20 instruction after discharge, and so on and so forth.

21 I think the patient should go with that
22 list in hand, and they are entitled to that
23 information if they are going to go through that kind
24 of a treatment. So, I think the patient should have
25 that available and ask those questions prior to going

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1 through the treatment.

2 And if they don't get the answers, then
3 I think they ought to perhaps look elsewhere where
4 they will feel more comfortable getting their
5 treatment, as it should be.

6 Thank you.

7 MR. CARPENTER: Thank you very much.
8 Good comments on informed consumerism there.

9 Christine, do we have any others on the
10 telephone?

11 OPERATOR: The next question comes from
12 No. 11.

13 You may ask your question.

14 ANONYMOUS: Well, okay. I am also a new
15 thyroid cancer patient, and I also am starting my
16 radioactive treatment on the 3rd of February. I am
17 going to have the Thyrogen shots, one and two,
18 February.

19 But I also have not been given any
20 information on how to prepare for this isolation.
21 Now I have gone online myself and found some numerous
22 sites that are helping me, but I am just wondering,
23 is there a way that you are going to be able to -- I
24 don't know how to say it -- police it up, go behind?
25 How are you going to regulate whether the patient

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1 ever gets any information? Because it sounds like
2 there are a lot of patients who never get any
3 information, and that doesn't seem right.

4 That's all I have.

5 MR. CARPENTER: Thank you.

6 Doctor?

7 DR. HOWE: In regulatory space, we
8 probably won't be able to write specific regulations
9 in that regard, but we can provide guidance to our
10 authorized users. And we are hoping that our website
11 that will send people to other sites to collect
12 information may make for more informed patient
13 consumers to know to ask the questions and to go to
14 the licensees and ask for more.

15 It is very difficult for us to write
16 prescriptive regulations, and it takes years. So,
17 we are hoping to address some of these issues in clear
18 and concise guidance.

19 MR. CARPENTER: Does that any your
20 question, ma'am?

21 ANONYMOUS: I guess so. Thank you.

22 MR. CARPENTER: Thank you.

23 Christine?

24 OPERATOR: At this time, I am showing no
25 further questions.

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1 MR. CARPENTER: Okay. We will go around
2 the room one more time.

3 Yes, sir?

4 DR. GHESANI: Yes, I think hearing these
5 comments, it looks like it may be something to
6 consider on our medical practice side, to see if there
7 could be a way for this becoming a standard practice,
8 where just about two or three weeks prior to the
9 actual delivery of the treatment, in addition to the
10 patient seeing a surgeon, you know, obviously, the
11 surgeon is doing the surgery in the OR, they are going
12 to set up a patient for a postop appointment to make
13 sure that the scar has healed; there are no
14 complications. That is a given, right? You don't
15 question that kind of a practice because you expect
16 that to be ingrained in the nature of surgical
17 practice.

18 What we don't have is a practice of seeing
19 the patients regularly two weeks before you actually
20 deliver the treatment. Hearing more and more about
21 these comments, I think it will be upon the medical
22 community to consider having that norm.

23 As I mentioned earlier, that also allows
24 you to give the right timing for the patients to
25 realize how important it is to start practicing

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1 hydration and low iodine diet, and what the timeline
2 of their appointment is going to be.

3 And then, you have a consult that goes
4 into the details of individual patients' situations
5 that may impact how you are going to recommend the
6 contact restrictions and how long that will be and
7 how severe that will be.

8 So, I think that, short of doing a routine
9 two-week prior treatment consult, I don't think we
10 can accomplish the full preparations for the patients
11 in making sure that they don't have a surprise on the
12 day of treatment or, suddenly, they find out that
13 there is no way I can arrange for all my family to go
14 away for a few days on a very short notice.

15 So, I think that is something upon the
16 medical community to consider, having it a routine
17 two weeks prior to treatment appointment in the
18 nuclear medicine department.

