UNITED STATES

NUCLEAR REGULATORY COMMISSION

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PUBLIC MEETING WITH THE ADVISORY COMMITTEE

ON THE MEDICAL USES OF ISOTOPES (ACMUI)

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THURSDAY,

MARCH 8, 2018

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ROCKVILLE, MARYLAND

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Chairman Svinicki and Commissioner Baran met in the Commissioners' Hearing Room at the Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, at 10:00 a.m., Kristine L. Svinicki, Chairman, presiding.

KRISTINE L. SVINICKI, Chairman

JEFF BARAN, Commissioner

ALSO PRESENT:

ANNETTE VIETTI-COOK, Secretary of the Commission

MARGARET DOANE, General Counsel

ACMUI MEMBERS:

PHILIP ALDERSON, M.D., Chair

PAT ZANZONICO, Ph.D., Vice Chair

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

CHRISTOPHER PALESTRO, M.D., Nuclear Medicine Physician

LAURA WEIL, Patients' Rights Advocate

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P R O C E E D I N G S

10:02 a.m.

CHAIRMAN SVINICKI: (presiding) Good morning, everyone.

I will be very precise in my terminology this morning. We meet now -- Commissioner Baran and I are conducting a public meeting this morning with the Advisory Committee on the Medical Uses of Isotopes.

Commissioner Burns sends his apologies. Due to a prior commitment, he could not attend today's Commission meeting with the ACMUI. The Commissioner will be informed of today's discussions upon his return to the office. I will just note that I know he sincerely regretted the scheduling of this meeting, but was not able to -- he had made this prior commitment and he wanted to honor that. So, again, I know he will take great interest in this discussion when he returns to the office.

Again, Commissioner Baran and I will hear views of our Advisory Committee on the Medical Uses of Isotopes on medically-related topics of regulatory interest. This is always a meeting where I take a lot on. The reason that the Advisory Committee on Medical Uses of Isotopes exists that we do have this regulatory jurisdiction over the medical uses. And yet, we are not squarely a medical-related regulator. So, this

Advisory Committee plays a very important role in providing perspectives and insights to the NRC staff in this meeting. In these public meetings that they conduct with the Commission, we get to hear directly and benefit from the expertise that you all provide.

Before we turn it over to the Committee members, I would ask if Commissioner Baran has any comments to make.

Okay. Hearing none, I will turn it over to the current ACMUI Chair, Dr. Philip Alderson, and if you would begin. And then, if you would like to hand off to each other, or you can hand it back to me, and I'll hand it off. It is a public meeting, so it could be maybe a little less formal, but whatever works.

And thank you again for being here today.

DR. ALDERSON: Thank you, Chairman Svinicki. It's our pleasure and honor to be here today, and Commissioner Baran, thank you for being here.

It's my role here to give you an overview of what we're going to discuss in the next few minutes. So, we will review, as we traditionally do, the ACMUI purpose and the membership, and then, the topics that we'll be discussing with you and some areas of future interest.

So, the ACMUI exists to advise the NRC staff and you, of course, as our Commissioners, on policy

on medical uses of radionuclides and to provide technical assistance and to serve as your consultants. This involves a number of membership positions, and they are listed on a third of the slides. They include a health care administrator, a nuclear medicine physician, two radiation oncologists, a nuclear cardiologist, a diagnostic radiologist, two medical physicists, a nuclear pharmacist, a radiation safety officer, a patients' rights advocate, an agreement state representative, and a representative of the FDA.

If you're looking at the materials in front of you, those positions that are followed by an asterisk are people who have currently been appointed, but are not fully yet approved to vote on the Committee.

In the next slide we'll review some of the topics that the ACMUI has addressed in the past year. We have spent a fair amount of time -- and you will hear a report on a moment -- about training and experience requirements. Now in the last year we began looking at 35.100 uses. That's unsealed byproduct material for uptake, dilution, excretion studies, for which a written directive is not required. And the plan was to move methodically sort of up the numerical rank through the various categories. As it turns out, as you'll hear in a moment, we've now moved forward to 35.300, and you'll hear more report about that in

a minute.

We also have been very interested in medical event reporting for all modalities except that of permanent implant brachytherapy. We've tried to clarify for your use, for ours, that of the Congress, what patient intervention really means, what does constitute patient intervention. Because if a patient intervenes, we don't have a medical event by definition. So, we've tried to clarify that a bit.

And we've also looked at the impact of medical event reporting on patient safety culture. We would like to see, we would encourage a positive culture that rewards near misses, rewards people for finding things that need to be corrected and correcting them. It is not punitive in nature. And you will, again, hear more about that in one of our follow-up reports.

We've also had an extensive look at guidelines for nursing mothers to whom diagnostic or therapeutic radiopharmaceuticals are administered. The issue there being that, if those pharmaceuticals are onboard, they can radiate the young child in two ways, just from emanating from the other and, also, from concentrating in and being part of the milk. So, you'll hear a good report on that particular issue.

Other topics: potential changes to the

NRC's Patient Release Program. This has been a topic for years and years as we continue to try to adjust the release criteria to current technology and approaches, and make it as safe and effective as possible for the patient and for the loved ones of the patient with whom they might come into contact.

We've also looked at the physical presence requirements for an authorized user when the Leksell Gamma Knife Icon, which is a new version of that machine, is used. And we have suggested potential changes that could make that a more efficient process.

We also have looked at, and hope to have made some progress, in improving the communications of the ACMUI, communications in various directions, communications just among ourselves; between the ACMUI and the staff, your staff, who work directly with us; between the ACMUI and you, the Commissioners.

And so, we hope to get the user community much more aware of the sorts of things we're doing to facilitate safety and efficiency and to hear person-to-person their comments. So, in that regard, a number of our people now are attending at and speaking at particular sessions in major national meetings of our constituents and getting a lot of good interaction and feedback.

We've also had continuing discussions, as

I said a moment ago, of the training and experience requirements, and the current focus is on 35.300 uses, about which you'll hear from Dr. Palestro.

Yes, we, indeed, have reviewed medical event issues, including the patient safety culture. We also have looked at Regulatory Guide 8.39, Release of Patients Administered Radioactive Materials, and looked at how to make that more efficient and more broadly-based. 8.39 tends to focus quite much on iodine-131, but there are a lot of other things coming along that need to be considered. So, the Committee has worked hard to try to broaden that perspective and, as I said earlier, ways to enhance communications with many different groups.

