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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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TELECONFERENCE

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WEDNESDAY, OCTOBER 28, 2015

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The meeting was convened by teleconference, at 2:00 p.m. Eastern Daylight Time, Philip O. Alderson, ACMUI Chairman, presiding.

MEMBERS PRESENT:

PHILIP O. ALDERSON, M.D., Chairman

PAT B. ZANZONICO, Ph.D., Vice Chairman

FRANCIS M. COSTELLO, Agreement State Representative

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

RONALD D. ENNIS, M.D., Radiation Oncologist

STEVEN R. MATTMULLER, Nuclear Pharmacist

MICHAEL D. O'HARA, Ph.D., FDA Representative

CHRISTOPHER J. PALESTRO, M.D., Nuclear Medicine Physician

JOHN H. SUH, M.D., Radiation Oncologist

LAURA M. WEIL, Patients' Rights Advocate

NON-VOTING: DARLENE F. METTER, M.D., Diagnostic

Radiologist

NON-VOTING: ZOUBIR OUHIB, Therapy Medical Physicist

NRC STAFF PRESENT:

JOSEPHINE PICCONE, Ph.D., Director, Division of Material Safety, State, Tribal and Rulemaking Programs

DOUGLAS BOLLOCK, Designated Federal Officer

SOPHIE HOLIDAY, Alternate Designated Federal Officer, ACMUI Coordinator

MARYANN ABOGUNDE, NMSS/MSTR/MSEB

ASHLEY COCKERHAM, NMSS/MSTR/MSEB

SAID DAIBES, Ph.D., NMSS/MSTR/MSEB

ANTHONY DELAMOTTE, NMSS/MSTR/MSEB

SARA FORSTER, R-III/DNMS/MLB

MICHAEL FULLER, NMSS/MSTR/MSEB

JEFF GRIFFIS, OCHCO/ADHRTD/STTB

LATISCHA HANSON, RIV/DNMS/NMSB-B

VINCENT HOLAHAN, Ph.D., NMSS/MSTR

ESTHER HOUSEMAN, OGC/GCLR/RMR

DONNA-BETH HOWE, Ph.D., NMSS/MSTR/MSEB

ERIC KENNEDY, RIII/DNMS/MLB

PENNY LANZISERA, RI/DNMS/MB

DENNIS O'DOWD, RIII/DNMS/MIB

GRETCHEN RIVERA-CAPELLA, NMSS/MSTR/MSEB

MEMBERS OF THE PUBLIC PRESENT:

RICH BEAUMAN, Oregon Health Authority

MIKE BLAKE, American Nuclear Society

ISABELLE BUSENITZ, Kansas Department of Health and Environment

JEFF COLVIN, American Association of Physicists in Medicine

PETER CRANE, *unaffiliated*

JERRY CUTTLER, *unaffiliated*

VICTOR DIAZ, New Mexico Environment Department Radiation Control

STEPHEN DRAGOTAKES, Beth Israel Deaconess Medical Center

WILLIAM DUNCAN, Texas Department of State Health Services

CHUCK FLYNN, Texas Department of State Health Services

SANDRA GABRIEL, International Atomic Energy Agency

WENDY GALBRAITH, University of Oklahoma Health Sciences Center

HILARY HASKINS, Oregon Health Authority

SCOTT KNISHKA, University of Wisconsin School of Medicine and Public Health Radiopharmaceutical Production Facility

RICHARD LAMBOI, Texas Department of State Health Services

DARYL LEON, Oregon Health Authority

SAM LEVERITT, Cardinal Health

MARVIN LEWIS, *unaffiliated*

RICHARD MARTIN, American Association of Physicists in Medicine

JOSEPH NOBLE, Louisiana Department of Environmental Quality

JUDITH SCHUERMAN, Louisiana Department of Environmental Quality

MICHAEL SHEETZ, University of Pittsburgh

JEFFRY SIEGEL, Nuclear Physics Enterprises

MICHAEL STABIN, Vanderbilt University

DAVID STEPHENS, Arkansas Department of Health

MIKE STEPHENS, Florida Bureau of Radiation Control

DAVID STRADINGER, North Dakota Department of Health, Radiation Control

BRUCE THOMADSEN, University of Wisconsin

CINDY TOMLINSON, American Society of Radiation Oncology

NICOLE TRAPHAN, Texas Department of State Health Services

ED TRUSKOWSKI, New Jersey Department of Environmental Protection

C O N T E N T S

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

(2:03 p.m.)