19 And I heard about the community
20 practices. Well, potentially, a radiologist can fill
21 in that gap, if that is a possibility in a community
22 hospital, maybe even a short consult, but at least it
23 addresses all the concerns and questions the patients
24 may have.

25 DR. HOWE: It also raises the gap when

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1 we have been talking this morning about the patient
2 being prepared for the release. But I am thinking
3 that you also need time for the facility to prepare
4 in case they can't release the patient.

5 DR. GHESANI: Yes.

6 DR. HOWE: So, the timeframe is important
7 from both perspectives.

8 MR. BLOOM: Thank you for those comments.

9 I think that one of the things I am
10 hearing is that we, as a patient organization, need
11 to really step up our side of this and try go make
12 sure that we have very visible and even more
13 comprehensive materials, so that we can be there as
14 an information portal to patients.

15 We don't exist to provide medical advice,
16 but we can create medical empowerment to people who
17 we reach which will allow them to initiate processes
18 when they aren't aware of them routinely.

19 As we discussed the different aspects of
20 how we all fit into the relationship, it is hard to
21 prepare for what you don't know anything about. So,
22 either, as Dr. Ghesani said, the medical community
23 has to initiate or those of us who have walked the
24 path before have to help try to lay it out. Either
25 way, unfortunately, there is still some wish and

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1 prayer here, that we are wishing and hoping that
2 people will find us one way or another, meaning
3 finding ThyCa or finding the Society for Nuclear
4 Medicine and Magnetic Imaging, to find these
5 materials which will help provide guidance when, in
6 fact, no guidance was offered.

7 I am specifically thinking of these two
8 ladies who are going to go into this process within
9 days of each other in less than two weeks. I don't
10 know if you have both been on the phone the whole
11 morning, but I am sure you are more empowered now
12 than you were earlier. There is still time to
13 intervene now, which is the good news for you, but I
14 am equally thinking about the people who are not part
15 of this phone call and don't know that they have a
16 problem. So, we need to strengthen our process all
17 the way from all sides.

18 DR. GHESANI: Thank you.

19 I think one consideration would be for
20 all the patient support groups, in addition to
21 providing the information about what kind of side
22 effects to expect or what kind of precautions or
23 personal experiences you share with the patients who
24 are going through it now, I think it may be important
25 if you also mention there insist on having a prior

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1 discussion with your nuclear medicine physician well
2 in advance of receiving your iodine.

3 I think if you put that comment in, more
4 and more patients will read that in advance, will
5 start thinking about it. So, we can decrease the
6 likelihood that those instances will happen in the
7 future.

8 MR. CARPENTER: Very good. Fine.

9 One last time on the telephones, any
10 comments?

11 OPERATOR: We do have a question.

12 No. 8, your line is open. I'm sorry, No.
13 8, your line is open.

14 ANONYMOUS: Hello. I was just wanting
15 to reiterate, as far as treatment, I do belong to an
16 online support group and the low iodine diet
17 community. Without them, I would not even have known
18 that there was possibly a necessity for isolation for
19 treatment.

20 I called in earlier. I have my treatment
21 in February.

22 I just want to say I think it would be
23 divine to meet a nuclear medicine doctor prior to our
24 treatment. Because what I am seeing online in
25 support groups is our endocrinologists are also

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1 giving us varied information. It doesn't seem to be
2 regulated completely.

3 The diet again, everyone is told
4 something different. We are told something different
5 about isolation, apparently, those who are told, even
6 though I wasn't.

7 And so, I think if somehow that could
8 become a regulation, that we meet prior, at least two
9 to three weeks, as everyone has been saying, with our
10 nuclear medicine doctor, because endocrinologists,
11 there seems to be some variation for the information
12 they are giving patients, too. And it is really kind
13 of murky and the waters are getting really muddy.