We currently have these issues and a number of others under discussion. And as new issues arise, including emerging technologies, we'll address those and provide advice on aspects relevant to safe handling of radionuclides.

Now that concludes my overview report, and I will now pass the baton to Dr. Palestro.

DR. PALESTRO: Thank you, Dr. Alderson.

My name is Chris Palestro, and I am the ACMUI nuclear medicine physician representative. I'm also the Chair of ACMUI Subcommittee on Training and Experience Requirements for All Modalities. Over the

next few minutes, I would like to update you on some of the work that the Subcommittee has done regarding training and experience.

May I have the next slide, please?

This Subcommittee on Training and Experience was established in 2016, and we are charged with the periodic review of the training and experience requirements currently in effect for all modalities, as well as to make recommendations for changes as needed.

Next slide, please.

So, the Subcommittee is responsible for reviewing the training and experience requirements currently in effect for the uses of unsealed byproduct materials, 10 CFR 35.100, 200, 300, and 1000, as well as the sealed byproduct materials, 10 CFR 35.400, 500, 600, and 1000.

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In order to accomplish our tasks, the Subcommittee developed a comprehensive review template, and it was developed to ensure that there would be a standardized review process; that we could have meaningful comparisons of reviews over time, and finally, that decisions about changes in training and experience requirements would be based on data.

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The Subcommittee planned to begin their initial reviews with 10 CFR 35.100, followed by 35.200, 300, et cetera. However, because of ongoing patient access concerns, the Subcommittee has been directed to prioritize its review of the training and experience requirements for the use of unsealed byproduct material for which a written directive is required, 10 CFR 35.390.

Next slide, please.

The Subcommittee has identified some significant developments. First, on January 26th of this year, the United States Food and Drug Administration approved lutetium-177 dotatate for treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors, including tumors of the foregut, midgut, and hindgut. And this approval is distinctly different from previous approvals of other unsealed sources in that it is a very broad indication, meaning that it has the potential to be used in a much larger number of patients than previously-approved agents.

In addition to that, these tumors, which were once thought to be relatively uncommon, are now recognized as the second most common tumor of the GI tract. So, there potentially will be a very high demand for lutetium-177 dotatate.

Along with that, the Subcommittee has identified the fact that there is a waning number of nuclear medicine physicians in the United States. There were fewer than 50 first-time candidates who sat for the 2016 American Board of Nuclear Medicine certification examination, and this is in contrast to the 80 to 100 candidates that had sat for this examination in previous years.

A review of the Accreditation Council for Graduate Medical Education database shows that a decade ago in academic year 2007-2008 there was 62 nuclear medicine residency programs with 157 residents. In the current academic year, 2017-2018, there are 41 nuclear medicine residency programs with 75 residents. So, over the course of a decade, the number of nuclear medicine residents has decreased by slightly more than 50 percent.

Now, although there is a much smaller number, if you look at the data -- I'm sorry, in the next slide of nuclear radiologists -- it also appears to be trending downward. If you look at 2013, '14, '15, there were 13, 11, 10; 2016-2017, only 2 and 5 individuals, respectively, sat for the American Board of Radiology Nuclear Radiology Certificate of Added Qualifications Examination.

And to put this into perspective, if we

were to look at data for nuclear medicine and for the American Board of Radiology, Therapeutic Radiology, approximately 250 graduates. There was approximately a total of 250 graduates from both of these programs on a yearly basis, all of whom would be qualified, once they passed their Board certification exam, to be Authorized Users. A decrease from that 250 of 40 to 45 individuals coming just from nuclear medicine represents a drop of somewhere between 12 and 15 percent of new Authorized Users entering the field, and that is not an insignificant decrease, in the Subcommittee's opinion. So, there certainly are emerging concerns.

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Previous discussions and presentations that we've held over the past two-and-a-half or three years focused on whether or not there was a sufficient versus an insufficient number of Authorized Users at the present time for administration of an infrequently used therapeutic radiopharmaceutical, Zevalin. No consideration really was given - it was a very focused review -- no consideration was given to future numbers of Authorized Users, nor to new agents that were under development or about to be approved. The Food and Drug Administration approval of the new CFR Part 35.390 drug lutetium-177 dotatate with a potential for a high volume suggests that reevaluation of the situation is in order.

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In considering the development of an alternate pathway, we clearly need to address, to the extent that we can, future needs. And it's also, I think, worthwhile to point out that over the course of the past few years the discussions have focused on a sufficient or an insufficient number of AUs. There's never been a suggestion raised that perhaps there was a surplus of AUs. So, I don't think that is an item of concern, that we have a surplus. That certainly is not an issue.

And then, finally, could a decrease in the number of Authorized Users and an increase in procedures in the 35.390 category affect patient access as new agents in this class of radiopharmaceuticals become available?

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And with the Commissioners' permission, I would like to restate the conclusion, not that it's time to reconsider developing an alternate pathway, but, rather, the time has come to develop an alternate Authorized User pathway for 10 CFR 35.390.

Thank you, and I will turn the microphone over to Dr. Dilsizian.

MR. ZANZONICO: I am not Dr. Dilsizian. I am Dr. Zanzonico, and I am actually the departing

nuclear medicine physicist and Vice Chair of the ACMUI. And I will be addressing the ACMUI comments on the staff's recommendations for revisions to the Patient Release Program.

Next slide, please.

The Subcommittee members were Dr. Sue Langhorst, the immediate past radiation safety officer member of the ACMUI; Dr. Palestro, whom you just heard from; Ms. Laura Weil, the patient rights advocate members, and myself.

Next slide, please.

The Subcommittee charge was to review and provide recommendations on the Draft SECY paper entitled, "Staff Recommendations for Revision of the Patient Release Program". And as you know, the patient release issue has been a persisting and at times contentious one for the ACMUI and the NRC in general. And so, this is an update, so to speak, on that issue.

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In terms of background, the current dose-based patient release rule, 10 CFR 35.75, replaced the longstanding activity-based rule, the so-called 30-millicurie rule, which was the basis of patient release following radionuclide therapy for many years. More specifically, the current dose-based rule allows a licensee to release a patient if the total

effective dose equivalent, or TEDE, to any individual from exposure to that patient is not likely to exceed 5 milliceverts, or .5 millirem.

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In June of 2011, the staff was directed, the NRC staff was directed to evaluate whether there are gaps in the available data regarding doses received by members of the public from released radionuclide therapy patients and, if such gaps were found, to provide a recommendation on whether and how such data could be accrued to fill in those gaps.