CHAIRMAN ALDERSON: Thank you. This is Dr. Phil Alderson. I am the Chair of this subcommittee on the linear no-threshold issue. I also happen to currently be the new Chair of the ACMUI.

So I'd like to welcome everyone to this teleconference to discuss the ACMUI's comments to petitions for rulemaking concerning the linear no-threshold model and standards for protection against radiation.

At this time, and before we proceed, I'd like to turn the meeting over to Mr. Doug Bollock of the NRC for some opening remarks.

MR. BOLLOCK: Thank you, Dr. Alderson. As the designated federal officer for this meeting, I am pleased to welcome you to this public meeting of the Advisory Committee on the Medical Uses of Isotopes.

My name is Doug Bollock. I am the Branch Chief of the Medical Safety and Events Assessment Branch, but I've been designated as the federal officer for this advisory committee in accordance with 10 CFR Part 7.11.

Present today as the alternate designated federal officer is Sophie Holiday, our ACMUI

coordinator.

This is an announced meeting of the committee. It is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and Nuclear Regulatory Commission.

This meeting is being transcribed by the NRC, and it may also be transcribed or recorded by others.

This meeting was announced on September 8th, 2015 in edition of the Federal Register Volume 80 --

(Telephonic interference.)

CHAIRMAN ALDERSON: Frank, Frank Costello, you need to mute your phone.

MEMBER COSTELLO: I am sorry.

MR. BOLLOCK: Thanks, Frank.

As I said, this meeting was announced in the September 8th, 2015 edition of the Federal Register, Volume 80, pages 53896 through 53897.

The function of the committee is to advise the staff on issues and questions that arise in the medical use byproduct materials. The committee provides counsel to the staff but does not determine or direct the actual decisions of the staff or the Commission.

The NRC solicits the view of the committee and values their opinions. I request that whenever possible, we try to reach a consensus on the procedural issue that we will discuss today but also recognize there may be minorities or dissenting opinions. If you have such opinions, please allow them to be read into the record.

At this point, I'd like to perform a roll call of ACMUI members participating today.

Dr. Phil Alderson, the Chairman?

CHAIRMAN ALDERSON: Present.

MR. BOLLOCK: Thank you. Dr. Pat Zanzonico, Vice Chairman?

VICE CHAIRMAN ZANZONICO: Present.

MR. BOLLOCK: Thank you. Mr. Frank Costello?

CHAIRMAN ALDERSON: Frank is still on mute.

MR. BOLLOCK: Yes, we heard Frank. Frank, are you --

MEMBER COSTELLO: Present.

MR. BOLLOCK: Thank you, Frank.

Dr. Vasken Dilsizian?

(No audible response.)

MR. BOLLOCK: Okay. Moving on. Dr.

Ronald Ennis?

MEMBER ENNIS: Present.

MR. BOLLOCK: Thank you. Dr. Sue Langhorst?

CHAIRMAN ALDERSON: She will not be here. She is --

MR. BOLLOCK: Okay.

CHAIRMAN ALDERSON: -- undergoing recovery from an accident.

MR. BOLLOCK: Okay, thank you.

Mr. Steve Mattmuller?

MEMBER MATTMULLER: Present.

MR. BOLLOCK: Thank you. Dr. Michael O'Hara?

(No audible response.)

MR. BOLLOCK: Okay, moving on. Dr. Christopher Palestro?

(No audible response.)

MR. BOLLOCK: Okay. Moving on, Dr. John Suh?

(No audible response.)

MR. BOLLOCK: All right. And moving on, Ms. Laura Weil?

MEMBER WEIL: Present.

MR. BOLLOCK: Thank you.

DR. METTER: Hello. This is Darlene Metter, and I am here.

MR. BOLLOCK: Thanks, Dr. Metter.