14 MR. CARPENTER: Thank you, ma'am.

15 Christine, any other comments?

16 OPERATOR: At this time, I am showing no
17 further comments or questions.

18 MR. CARPENTER: Okay.

19 Shall we go on to the next topic?

20 DR. GHESANI: Sure.

21 MR. CARPENTER: Okay.

22 DR. HOWE: Okay. The next topic is a
23 Brochure for Nationwide Use. The Commission thought
24 that it would be important if there were such a
25 brochure that could be sent out nationwide that would

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1 give patients certain minimum information about the
2 treatment and what they need to do to keep radiation
3 doses to others as well as reasonable, would be a
4 thing that might be important.

5 And so, what we are asking is for people
6 out there that have a lot more experience with this
7 than we do, do you know of a brochure or a pamphlet
8 that you believe would be good for distribution,
9 either by a professional society or the NRC, for
10 nationwide use that would provide additional clarity
11 to patients on I-131 treatments?

12 And so, if you do know of such a brochure,
13 to identify it to us and provide us with a copy or a
14 link to it, so that we would have a chance to look at
15 it and see if we thought it was good for a nationwide
16 distribution.

17 We know that there are several brochures
18 out there from different groups. And so, we are
19 interested in getting as wide a poll as possible for
20 maybe other things that are not as well-known.

21 And I believe at this point we can open
22 it up for a discussion.

23 MR. CARPENTER: Okay. Since we went
24 around the room first last time, let's go to the
25 telephones.

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1 Christine, any commenters?

2 OPERATOR: At this time, I'm showing no
3 comments.

4 MR. CARPENTER: Okay. We will come back
5 to you on the telephone.

6 In the room?

7 MS. KUBLER: Hi. This is Caitlin Kubler
8 with the Society of Nuclear Medicine.

9 We have a brochure that is available for
10 print as well as online. It covers several topic
11 areas that the NRC is seeking information on.
12 Perhaps we can amend that to include some of the other
13 areas.

14 But, just to start, it includes what is
15 radioiodine therapy? How long does it stay in the
16 body? How can you reduce exposure to others? And
17 then, it talks about the first eight hours, the first
18 two days, the first week. And then, it also talks
19 about specific recommendations for those who are
20 breastfeeding and pregnancy. And then, it also talks
21 about what you should know during the first week of
22 your treatment.

23 And there also is a caveat on there for
24 every specific case is different and you should meet
25 with your physician to talk about your specific

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1 situation because, although we can provide general
2 guidance, we can't talk to every specific case. As
3 Dr. Ghesani has mentioned before, those are
4 conversations that you should have with your
5 physician.

6 We will be happy to provide that in our
7 formal comments, and I will be happy to share the
8 link. That is easily accessible on our website and
9 can be searched, and there is no cost for it. It is
10 provided free.

11 MR. CARPENTER: Sorry, could you give
12 your website for the people who are on the telephone
13 that may want to look at it now?

14 MS. KUBLER: Sure. It is snmmi.org.
15 And then, you can just search "patient materials,"
16 and it will be under the radioiodine section, the
17 fact sheet.

18 MR. CARPENTER: Okay. Thank you.

19 Any other comments in the room?

20 (No response.)

21 Okay. Back to the telephone. Any
22 commenters on the telephone, Christine?

23 OPERATOR: Yes, sir, we do.

24 At this time, No. 9, your line is open.

25 ANONYMOUS: This is a question for NRC

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1 staff. What is the end purpose that you are looking
2 to achieve here? Are you looking for a singular
3 brochure? And who would be the entity that would be
4 responsible for this? Is this going to be an NRC
5 document or are you looking to have some professional
6 organization sort of develop, or I mean distribute
7 this and be responsible for its update? Or are you
8 looking for multiple brochures?

9 DR. HOWE: At this particular point, we
10 are collecting information. I think the Commission
11 in its direction to us was thinking in terms of if
12 there was a brochure that could provide good, basic,
13 clear information to patients, that that is something
14 that we may want to support, to help provide clear
15 and concise information.

16 So, the actual specifics of whether NRC
17 would distribute it or we would put links to it, that
18 particular part has not been decided yet. We are
19 still in the information-collection mode.