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In a SECY paper from 2012 entitled, "Data Collection Regarding Patient Release," gaps were, in fact, identified related specifically to internal doses to members of the public and, also, internal and external doses to members of the public from patients released to locations other than their primary residence, their homes. And that is released to locations such as hotels and nursing homes.

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So, the documents which the Subcommittee reviewed were the subsequently prepared Draft SECY paper and two support documents, a licensee survey entitled, "Assessment of Where Patients Reside Immediately Following their Release Report" and a

literature survey plus a compilation of model calculations entitled, "Patient Release Following Radioiodine Therapy, A Review of the Technical Literature, Dose Calculations, and Recommendations".

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So, among the findings and comments of our Subcommittee was that the literature review was thorough and the model calculations sound. The model calculations were based on Monte Carlo simulations. And if you have a background in reactor technology, you're certainly aware of Monte Carlo simulations and recognize it as the gold standard for these sorts of calculations.

We subsequently found -- and I think this is perhaps the most important conclusion we came to -- that the current dose base, absorbed dose base, approach to assessing patient releasability was validated as more protective of public safety than the prior activity-based approach. And we often cite the example where hyperthyroid or Graves disease patients treated with as little as 10 millicuries of I-131 iodide actually deliver a higher dose to individuals around them than thyroid cancer patients treated with an order of magnitude or more higher activity because of the difference in the pharmacokinetics in those two patient classes.

So, we, therefore, concluded and reiterate our conclusion that the current 5-millicevert, or 500-millirem, projected dose limit should remain in effect as a per-event limit and is appropriate for all potentially exposed cohorts, including pregnant women and children. And I should emphasize that the National Council on Radiation Protection and Measurement, NCRP, endorses that position as well.

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A second set of conclusions is that the assumption in regulatory guidance that the internal dose contribution is negligible has been validated rather emphatically. There actually is a large peer-reviewed scientific literature evaluating internal or possible internal contamination of family members and others in close contact with the patient receiving radioiodine, for example, radioiodine therapy immediately following their therapy and release. And among these data are thyroid radioiodine measurements of relatives, including children, of such patients, and that's a very sensitive bioassay of internal contamination because the thyroid concentrates iodine so avidly. And from those data and others, as I say, it has been validated that there is, in fact, negligible internal contamination.

Other assumptions and methods in the

pertinent regulatory guidance, Appendix U of NUREG-1556, as well as Reg Guide 8.39, if anything, are excessively conservative. And we again point to NCRP Peer Report No. 155 entitled, "Management of Radionuclide Therapy Patients" for what we feel are more realistic and more real-life-relevant sorts of assumptions, although I have to make a disclaimer. I was a coauthor of that report. So, it's near and dear to my heart.

Importantly, it was found that a patient staying at a hotel or a location other than their primary residence immediately following radionuclide therapy is not a common practice -- and that was based on the licensee survey that was performed -- and is unlikely to result in doses to workers and others exceeding even 1 millicevert, or 100 millirem, and that's consistent with prior analyses and reports of the ACMUI.

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Certainly, instructions, written instructions, should be provided to the patient well in advance of a planned therapy, so that the patient can make plans consistent with radiation safety precautions recommended following such therapy, but we stopped short of recommending a specific time interval since we could envision clinical scenarios where that might interfere with timely administration

of a needed medical therapy. And I again point out that in NCRP Report No. 155 there is a model set of radiation safety precautions that can easily be personalized to individual patients.

We also recommended that the NRC should consider updating Appendix U and NUREG-1556 which deals with patient release and post-release precautions to reference Regulatory Guide 8.39 rather than eliminating 8.39, since that latter document is so familiar and so widely used by the user community.

So, next slide, please.

To wrap up, the findings and recommendations in the Draft SECY paper and support documents really, we feel, validate not only the existing dose-based release criteria rule, but also the ACMUI's report, patient release report, in 2010. And has been alluded to, the Patient Release Program should be applicable to all radionuclides. It should not be radio-iodine-specific, especially as we anticipate in the near-term additional promising treatments for cancer and other diseases using systemically-administered radionuclides. And this program should be flexible, not overly conservative, not overly restrictive, so as not to encumber the development and clinical implementation of new medical procedures.

And with that, I conclude and now turn the microphone over to Dr. Vasken Dilsizian.

DR. DILSIZIAN: Thank you very much. It's a pleasure to be presenting the top of medical event reporting and impact on medical licensee patient safety culture, which represents really a summary of reports from several Subcommittee members addressing this topic.

Medical event reporting -- next slide, please -- has not really changed significantly over many years, and the annual number of reports is really extremely low considering that an estimate 15 million diagnostic and 150,000 therapeutic procedures are performed annually.

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So, given that the medical event rates are extremely low, the question is, does it accurately reflect the true number of cases? And given the perception of a medical event being potentially punitive, are centers reluctant to report medical events? Such is the question that's being posed to us.

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Medical event versus medical error. Even though a medical event is not necessarily a violation, however, failure to report it is a violation, and

reporting such medical events by a physician may be perceived negatively in most medical centers. And particularly when the physician has to also communicate that error or event with their patient and referring physicians, there is a perception that this is really a serious medical error.

And so, what is the problem that we are trying to solve, therefore? Can we identify potential ways that improve the effectiveness of the medical event self-reporting to support a culture of safety? And can we suggest ways that we can share these medical event reports and lessons learned, if you will, from the medical community to promote safety?

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So, if we look at this list -- oh, next slide, please -- reporting of medical events, what we're trying to say is that it should be educational rather than potentially punitive. And the whole goal of medical event reporting should actually track a specific event or trends, identify the problem, report it to the medical community, recommend corrective action with feedback loop for constructive improvement, and learn from these mistakes.

And next slide, please.

So, based on these concepts, the guiding principles, therefore, should be that, ideally, the

NRC should enhance patient safety culture while maintaining its regulatory authority to protect patients during medical use of byproduct materials, and the focus on medical event reporting should be, therefore, on learning and how to avoid or reduce the likelihood of such events in the future, rather than punitive-appearing action. And I will expand on that.

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For example, medical events rarely cause patient harm, but why is a notification required so quickly. That is, no later than the next calendar day after discovery of the medical event. And, of course, soon after this notification, NRC inspection generally takes place, looking for violations as a cause of the medical event, within five days of the reporting.