Okay. And just going through again, we have Dr. Dilsizian?

MS. HOLIDAY: I'd like to point out that Dr. Vasken Dilsizian, Dr. Michael O'Hara, and Dr. Christopher Palestro are on the GoToWebinar.

MR. BOLLOCK: Okay.

So are Drs. O'Hara, Palestro, or Dilsizian able to speak on the teleconference?

MS. HOLIDAY: They ought to be able to, but I am not sure if they have called in yet.

MR. BOLLOCK: Okay.

All right. We only have six members. We need seven for a quorum, but we will check back just so Drs. Dilsizian, Palestro, O'Hara, if you hear us, just when you have the chance, let us know that you are present for a quorum. Thank you.

Also on the phone, we have Dr. Metter, and I also heard Mr. Zouhir Ouhib. Dr. Darlene Metter has been selected as our ACMUI diagnostic radiologist, and Mr. Zouhir Ouhib has been selected as our ACMUI medical physicist.

Both Dr. Metter and Mr. Ouhib are pending

security clearance but may participate in this meeting. However, they both do not have voting rights at this time.

I now ask NRC staff members who are present to identify themselves. I will start with individuals in the room here, going around to my right.

MR. FULLER: Mike Fuller, Medical Radiation Safety Team, Team Leader.

MS. ABOGUNDE: Maryann Abogunde, Medical Radiation Safety Team.

DR. DAIBES: Said Daibes, Medical Team.

MS. HOUSEMAN: Esther Houseman, attorney, OGC.

DR. HOLAHAN: Dr. Vincent Holahan, Senior Level Advisor.

MR. DELAMOTTE: Anthony Delamotte, Medical Team, NRC.

DR. HOWE: Dr. Donna-Beth Howe, Medical Team.

DR. PICCONE: Dr. Josie Piccone, Director, Division of Material Safety, State, Tribal, and Rulemaking.

MR. BOLLOCK: Thank you.

Next, we have any NRC regional offices. Do we have anyone from Region I?

(No audible response.)

MR. BOLLOCK: Okay. Hearing none, do we have anyone on the call from Region III?

(No audible response.)

MR. BOLLOCK: All right. Moving on, do we have anyone on the call from Region IV?

(No audible response.)

MR. BOLLOCK: Okay. Is there -- is there anyone else from our NRC Headquarters office that are calling in remotely?

MS. COCKERHAM: Ashley Cockerham, Medical Team.

MR. BOLLOCK: Thank you.

MS. HOLIDAY: Sophie Holiday, Medical Team.

MR. BOLLOCK: Thank you. Anyone else? Any other NRC employees calling in?

(No audible response.)

MR. BOLLOCK: Thank you.

MEMBER O'HARA: This is Mike O'Hara. I am on the line now.

MR. BOLLOCK: Thank you, Dr. O'Hara, appreciate it.

MEMBER DILSIZIAN: And Vasken Dilsizian on the line now.

MEMBER SUH: And also John Suh.

MR. BOLLOCK: Thank you Dr. Dilsizian and Dr. Suh. Okay, so we have confirmed we do have a quorum of over seven members. Thank you.

And members of the public who notified Ms. Holiday that they would be participating in the teleconference, that will be captured in the transcript. For those of you who did not provide prior notification, please contact Ms. Holiday at sophie.holiday@nrc.gov, that's S-O-P-H-I-E dot H-O-L-I-D-A-Y at N-R-C dot gov, or at her number, 404-997-4691.

We have a bridge line available, and that number is 1-888-889-5011. The passcode to access the bridge line is 7499997 followed by the pound sign.

This meeting is also using the GoToWebinar application to view this presentation and handouts in real time. You can access this by going to www.gotomeeting.com and searching the meeting ID, 138-291-851.

The purpose of this meeting is to discuss the ACMUI subcommittee's report on the ACMUI review and comments of three Petitions for Rulemaking, Petition for Rulemaking 20-28, 20-29, and 20-30, on linear no-threshold model and standard protection against

radiation.