20 And we are hoping people have things that
21 they like and they will tell us about it.

22 MR. CARPENTER: Does that answer your
23 question, sir?

24 ANONYMOUS: Yes. Thank you.

25 MR. CARPENTER: Very good.

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1 Anyone else on the telephone?

2 OPERATOR: The next question comes from
3 No. 10.

4 You may ask your question.

5 ANONYMOUS: A question regarding the
6 Society of Nuclear Medicine website. If a patient
7 has a question or requires a clarification, who would
8 be handling that?

9 Thank you.

10 MS. KUBLER: Well, we don't like to get
11 in the practice of intervening with a patient and
12 their instructions. We advise that patients contact
13 their physician directly for specific instructions.

14 DR. GHESANI: Actually, your question
15 does bring up an interesting point, which is that, as
16 Caitlin mentioned earlier, we are open at SNMMI to
17 update this document as needed. I think it may be a
18 worthwhile practice to have, that those organizations
19 that are directly dealing with treatment, radioiodine
20 treatment of patients, both for hyperthyroid and for
21 thyroid cancer, can work with the patient groups.

22 And then, it will be actually very rich
23 material that can come out of it because, on one hand,
24 the Society for Nuclear Medicine does provide the
25 data that is from the professional side. But we

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1 always have learned that many things that science
2 mentions are not ultimately what we hear from the
3 patients.

4 And patients' experiences, maybe there is
5 a potential for adding some additional instructions
6 that may be even more beneficial. So, I think it may
7 be an ongoing dialog. You know, we have our
8 Societies' meetings where we do have sessions for the
9 patient support groups. And maybe we can create a
10 group, a larger group, which covers both professional
11 organizations and patient support groups, and they
12 can all come on the same platform, whether by call or
13 any other means. But we can work together to refine
14 and update this document as needed.

15 The other question that came up on the
16 phone was, who will be in charge updating it, right?
17 You know, the document, as good as you refine it, may
18 only be relevant now. If things change in the future,
19 it may lose its relevance. So, it needs to be
20 constantly updated as well.

21 And we do have our committee that looks
22 at these documents, but I think it will make it richer
23 if there is a partnership with the patient support
24 groups as well on it.

25 MR. BLOOM: Certainly, we would welcome

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1 the opportunity to work in such a collaboration. We
2 have created materials in collaboration with medical
3 specialists across the disciplines, as you have
4 mentioned earlier. We would welcome this opportunity
5 to help enrich your product and also to distribute
6 it. We distribute materials worldwide free of
7 charge, as well as making them available for download
8 from our website.

9 So, we are very enthused about the
10 opportunity to partner with you. I mean, we would
11 be coming to your members anyway because this is a
12 product that would require medical validation. So,
13 to actually initiate it out in the open, it is
14 perfect.

15 And to the gentleman who was speaking for
16 the community side, we would want your participation
17 as well because I think that is an important
18 perspective as well.

19 MR. CARPENTER: Caller on the telephone,
20 did that answer, if you are still there?

21 ANONYMOUS: Hello?

22 MR. CARPENTER: Yes?

23 ANONYMOUS: Yes, I think that answered
24 the question. Thank you.

25 MR. CARPENTER: Thank you very much for

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1 the comment or the question.

2 Christine, any others on the telephone?

3 OPERATOR: At this time, I am showing no
4 further questions.

5 MR. CARPENTER: Okay. One more time
6 around the room, any other comments?

7 (No response.)

8 No more comments in the room?

9 One more time to the telephone.

10 OPERATOR: Showing no further comments.

11 MR. CARPENTER: Okay. Let's go to the
12 next one.

13 DR. HOWE: So, that takes us to closing
14 of the meeting. The most important thing I can say
15 to you is that the submissions are due to the NRC on
16 February 16th, 2016. We have heard a lot of important
17 information here, a lot of important concepts here.
18 But, in order for us to respond to it adequately, we
19 need you to submit your information to us on patient
20 release in a formal manner.