So, next slide.

If we think about safety culture in general, and the NRC representing nuclear safety culture, which actually impacts patient occupational and public safety culture, there are other patient safety culture organizations such as the CMS-approved Joint Commission or the patient safety organization like the HHS.

And the next slide, please.

And we try to compare and see how those organizations treat patient safety issues versus the

NRC. One major difference would become the patient or individual -- not the patient -- the individual licensee identity. So, on the left-hand side, the NRC reporting information includes licensee identity, which is also on the NRC website. And unfortunately, it remains there, even if the event later is determined by the NRC not to be a radical event. On the other hand, accrediting or patient safety organizations reporting tends to be anonymous to those outside the hospital, the patient, or patient advocate.

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Regarding information sharing, NRC approaches it by, besides posting the event report on the NRC website, the NRC also posts the inspection reports, and those are the violations and licensee responses. And this is important because, if similar events occur, the NRC will issue a regulatory summary documenting and alerting licensees or may initiate rulemaking to prevent future events. On the other hand, the accrediting or patient safety organizations tend to provide databases to track events, provide education or tips on tools, best practices to prevent errors, and general patient safety initiatives to improve safety culture.

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So, what possible things we can recommend

to the NRC that may make sense, but not really change the current reporting system? One question is, are all medical events unnecessarily high-impact events? Can we grade them, if you will, based on high versus low impacts? And, accordingly, if the impact is high, there would be no change in the form of current reporting. There would be timely notification of the NRC within 24 hours with a reactive inspection within five days.

On the other hand -- again, we haven't decided this what is considered low versus high impact -- if the ACMUI along with the staff comes up with some type of a criteria that would define what a low-impact event would be, that would not require immediate notification. They would be notifying the NRC, but not within 24 hours, if you will, allowing, therefore -- next slide -- the low-impacts will, then, undergo some self-evaluation, the recommendation of corrective action, which should be reported to the NRC at a later date, through either NRC or NRC-approved patient safety organizations.

Ideally, only high-impact events should be made public. Low-impact events should be perhaps anonymous to licensee information location and be used as educational purposes for corrective action and, therefore, encourage more reporting rather than

discourage reporting because it appears very punitive in nature.

Next slide.

So, as we were discussing this, the NRC staff suggested that the ACMUI could explore a program like the reactor oversight process and the way in which the NRC and the reactor community has developed and tested this change in the regulatory oversight, for possible methods of implementing NRC medical event oversight improvements using current Part 35 reporting regulations.

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So, for example, a short-term recommendation would be for the NRC to develop and test a pilot program, like done with the reactor oversight process, to allow a medical use licensee to evaluate medical events. Perhaps with or without an approved patient safety organization program, the NRC itself can develop a program to also look at the low-event rates and reporting.

The next slide, please.

The licensee will report medical events, per current requirements. NRC, however, will not post events on its website or will make posting anonymous. Those are the low events. It will continue, obviously, reporting the high events. And hopefully,

with these low-event cases as defined will not come down to inspection except for the high-impact medical event cases.

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So, a licensee, therefore, will develop a written report6 of low-impact medical events soon after the event occurs to review either immediately, sometime later on, or before the next NRC inspection. NRC will develop temporary inspection procedures for reporting reviews and to evaluate enforcement manual changes for medical events to support a test program. The number of participants and the length of time will be determined, if this is agreeable, and the medical events, obviously, will be reported to ACMUI for evaluation during this testing pilot period.

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After the pilot test period is completed, the NRC should consider opening the program to all NRC medical use licensees who request approval of their patient safety program as well as to the agreement states who request to implement the program with their medical licensees.

Thank you very much for your attention. This is the end of my presentation, and I would like to introduce Ms. Laura Weil, who is going to be talking about patients' right advocacy perspectives.

MS. WEIL: Thank you. Thank you for the opportunity to present some patient advocacy perspectives today.

I'd like to clarify that these are my thoughts and do not necessarily represent a consensus of the ACMUI as a whole.

So, I'll start with the training and experience requirements. I was a member of that Subcommittee as well. And given the realities of this Subcommittee -- it's just four members -- with an inevitably rotating membership, it makes sense for us to solicit, and perhaps rely on, training and experience recommendations from professional societies and physician organizations. But one should be aware that there's a potential for a subtle conflict of interest and the potential for the impact of bias on these recommendations.

Medicine in the United States is a business. And certain stakeholder groups like healthcare facilities and specialty physicians, individual medical practices, all have an economic interest in capturing advantageous patient groups, as defined perhaps by age, geography, insured status, sometimes disease.

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This economic pressure can lead to turf

issues, as various stakeholder groups vie for business in order to survive financially. One might conceivably argue that these pressures could increase conscious or unconscious biases that might influence the recommendations for training and experience by physician groups and professional societies, although certainly with an overt and honest goal of maximizing safety and quality of care, but with the accompanying effect of preserving exclusivity.

Relaxing the 700-hour training and experience requirement would enable clinicians outside the traditional specialties to offer treatments and reap financial rewards that are currently a proprietary practice area that happens to come with exclusive access to the resultant revenues. This is not to say that members of these professional associations would behave in an unprofessional or unethical manner, but simply that the possibility of bias does exist.

While the original request to develop a new alternate pathway for 35.390 drugs was related to one particular drug whose use is reported to be minimal for various reasons, new drugs represent a much larger potential market and the ability to benefit many patients. This, coupled with the reported waning of nuclear medicine physicians in training, makes compelling argument for considering the question of

a potentially more accessible, yet still safe, alternate pathway, while another element of concern is the very real potential for decreased investment in research and development of innovative radiopharmaceuticals if patient access is unduly or unreasonably limited and the market for new and potential drugs is curtailed due to decreasing numbers of Authorized Users.

The pharmaceutical industry is almost exclusively in the for-profit sector, and no company is going to invest resources in development of drugs that patients can't get to. Contributing to that concern is the concentration of existing Authorized Users in major medical centers and not in geographic areas with only smaller community health facilities or narrow geographically-restrictive insurance networks. This effectively makes some therapies inaccessible to patients who may be financially or logistically unable to seek care in major centers where traditionally-trained Authorized Users tend to concentrate.

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So, what we need to think about perhaps is how well has the 80-hour alternate pathway in 35.394 worked for patients receiving iodine-131. Does the significantly curtailed training and experience

requirement have an impact on the issues surrounding patient release? Are all physicians administering iodine-131, especially in the non-hospital setting, adequately prepared and aware of radionuclide safety issues?