Individuals who would like to ask a question or make a comment regarding specific issues the committee has discussed should request permission to be recognized by the ACMUI Chairperson, Dr. Phil Alderson. Dr. Alderson at his option may entertain comments or questions from members of the public who are participating with us today.

Comments and questions are usually addressed by the committee near the end of the meeting after the committee has fully discussed the topic.

I'd also like to add that the handouts and agenda for this meeting are available on the NRC's public website.

At this time, I ask that everyone on the call who is not speaking place their phones on mute. If you do not have the capability to mute your phone, please press star 6 to utilize the conference line mute and unmute function.

I would ask everyone to exercise extreme care to ensure that background noise is kept at a minimum as any background sounds can be very disruptive on a conference call this large.

At this point, I'd like to turn the meeting back over to Dr. Alderson.

CHAIRMAN ALDERSON: Thank you, thank you Mr. Bollock.

I would like to remind everyone, as was just stated, that the purpose of this meeting is to receive the subcommittee's report, the Linear No-Threshold Subcommittee report for our discussion and vote.

We will begin the proceedings by going through the subcommittee's recommendation. I will do that now.

The recommendation reads as follows: "The correct dose response model for radiation carcinogenesis remains an unsettled scientific question. There's a large and growing body of scientific literature as well as mechanistic considerations that suggest that the LNT model may overstate the carcinogenic risk of radiation in diagnostic, medical, occupational, and environmental doses, and that such low doses may in fact exert a hormetic, that is, beneficial, effect.

However, in the absence of definitive refutation of the LNT model, and while strongly encouraging continued investigation critically comparing alternative models, regulatory authorities should exercise prudent though not excessive

conservatism in formulating radiation protection standards.

The ACMUI therefore recommends that for the time being and subject to reconsideration as additional scientific evidence becomes available, the NRC continue to base the formulation of radiation protection standards on the LNT model."

Now, as we proceed with the subcommittee discussion and vote, I have to bring to your attention a logistics issue, which is the one I mentioned when this call began, that I indeed was the Chair of this subcommittee, but subsequent to completing the subcommittee's work, on October the 15th, I became the Chair overall of the ACMUI.

Therefore, following general protocol, it would not be proper for me to lead this discussion. Accordingly, I turn to Pat Zanzonico, who has agreed to lead this discussion of the subcommittee report.

Dr. Zanzonico, I pass it to you.

VICE CHAIRMAN ZANZONICO: Okay, thank you very much Dr. Alderson, and hello everyone. This is Pat Zanzonico from -- from New York.

And as Dr. Alderson said, as a matter of procedure, because he had chaired the subcommittee which drafted the report, we thought it prudent that

someone other than he moderate this teleconference and discussion, and so even though in the interest of disclosure I am on the subcommittee, I -- I will be moderating the -- the teleconference and the discussion.

I just want to bring to your attention or point out that the members of the subcommittee, Dr. Alderson as pointed out was the Chair, it also included Sue Langhorst, Chris Palestro, John Suh, Laura Weil, as well as myself.

And the procedure we will follow is to first solicit comments and discussion from the members of the subcommittee, and then subsequently from other members of the ACMUI, and finally, from members of the general public who are on the line, and at that point, the instructions for doing so for members of the general public to -- to make comments will be repeated.

Again, I want to emphasize, as Dr. Alderson has said, that the objective of this teleconference is really by necessity very focused, namely addressing the report of our subcommittee.

We all recognize that the issue of the linear no-threshold model of radiation carcinogenesis versus a hormetic model versus an alternative model remains highly controversial and really engenders very

strong emotions from folks on different sides of the question.

We're not here to debate that issue. That is really impractical. We are here, as I -- as I said, to focus on the subcommittee report and the elements thereof, and -- and so as needed, I will keep everyone on the straight and narrow if their comments wander into a broader area that really isn't appropriate for this teleconference, so please bear that in mind.

So having said that, at this point I would like to invite any members of the subcommittee to offer any comments or discussion that they may have, so the floor is open to the members of the subcommittee, so please identify yourself and then follow up with your comments.

Do we have any -- any comments from members of the subcommittee?

(No audible response.)