21 If you have questions on electronic
22 submissions -- and this information is in The Federal
23 Register notice -- then you can contact Carol
24 Gallagher. Her telephone number is 301-415-3463.
25 Her email is carol.gallagher, G-A-L-L-A-G-H-E-R, @

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1 nrc.gov.

2 If you have technical clarification or
3 questions, you can contact me. My telephone number
4 is area code 301-415-7848. Again, that is
5 301-415-7848. And my email address is donna-beth,
6 D-O-N-N-A, hyphen, B-E-T-H, .howe@nrc.gov.

7 If you need a copy of The Federal Register
8 to see exactly the information that we are hoping to
9 collect, then just contact me and I will send a copy
10 of The Federal Register notice to you.

11 How do you submit information to the NRC?
12 You can submit it electronically by going to the
13 website <http://www.regulations.gov>. Search for our
14 docket number, which is NRC-2015-0020.

15 And if you are not electronically
16 comfortable, you can send things; you can mail
17 information and comments to Cindy Bladey, the Office
18 of Administration at the Nuclear Regulatory
19 Commission, and her mail stop is OWFN, One White
20 Flint, -12-H08, at the U.S. Nuclear Regulatory
21 Commission, Washington, D.C. 20555-0001.

22 Are there any other questions that you
23 have for NRC or that you would like answered by us or
24 members on the phone?

25 MR. CARPENTER: And we will go to the

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1 phone first.

2 OPERATOR: Once again, if you have a
3 question or a comment, please press *, then 1.

4 One moment.

5 (Pause.)

6 At this time, sir, I am showing no
7 questions.

8 MR. CARPENTER: Thank you very much,
9 Christine.

10 Anyone around the room?

11 DR. GHESANI: I just want to congratulate
12 both of you and NRC. This is a wonderful initiative.
13 This is something that brings up the points about how
14 our patients, our medical community, and our
15 regulators can work together to improve the care.

16 I am sure many of us have heard the
17 individual experiences as well as the general trends
18 and the differences in the practice patterns
19 throughout the country. I think something like this,
20 to have it in a forum like this, is very refreshing
21 to see.

22 So, thank you and congratulations.

23 MR. CARPENTER: And thank you for your
24 participation in this.

25 Anything else?

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1 MR. BLOOM: I will add my thank you as
2 well. I think it is a great opportunity to connect
3 both with the NRC people, who have great interest in
4 our health as far as this matter is concerned -- so,
5 thank you for that -- and, also, to connect with the
6 medical professionals, both as associations and as
7 individuals. It is a great opportunity to meet and
8 to initiate the opportunities for collaboration,
9 which will benefit everyone.

10 So, thank you all for putting this
11 together.

12 MR. CARPENTER: And we do appreciate both
13 the medical community and the patient advocacy
14 committees coming in and talking and giving us this
15 feedback, as well as all the people on the telephone.

16 Let me go one more time to the telephone.
17 Any other comments on the line, Christine?

18 OPERATOR: At this time, I am showing no
19 further comments.

20 MR. CARPENTER: Okay. Christine, thank
21 you very much for all the assistance that you have
22 done today. You have been wonderful.

23 To the people on the telephone, thank you
24 very much for your participation and for all of your
25 questions and comments.

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1 On a very personal note to those patients
2 who called in specifically, I wish you the very best
3 and a very speedy recovery. Hopefully, everything
4 will work out very soon.

5 At this time, again, I reference you to
6 both the regulations.gov website and to the materials
7 that Dr. Howe has put out on our website previously.

8 Please provide any questions/comments
9 that you have to us in as timely a manner as possible.

10 Thank you very much for your
11 participation again.

12 With that, I would like to go ahead and
13 conclude the meeting.

14 Donna-Beth, thank you.

15 Thank you all.

16 OPERATOR: This concludes today's
17 conference. Thank you for your participation. You
18 may disconnect at this time.

19 (Whereupon, at 2:10 p.m., the meeting was
20 adjourned.)

21

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