So, I would like to move on -- next slide, please -- if I may, to this related question and talk about the SECY paper regarding patient release that was recently released. And I would like to focus on one aspect of the paper's research and recommendations, which is the instructions that iodine-131 patients receive, and I would like to read some relevant quotes from the SECY paper.

Next slide, please. Oh, that's it.

"The data indicates that the spread of contamination from patient to other persons can be minimized by following instructions."

Next slide, please.

"Family members of patients receiving the highest does of iodine-131 administrations often receive some of the lowest doses. This points to the importance of behavior patterns and following ALARA guidance and instructions provided by the licensee."

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"For cancer patients, all transportation exposure scenarios indicate that transportation

situations pose a radiation concern for members of the public. And the SECY paper recommends that the licensee's assessment of the patient's likely behavior after release is required and necessary."

Next slide, please.

"The decision to release the patient should be reviewed before starting treatment to determine the conditions under which the patient is expected to be released and whether the living arrangements, modes of transportation, and staying at a hotel are such that releasing the patient is unlikely to result in doses over 5 millicevert."

So, those are all direct quotes from the SECY paper. And it concludes that "The dominant factor determining both internal and -- next slide, please -- external doses to members of the public from exposure to a patient that's been administered iodine-131 is the behavior of the patient after release."

Next slide, please.

The ACMUI Subcommittee on Patient Release presented in the fall of 2017, and discussed here today, recommended, and I quote, "Written and oral instructions must be provided to the patient far enough in advance of treatment without compromising patient care to ensure that the patient has sufficient time

to determine whether or not he or she can actually comply with the instructions and make whatever arrangements may be necessary for compliance."

It's clear from The Federal Register comments on the proposed changes to the patient release rule and my anecdotal discussions with patients over the years that there's uneven provision of clear, timely, language-appropriate, and consistent instructions to patients. And while major medical centers of excellence and well-respected healthcare facilities may have the resources to assure that this aspect of care is performed well, patients who receive care in non-hospital settings or patients who are handed off to remote facilities for their radioactive iodine may have less consistent access to timely and appropriate instructions.

Next slide, please.

One thing the discussion has not adequately addressed is the fact that the 1997 patient release rule effectively allowed insurance and third-party payers to refuse to reimburse for hospitalization after iodine-131 therapy. And as a result, financial responsibility for hospitalization in those rare instances when it is necessary is left to the patient or to the hospital or the healthcare facility to absorb as unreimbursed care.

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In addition to appropriate dose or activity limits that are now considered for patient release, clear and formal regulatory language for assessing behavior or logistical parameters should be developed to justify patient release or to justify insurance-covered hospitalization, if that's required to keep radiation exposure to caregivers and the public ALARA.

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It's been argued that the timing of provision of these release instructions, when and how to assess the likelihood of patient adherence, and when to require hospitalization or delayed release is a clinical and practice-of-medicine issue. I contend it's a public health issue and well within the purview of NRC regulation.

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So, I'd like to move on to talk about safety culture and the ACMUI recommendations regarding patient safety organizations. There are really two basic reporting paradigms. One is the identified required reporting, and the other is de-identified voluntary reporting. And these are really mutually-exclusive paradigms. One could view these as variations of the carrot-and-stick concept.

Slide, please.

The de-identified paradigm is voluntary and it is seen by the medical community as non-punitive. The goal is to proactively order the community detail of problematic systems issues and/or events in order to facilitate preemptive corrective actions based on the possibility of similar occurrences in similar situations. There are major strikes to this paradigm, its non-punitive image. There's no downside to reporting, and the goal is global education. The weakness is its voluntariness. It's not clear what percentage of incidents are actually reported nor how often the information about events and near-misses is actually accessed and used for program improvement at other facilities. There's the absence of a stick here, but not everyone is taking advantage of the carrot.

The identified required reporting paradigm is seen as extremely punitive and, thus, facilities are very reluctant to disclose events. This leads to a culture of hiding and underreporting that's really counterproductive to a process of proactive assessment and preemptive correction. Healthcare facilities and individual clinicians who are identified with medical events or errors risk financial losses resulting from lost patient volume and the related revenue or disadvantaged reimbursement negotiations with

third-party payers. There's clearly a stick here, but there's no carrot at all.

Next slide, please.

The ACMUI proposes that NRC pilot a limited trial to test the effectiveness of a sort of hybrid program, an anonymous, but required reporting paradigm utilizing recognized patient safety organizations in lieu of the existing NRC approach. Here we have the stick, required reporting, coupled with a carrot, anonymity, and the opportunity to participate in a proactive process. And while such a trial might not be easily implementable at this time, it would be advantageous to try to incorporate some of the benefits of de-identified reporting where possible in the NRC process.

Thank you.

CHAIRMAN SVINICKI: I take it that's -- I don't just take it -- that is the concluding presentation of the panel. And I want to thank each of the presenters again, but the Committee members as a whole. I realize that the work that you have presented was contributed to by many members of the Committee. So, thank you all for your work.

By my notes, we would have Commissioner Baran begin the question period, if you're ready. Thank you.

COMMISSIONER BARAN: Sure. Thanks.

Well, let me echo that thanks. We really appreciate your thoughts and all the work you put in on this.

Let's start with training and experience. Dr. Palestro, during our last Commission meeting together, we had a good discussion about the current training and experience requirements for Authorized Users. And I appreciate that the Subcommittee has prioritized its review of the appropriateness of the requirements for alpha and beta emitters. Can you update us on this effort and give us a sense of the Subcommittee's latest thinking? How far along are you on that?

DR. PALESTRO: In response to your question, we are aware that the staff has to provide you with an update at the end of August. So, it's our intention to work closely with the staff over the next several months to prepare, certainly, a preliminary outline of what that sort of alternative pathway would be.

COMMISSIONER BARAN: Okay. And you talked about FDA's approval of lutetium-177 for the treatment of certain neuroendocrine tumors and the Subcommittee's expectation that there could be a high demand for that beta emitter. It sounds like the

Subcommittee is now concerned that there may not be enough Authorized Users to meet this demand, and that's a pretty big change from the discussion we were having last year. What is -- and maybe it is too preliminary -- but let me just ask, what's your current thinking on how we should address this potential shortage of Authorized Users? Are you contemplating a change to the 700-hour training and experience requirements, and how does that relate to the review you all are doing that's alpha and beta emitters?