VICE CHAIRMAN ZANZONICO: Hearing none, and obviously if at some point members of the subcommittee do have comments, you can offer them at that point, but hearing none at this point, I'd like to welcome any comments from other members of the ACMUI on the subcommittee's report.

(No audible response.)

VICE CHAIRMAN ZANZONICO: Any -- any comments from other members of the subcommittee -- I mean of the full ACMUI?

(No audible response.)

VICE CHAIRMAN ZANZONICO: Again, if -- if members of the ACMUI have comments at any subsequent time, please feel free to offer them, and at that time, identify yourself and make your comments.

So there were no comments offered either by members of the Subcommittee or by other members of the ACMUI, so at this time, I'd like to welcome any comments from members of the general public on the line.

And again, please remember that these proceedings are being transcribed, so please clearly state your name, if you like, your affiliation, when you speak.

And again, we potentially have many members of the public who will be making comments, so we really need to -- to limit the time in the interest of giving everyone who would like to make a comment an opportunity to do so.

So I really would ask everyone to keep their comments at this point to no longer than several minutes, and frankly, I will cut you off if you go beyond that time excessively. And also, please keep your

comments focused on the subcommittee report, and I believe at this point, the Operator who will be queuing up the comments from the general public can come back on the line and remind us of the procedure for requesting to make a comment.

THE OPERATOR: Thank you, sir.

If you would like to ask a question or you do have a comment, please press star, then 1 at this time.

You will be prompted to record your first and last name to ask your question. To withdraw, you may press star, then 2.

Once again, to ask a question or if you have a comment, please press star, then 1 at this time, and record your first and last name. One moment please.

VICE CHAIRMAN ZANZONICO: Okay, so at this point, we're giving members of the general public who may be on the line an opportunity to -- to request the opportunity to make a comment.

THE OPERATOR: At this time sir, I am showing no comments.

VICE CHAIRMAN ZANZONICO: We will just wait a bit longer. It's our understanding that a number of members of the general public had registered in advance of the meeting, and so we anticipated at

least some comments.

So as exciting as this is to listen to a silent telephone line, we'll wait a bit further so -- to ensure that everyone who wishes to make a comment does have an appropriate opportunity to do so.

THE OPERATOR: We do have a comment from Jeffry Siegel. Your line is open.

VICE CHAIRMAN ZANZONICO: Dr. Siegel?

DR. SIEGEL: Thank you, Dr. Zanzonico. Thank you for allowing me to present some brief comments. I promise only three minutes, and if I go outside your boundaries, please stop me.

VICE CHAIRMAN ZANZONICO: I absolutely will. Please, Dr. Siegel, the floor is yours.

DR. SIEGEL: Thank you.

First off, as noted by UNSCEAR 2012, radiation-inducible malignancies cannot be unequivocally attributed to radiation exposure because it is not the only possible cause, and there are generally no available specific biomarkers.

With respect to the LNT model and epidemiological studies, as discussed in the ACMUI subcommittee report, there are good and bad faith disagreements on both sides of the issue.

If these studies do not support LNT, many

claim it is because the dose of studies are too low, which suggests that the effect which they claim must be there is likely too small to be detected because of insufficient statistical power.

If, on the other hand, the study supports LNT, many not only claim that it's because of the dose of study being too high or low, but also demonstrate it's because of erroneous assumptions in mathematical manipulations imposed on the data, with biology being ignored or discounted, rendering the conclusions suspect.

Therefore, the entire class of epidemiological papers must be held to account and subjected to careful scrutiny, and not just glossed over and accepted or rejected, because the enormous good or bad for which their conclusions can be responsible.

And then there is the mainstream of expert scientific opinion. Again, careful scrutiny is required here as well.

Not to pick on BEIR VII, but it contains a myriad of questionable pronouncements.

As just one example, this report states, "The evidence for a specific mechanism that acts to reduce both spontaneous and radiation-induced damage

after a low-dose radiation exposure is weak and indirect and is contradicted by direct measures of DNA double-strand break repair."

For this statement, the BEIR committee cites a singular reference by Rothkamm and Loebrich. This study did indeed indicate that low-dose-induced DSBs remain unrepaired.

However, this was only in cultures of non-dividing primary human fibroblasts. The DNA report failed to mention that in the very same study, the level of DSBs decreased to that of unexposed ones if the cells were allowed to proliferate after a radiation, and another study by the same group demonstrated that individuals repaired DSBs to background levels after in vivo exposure to low doses of radiation from CT.

I was very encouraged by the ACMUI subcommittee's recognition that there was a vast and ever-growing body of scientific literature refuting the LNT model.

Still, many believe that any LNT-model-derived regulation or policy will at least be protected. But in the aftermath of recent nuclear accidents, this is demonstrably false. Overestimating risks has had a devastating effect, and

now radiophobia promoted also by the ALARA principle, which was not specifically addressed in the ACMUI report, has spread into the practice of medical radiological imaging, where the focus is primarily on undocumented radiogenic risks, distracting attention from other more likely and documented risks and potential benefits.

Consensus at this point in time is likely too much to expect, but I look forward to the day when scientific evidence such as the research recently awarded the 2015 Nobel Prize in Chemistry describing molecular systems that continuously monitor and repair damaged DNA advances our understanding to the point where the need for significant changes in radiation protection standards will be evident.

Thanks very much.

VICE CHAIRMAN ZANZONICO: Thank you, Dr. Siegel.

Just, as I said earlier, while we very much appreciate the scholarship of your presentation, we want to remind any commenters to address their comments directly to the ACMUI report.

Do we have any other members of the public on the line who wish to make a comment?

MR. LEWIS: Marvin Lewis.

VICE CHAIRMAN ZANZONICO: Before -- before yours, again, we're at this point limiting comments to several minutes to ensure that everyone has an opportunity to -- who wishes to, has an opportunity to make a comment on the record.

So the floor is yours.

MR. LEWIS: Thank you, sir.

No, I am not the Marvin Lewis, the retired physician from California. I am the Marvin Lewis from Philadelphia, a retired professional engineer.

My point is simple. I have been in this mess for -- since 1970, and I have been taken aback again and again by so much being ignored, specifically this business of looking only at a cancer risk or a death risk or a this risk, without looking at this newly discovered epigenetics, where the gene can be turned on and off for many generations just by exposure to radiation.

And ignoring that completely, and then you come up with any kind of a number you want to by manipulation of numbers, mathematical manipulations, just as the Volkswagen has shown, and I'm sorry to say that this should not be as cavalierly handled as Volkswagen has handled pollution numbers.

I think we need to look at more than what

this subcommittee report looks at, and I hope the NRC shall do so.

Thank you.

VICE CHAIRMAN ZANZONICO: Thank you, Mr. Lewis.

The subcommittee has a very specific charge, and -- and endeavors to fulfill that charge, and that's what we're addressing today, but thank you for your comments and for your brevity.

Is there anyone else on the line from the general public, from the public, who would like to make a comment at this time?

(No audible response.)

THE OPERATOR: Once again, if you have a comment, you may press star, then 1.

MS. HOLIDAY: Dr. Zanzonico, this is Sophie Holliday. May I make a comment?

VICE CHAIRMAN ZANZONICO: Please.

MS. HOLIDAY: I just want to inform everyone on the call that as Dr. Zanzonico and Dr. Alderson stated, the purpose of this teleconference today is to receive comments related to the subcommittee's report.

For those of you who actually want to submit comments on the petition for rulemaking itself,

you will have to go to regulations.gov or any of the appropriate methods listed on the Federal Register notice to submit your comments onto the docket.

Those comments are due no later than November 19th. Thank you.

THE OPERATOR: We do have a comment from Peter Crane. Your line is open.

VICE CHAIRMAN ZANZONICO: Mr. Crane, welcome --

MR. CRANE: Thank you.

VICE CHAIRMAN ZANZONICO: -- and the floor is yours, and again, we're by necessity restricting comments to no more than several minutes at this point to ensure that everyone has an opportunity to speak.

MR. CRANE: I understand.

Thank you, Dr. Zanzonico and members of the Committee. I want to thank you all for your thorough and conscientious work.