DR. PALESTRO: The answer is not changing the 700 hours because that pathway includes not only the 390, but also the 100 and 200 categories, but, rather, creating a very specific, very focused alternate pathway limited to the use of unsealed sources in the 35.390 category.

COMMISSIONER BARAN: Okay. So, this is more of a kind of class of radiopharmaceutical-specific-type approach that you're contemplating?

DR. PALESTRO: That's correct.

COMMISSIONER BARAN: Okay. Well, I look forward to hearing what you all come up with there, and I appreciate your work.

Is there anything you wanted to share on that? It sounds like you're still a little bit at the

beginning of that process.

DR. PALESTRO: We are at the beginning, but I think that there are three components to this. One is the development of the curriculum, the educational program. Two, we have to define how competency will be determined. And, three, determining competency at one point in time is no longer sufficient. There has to be a method of ensuring that there is maintenance of competency over time, very much paralleling what goes on in the medical field today.

COMMISSIONER BARAN: Okay. Thanks.

I also want to ask about medical event reporting. In 2017, there were 43 medical events reported. There were 50 in 2016 and 57 in 2015. So, as Dr. Dilsizian pointed out, that's a pretty low number compared to the millions of procedures performed each year. And it's good that that number is low, as long as we're getting good, complete reporting.

I heard the concern expressed that NRC's reporting requirements are viewed as punitive and may encourage Authorized Users to hide medical events. Do you think there is widespread noncompliance with our medical event reporting requirements?

DR. DILSIZIAN: Shall I take that? Well, to answer the last question, we won't know that. I don't think we can guess that.

But we do know that in other models of patient safety culture, when you allow residents, for example, to report that their hours are longer than what agency generally requires, when you have a safety culture, you do see more events being reported. But we don't know whether that applies to us directly.

I just want to address a couple of points, if I may. One is that, while we realize that the event rates are low relative to the number of procedures that are being performed, however, I think we should not accept no change; that the NRC should actually see a decline over time. If you look at the number of years, it's always been in that range. But we should actually see a decline, and, hopefully, the goal should be zero. And so, where is the educational part of this, so we can just be very happy with these numbers? But I think we should have a higher goal. And any patient who is being inappropriately treated, it should be that there should be some teaching point that should be present. That would be one of the recommendations we would like to recommend.

COMMISSIONER BARAN: I definitely agree with that as a basic goal. I guess the question is how we get there. You know, one way is to actually have a situation in which medical events are occurring, and another way is to define a certain number of medical

events away, so that the number goes down. And I think the former is a much better way to get to zero.

As I understand it, the Committee is suggesting that NRC pilot a change, and the idea is that licensees wouldn't report medical events to NRC right away, like they do now. NRC would no longer post the event reports on our website for the public to see. And if we did post them, we redact the licensee's name to keep that information from the public. And then, NRC would only conduct a reactive inspection if someone died or was permanently harmed or needed to be treated as a result of the medical event. Is that a fair summary of the proposal?

DR. DILSIZIAN: Well, again, I will just take a more moderate view of that, in that there are, for example -- I mean, I will give one example. When you take a patient post-thyroid-surgery, and if there is an isolated node, the medically-indicated therapeutic range is between 100 millicuries and 150. So, if you have a prescribed dose of 120 and the individual gets 145, on the regulatory says that's above 20 percent, that should be reported as a major event. From the medical perspective, that's the therapeutic range of treatment. So, the patient actually got the proper treatment. From the regulatory perspective, that's a major mishap.

Now I'm not saying it shouldn't be it is a mishap; that it should be researched as to why is it that nobody paid attention to 20 percent; why did they miss it? That's fair. But does it require the high impact of immediate inspection, reporting? And that's where we're trying to balance it. We're trying to balance what is an error that's acceptable medically versus clearly unacceptable and the patient did not get the proper treatment as medically indicated.

COMMISSIONER BARAN: Well, I take your point and I understand the point you're making there. And I like to think of myself as an open-minded person. And I say this with great fondness and respect. But this struck me as a really terrible idea, what you are proposing here.

The notion of the reactor oversight process being kind of a model for this was discussed, but this is not at all how the reactor oversight process works, how you're describing this. We don't require a radiological event to kill or injure someone before conducting an inspection. All of our inspection reports are online unless they include sensitive security information. Non-emergency reactor events are reported within one hour or four hours or eight hours, depending on the situation. So, elements of what you're proposing are like the opposite of what

we do in the reactor oversight process.

As I understand this, under the proposed approach, NRC wouldn't even conduct a reactive inspection if you had a series of over- or underexposures at a facility as long as no one ended up either with no fatalities or serious injuries, or something that required immediate treatment.

So, I said a lot there, and I want to give you all a chance to respond to that. Obviously, I'm pretty skeptical about this as a pilot even. I don't see how the benefits would accrue to the public of this type of approach. But let me give you a chance to answer whether I'm missing something here or you think I'm being unfair or you think I'm mischaracterizing what is being proposed.

DR. DILSIZIAN: No. No, I think you're being fair. I think that the Committee is not ready to tell you what is a low impact at this time. I think to characterize it that we're not going to report anything except for if someone dies --

COMMISSIONER BARAN: Right.

DR. DILSIZIAN: -- I think is the extreme view. That's not what we are proposing.

We are saying there are gradations of impacts, and that perhaps, for encouraging people to report without the consequences of this being a major

event, if it wasn't, we should have an alternate way of reporting. We haven't defined that yet. And as you know, there's Y-90, there's I-131. There's all these different procedures.

If it's agreeable, obviously, you have to be given the charge to go into it. If not, then we can maintain it the way it is. We are simply trying to address what hasn't changed for many years. Maybe it's a good thing. Maybe nothing needs to be changed. But we were asked to address that issue.

COMMISSIONER BARAN: Okay. All right. Well, we're not voting on anything today. You could mark me down for a "don't pursue it".

(Laughter.)

But I appreciate your response, and please take my comments the way they are intended, which is just having the respectful discussion about this as an idea, it was not an idea that struck me as a good one. But maybe others have different views. So, thank you.

CHAIRMAN SVINICKI: Well, thank you, and let's hear from someone right now who has a different view.

(Laughter.)

This is the way --

COMMISSIONER BARAN: Is the way it's

supposed to work.

CHAIRMAN SVINICKI: -- it's supposed to work, and we talk about this before Congress and others. We compliment them on their wisdom of having a Commission structure on these difficult issues. It's the same reason why we have a committee structure, so that you all can provide your views. There can be this kind of give-and-take. And I actually appreciate very much my colleague's very candid reaction, and these kind of patient house issues are something that aren't entirely familiar terrain for 90 percent of what we do here. So, I struggle with some of the same things. On this particular issue, I might be struggling with a different subset of issues.

But let me begin again by thanking you all for the work that you do, which is very, very valuable to me in getting my arms around these issues. And a lot of the things we regulate, all the consequences fall so squarely within our own regulatory jurisdiction. This one I think is more complicated because it has a connection to the practice of medicine, to health care. And, therefore, we try to make good decisions and have consequences that are predictable and not have consequences to patient health that fall so far outside what we expected. So, your input is very helpful to us in trying to predict what that range

is.

I did want to just comment on the overview slide about the composition of individuals on the Committee, the vacancies, and the little asterisk to say that security clearances are pending. I just want to clarify for anyone listening that that is a system wide issue. It has, to my knowledge, zero to do with the very wonderful individuals that we are attempting to push through that process. It's becoming somewhat chronic and there's a lot of delay in that system. So, I appreciate the patience of individuals on the Committee with the long timeframes that that can take. And so, again, we need the expertise. So, please don't give up in frustration. It's not unique to the particular individuals, and I just wanted to clarify that.

I appreciate, also, that you've looked at communications issues and how it is that you can be most effective in engaging both the Commission, the NRC staff, and your broader community of practitioners to try to bring a diversity of views back to our deliberations. The uniqueness about the ACMUI is that you are, many of you, I think, to a person, current practitioners of the areas of expertise. I would contrast this with some other government advisory committees where, if individuals are actively involved,

they're not supposed to be giving advice because of conflict of interest. It is one of the reasons why the ACMUI engages with the NRC staff and is not an advisory committee to the Commission directly. But I view that as the benefit of your advice is that you are current practitioners and these are rather dynamic areas, but it does, as a result, lead to things, I think, as Ms. Weil pointed out very eloquently, is there a tension of interest there? Is there kind of a push and pull, conflict of interest, and other things? So, we take that in and balance that upon receipt of the advice.

And the patient access concerns is something that I have focused on. This is the first time in the years I've served here that ACMUI has reported, again to my memory, on these trends of lower numbers of -- both lower numbers of residency programs and lower number of practitioners going into some of the specialties. Is there any broader contributors to that that we're just not aware of, as the Nuclear Regulatory Commission? Is it a particularly non-lucrative field or something like that? I mean, what do you, if you had to at least hypothesize some contributors to those declining numbers, what do you think they are?

MR. ZANZONICO: I think there are numerous

factors involved. I would say -- and again, this is my own personal opinion -- that regulatory issues are at the very bottom, the least significant of all of those factors. I think probably one of the most important contributing factors has to do with economics. If you look at the average hospital across the country, there simply isn't a sufficient enough volume of nuclear medicine procedures to justify the presence of a full-time nuclear physician. And I think that's the biggest issue.

For example, there are six people, including myself, in my Division of Nuclear Medicine, but we also are responsible for 12 sites, including nine hospitals and three outpatient facilities. And I would say that, if you look at the numbers in terms of how they're measured today, that's a sufficient volume to support the six of us.

CHAIRMAN SVINICKI: And that gets to the heart a little bit of why I asked the question about the broader contributors. Because although regulatory issues may not be a contributor to the decline, they may be a very fruitful way to address and try to offset the effect of the decline. So, I took your recommendations about areas to evaluate and look at in that spirit, meaning not that regulatory burdens contributed to the decline, but should we look at the

regulatory framework to provide some offsetting effect in terms of patient access? And I take the Committee's recommendations in that spirit and think that that's worth us taking onboard and thinking about.

On the patient release, I also have served on the Commission long enough to know that this is something that I think we're circling again to and reevaluating, and I think there's benefit in that, of course, because things change over the course of time.

But, Dr. Zanzonico, your slide 9 with the conclusion that a patient staying at a hotel following radionuclide therapy is not a widespread practice, there are, of course -- and the Committee is well aware of this -- constituencies that disagree with that very, very violently. So, what I think is helpful, and that the Committee has taken a look or once again taken a look, at a survey of licensees' understandings of where patients are going upon their release. Of course, that is as good as the licensees' awareness of and the patient's willingness to be forthcoming with their practitioner about where it is they are going.

But, again, it has been, I won't say frustrating, but I've had no great ideas on how we could resolve the kind of belief set of constituencies that this is a widespread thing. And yet, when we go and look at it systematically, or the Committee looks at

it, we're not finding that. So, I don't know if there is a disconnect there and what it is, but I appreciate that that constituency is very, very well-motivated on this point. And so, I appreciate that they certainly know why they observe this. And our ability to bring that into alignment is just something that I'm short on ideas of how to do that, I think. I appreciate the Committee having looked at it and looked at the licensee survey and, then, of course, the NRC staff will evaluate that as well. So, that's just a little bit of commentary.

I just wanted to point out that we don't have that constituency here on the Committee, so they're not presenting anything today. But I want them to know that the Commission is well aware that there's a different view out there about that. How to resolve it, I'm not sure, but I think we can just stay open and keep taking in the data as we find it.

So, let me turn to medical event reporting. In my time here, I've even had votes that are publicly available where I have been forthcoming about how I struggle with knowing that medical event reporting -- a medical even does not necessarily indicate any kind of adverse health outcome or even a probability of or even a low probability. It is a very binary thing.

And so, when I read about the comparisons

to the reactor oversight process, maybe I came at it more simply. At first, I had to think about it for a minute, but, then, my thought was the reactor oversight process has a graduated set of escalations of things. And I took your comparison to be more about that than necessarily kind of a consequence-based. But the medical event reporting is, once you hit the threshold, it's completely divorced from the probability of an adverse outcome and, as we've heard today, can even be the appropriate therapeutic range.

And so, I am not a medical practitioner. I've been a patient and I have loved ones that have had cancers that have some of the therapies that you all talk about. And I try to stay current on just what any average person should know about health care. There is increasing research, although I don't purport to be an expert on it, on the health effects of chronic low-grade stress. So, when we add to the stress of a patient who is receiving these therapies, may have compromised immune system, may have other things, the chronic low-grade stress of being told that there was a medical event in their treatment, I can't imagine that that's a positive health outcome for that patient or their loved ones. And I've spoken to this in votes that I've filed, of how I struggle with this. It sounds like you can just tell people this doesn't mean

anything; don't be upset, until it's your loved one or you're the patient, and I think you feel it very, very keenly.