I applaud the outcome, which I understand to be a finding that although there is, you know, suggestive and interesting data on all sides of the question, getting to the point of actually changing existing approaches including ALARA and the LNT is too high a bar to be met at the present time, but that one shouldn't be closed-minded.

Is that a fair statement of where you're at?

What I wanted to say is one thing that somewhat disappointed me in the report is not what's there but what isn't there, in that there was considerable information or assertions made in the submission in particular of Dr. Marcus to the proven effects of LNT on radiation, including a comment that the post-Chernobyl thyroid cancers were not and could not have been caused by radiation.

There are some 7,000 of those, and though it's certainly true that you cannot say of any particular cancer that this was definitely caused by radiation, although there is one German study out of Munich a few years ago suggesting that there is a distinguishing marker, but my point is I don't know of any support in the literature for this proposition, and I wish that the -- that the subcommittee had taken to task, or had come to grips, with some of the factual assertions. If you have views on it now, I'd be delighted to hear them.

And that is my comment. Thank you for the time. I appreciate it.

VICE CHAIRMAN ZANZONICO: Thank you, Mr. Crane, for your comments, and likewise for your

brevity.

And I should point out that the charge of the subcommittee was essentially to make actionable recommendations to the NRC. There was an enormous amount of scientific content and opinion, frankly, in the petitions, and we felt it was beyond the specific charge of the subcommittee to delve into that in depth, but rather to distill it to an actionable recommendation. But your comments are appreciated.

MR. CRANE: Thank you very much.

VICE CHAIRMAN ZANZONICO: Is there anyone else on the line who would like to make a comment?

(No audible response.)

VICE CHAIRMAN ZANZONICO: May I ask the Operator, is there anyone in your queue, anyone further in your queue waiting to make a comment?

THE OPERATOR: At this time, there are no comments.

VICE CHAIRMAN ZANZONICO: Okay.

We will -- I'm don't want to say we're ahead of schedule, but we're not behind schedule, so I would ask everyone's forbearance, and before proceeding, just wait a few more moments to see if anyone else on the line would like to make a comment.

So you may hear some radio silence for a

few moments, but again, since we're not behind schedule, I think we can afford that.

MEMBER MATTMULLER: Dr. Zanzonico, this is Steve Mattmuller. I would like to make a comment.

VICE CHAIRMAN ZANZONICO: Oh please, Steve.

MEMBER MATTMULLER: And it doesn't involve what happened in Kansas City this morning in regard to a certain baseball team.

Anyway, in regard to the recommendations on the report, in the middle, there is a statement, "However, in the absence of definitive refutation of the LNT model, and while strongly encouraging continued investigation, critically comparing alternative models," and so on.

I guess I have an issue -- the definitive refutation of the LNT model to me seems to imply there's definitive proof that the model actually works, and that just struck me as being a bit -- I don't want to say misleading, but not giving a full picture of the actual discussion on the LNT model.

It seems to be creating an unfair burden that everyone has to prove it doesn't work, where there doesn't seem to be a large substantial body of proof, or even a small body of proof, that it does work,

especially with what we know now in terms of especially DNA repair, which is something that as I understand it the report -- or, excuse me, the model was originally based on, that a single break in a DNA strand would lead to the development of cancer in a single cell, which 30, 40 years ago was reasonable, but of course now we know that's no longer true.

And this is -- and Dr. Siegel highlighted with the recent announcement of the Nobel Prize for the investigators who have proven, or did work, or who did their work on DNA repair.

Thank you.

VICE CHAIRMAN ZANZONICO: Okay. Thank you, Mr. Mattmuller, for your comment.

I -- all I would say, speaking for myself, if not on behalf of the subcommittee, is that we -- we made an effort, a considerable effort, to formulate the subcommittee report, and in particular the recommendation, in for lack of a better term neutral language, namely neither to endorse nor refute the LNT model, the hormetic model, or any other model.

But based on the recommendations of authoritative advisory bodies like the BEIR Committee, the ICRP, and so forth, recommended in effect a continuation of formulating radiation protection

standards based on their recommendations, but without endorsing any model as more or less scientifically valid than another.