So, I looked at the pilot proposal, and I can acknowledge this much today: it is the Committee's creative kind of thought process of how could you take a carrot, take a stick, to use Ms. Weil's terminology, but how could you foster an environment where at least the likelihood of covering up something or not reporting it, or being in noncompliance with the regulations, was significantly diminished? And therefore, that could do two things. You would learn a lot more and, second of all, you might create that learning culture that you could get back to those practitioners.

But I did join this Commission early in the time when there was national controversy over a practitioner at the Veterans Administration and a large number of administrations. So, I know the deep concern that that can cause. So, I'm not ready, and we're not voting today on anything. And I don't know, but I think the notion of setting some thresholds and having different processes, again, parallel to the ROP, having a graduated set of regulatory responses, is perhaps worth thinking about.

And I confess this is my view because I've

struggled with this over the years of just the trigger is so absolute on these medical events. And when I follow this later and see, you know, a year later, two years later, did we ever have a report of an adverse health outcome, I don't -- if I've seen any, they're so few that I can't really even remember them, and the onslaught of the ones where there was no adverse health outcome.

So, I have -- as I tend to do at these, because I find this all so very thought-provoking -- I've said a lot. Is there anyone who would just quickly -- I'm a little over my time -- but maybe, Ms. Weil, would you like -- I've referred to your presentation. Is there anything that you would like to add? I'm fascinated by your work, and really you've presented a number of times. Thank you. You struggle, I think, with the most philosophical aspects. So, they are both the most interesting to me, but also the toughest.

With that, does my colleague have anything further?

COMMISSIONER BARAN: Can I just two minutes? I'm curious on patient release. From the presentation, it sounded like the Subcommittee's view was -- and maybe the whole Committee's view was -- yes, instructions should be provided well in advance, so

that people can make the appropriate plans, but trying to specify that in any kind of prescriptive way in a regulation isn't a good idea. I got the sense that you had a different view on that. Do you have, is there a particular requirement there that you have in mind that you see would be workable? Or is it more -- let me just stop the question there.

MS. WEIL: Well, you know, the requirement is that patients be treated as individuals and their individual situations be considered in planning for release. And the provision of instructions needs to be individualized as well, when that happens. If you're a nursing mom, then you need to know well ahead of time that you need to stop nursing many weeks, months, before iodine is administered. You need to plan for that. If you have little kids at home and one bathroom, you need time to plan.

The thing we struggled with is that these recommendations are not iodine-specific. So, any particular time provision that we recommended would perhaps impact problematically on the ability of clinicians to administer other radionuclides that perhaps have more urgency. There isn't a great deal of urgency in providing iodine for thyroid cancer patients. You can wait. But, you know, there are other situations where it might not be beneficial to

wait, and that's very hard to balance.

COMMISSIONER BARAN: Is that something you think can be balanced well in the guidance? Is updating the guidance the best way to go here, from your point of view, or --

MR. ZANZONICO: Well, first, I would like to reinforce what Ms. Weil said. There was unanimity on the part of the Subcommittee and the Committee as a whole that instructions can, and certainly should be, provided well in advance of the treatment.

I would think there is also unanimity that, certainly, there shouldn't be a prescriptive timeframe written into regulation. That would just be too ironclad, I think. And conceivably, as new radionuclide therapies are introduced -- we heard about lutetium-177 dotatate, and so forth -- you know, additional ones on the way, that putting a number into regulation could be an impediment to therapies and appropriate medical care in some instances.

Conceivably, it could be incorporated into guidance. A concern always with guidance is that it's viewed, appropriately so, as best practice and, in turn, has a constraining effect on actual practice. And as Ms. Weil said, that is what we struggled with, to convey to practitioners and licensees that they really should and must provide instructions, written, oral, and so

forth, as far in advance of treatment as possible, but at the same time not constraining treatment in instances where there may be some urgency.

And it certainly should not be in regulation, in guidance. That would be preferable to regulation, but, again, that imposes some constraints, some limitation, as well, we think, on practitioners. So, it's a difficult issue to address, and I would stop short of even personally recommending it in guidance.

COMMISSIONER BARAN: Ms. Weil I think said that your sense from over the years, and the folks you've talked to, is that there's kind of a wide spectrum of practices in this regard. Some people are doing it exactly the right way and some not so much, and people have less time to really get prepared.

I mean, as a Subcommittee or Committee, is there some sense about, well, how do you meaningfully address that kind of breadth of practice in the area, so that you have more people providing more time for folks to make the appropriate plans? So, regulations on one end of the spectrum, it sounds like that you don't think that's a good idea. I could see the argument there. Guidance is kind of moving this direction. I guess presentations at medical conferences or something, maybe it's further down.

Do you have a sense of what's -- I know it's tricky, but how do you strike the balance on that, so you have an improved practice in this area without doing something that's going to constrain?

MR. ZANZONICO: Well, I think even without specifying some numerical timeframe --

COMMISSIONER BARAN: Yes.

MR. ZANZONICO: -- by specifying very emphatically that there is a need, a requirement, for providing written and oral instructions well in advance of the treatment, I think that would impact prospective users as well. Because I think, as Ms. Weil has said at times, and unfortunately, as we know, sometimes patients who are about to receive some radionuclide therapy, immediately prior to the administration of the therapy are told for the first time that there are some applicable instructions. I mean, that's unacceptable.

So, including even in guidance and even regulation, but without a specific numerical timeframe, that instructions must be provided in advance, and as far in advance as practical of the treatment, would have an impact as well.

Also, in terms of variability of instruction, we certainly know that's the case as well. That's why I referenced the model procedure and NCRP

Report No. 155, which really addresses not only the issue of releasability of patients, but of post-release precautions, and so forth.

So, I think regulation and/or guidance can make an impact on that without the necessity of specifying a specific time interval.

COMMISSIONER BARAN: Okay. Thank you. Thanks.

CHAIRMAN SVINICKI: All right. Again, thank you all for your presentations today.

And Commissioner Baran and I will now conclude our public meeting.

Thank you very much.

(Whereupon, at 11:20 a.m., the meeting was adjourned.)