For members of either the subcommittee or the Committee as a whole, if -- and while trying to avoid wordsmithing in real time, online, if there is specific verbiage that you would like to offer as an alternative, perhaps you can do so.

Again, we want to avoid wordsmithing, but again, if there's language that -- that conveys an inappropriate meaning, perhaps you could offer an alternative.

So Mr. Mattmuller, do you have an alternative you would like to suggest to, for example, definitive refutation?

MEMBER MATTMULLER: No, I have to think about that, I am sorry.

VICE CHAIRMAN ZANZONICO: Okay, that's all right, I did not mean to put you on the spot, and I'm not entirely sure it was appropriate to do so in real time, but I just wanted to give you the opportunity to do so if you were so disposed.

MEMBER MATTMULLER: I certainly appreciate your efforts and share the hot spot that you're in, and I applaud your efforts in this. But not

at this time, thank you.

VICE CHAIRMAN ZANZONICO: Okay, thank you.

Do we have any other comments from members of the general public or from members of the subcommittee or other members of the ACMUI?

MEMBER PALESTRO: Pat?

VICE CHAIRMAN ZANZONICO: Yes.

MEMBER PALESTRO: Chris Palestro. I have been on the call. I think for some reason I had trouble speaking.

But I don't think that the subcommittee's report was intended to endorse the LNT approach, but rather to indicate that we would continue to review it, and at some point in the future, when there were sufficient evidence and documentation that there was a better way to approach it, we would then change.

So I don't think this was an endorsement of the LNT model per se.

VICE CHAIRMAN ZANZONICO: Thank you for your comment.

So I think that is exactly right. It was not intended to be an endorsement of LNT or any other model at this point, and as I said, we tried to craft our language to -- to avoid appearing to endorse any

particular model.

Other comments?

(No audible response.)

VICE CHAIRMAN ZANZONICO: May I ask the Operator again, is there anyone else online in your queue?

THE OPERATOR: At this time, I am showing no comments.

VICE CHAIRMAN ZANZONICO: Okay, thank you.

THE OPERATOR: We did just get a comment come up from Jeffry Siegel. Your line is open.

DR. SIEGEL: I am sorry to chime in again, but since nobody wants to talk and I'm not afraid, here I go.

I have to say I would love to know how the subcommittee and the ACMUI feels about LNT vis-a-vis ALARA. Are they married? Are they separate? Can you have one without the other?

Thank you.

VICE CHAIRMAN ZANZONICO: Thank you for your comment and question Dr. Siegel. That's -- I don't want to call it a loaded question, but it's a full question.

And I -- I think I'm going, frankly, to punt

on that one and say it is beyond the scope of the charge of the subcommittee. I think the individual subcommittee members have differing opinions, differing scientific opinions, and I don't want to say we put those aside in formulating a recommendation, but the purpose of this call is to focus on the content of the report and the recommendation and to avoid a discussion of really the broader issues outside the scope of the subcommittee charge.

CHAIRMAN ALDERSON: Pat, this is Dr. Alderson.

VICE CHAIRMAN ZANZONICO: Yes?

CHAIRMAN ALDERSON: I would just like to chime in. I think you've made exactly the right statement. The purpose of this meeting is to receive the subcommittee report, and this goes well beyond that.

VICE CHAIRMAN ZANZONICO: Are there other comments on the report?

(No audible response.)

VICE CHAIRMAN ZANZONICO: In that case, hearing none, at this point, the procedure would be for the subcommittee to make a motion for a report on -- for a vote, rather, on their report. And no second is needed at this point. It is coming from the

subcommittee.

So Sophie, just in terms of a procedural matter, can I just solicit a voice vote from the subcommittee? Does it have to be a person-by-person vote?

MS. HOLIDAY: No, you can do a blanket vote.

VICE CHAIRMAN ZANZONICO: Okay.

So at this point, hearing no further comments, I would like to -- for all of those on the committee -- so this is a vote of the full committee, correct, Sophie?

MS. HOLIDAY: That is correct.

VICE CHAIRMAN ZANZONICO: Right.

MS. HOLIDAY: Would someone from the subcommittee make a motion for the vote?

VICE CHAIRMAN ZANZONICO: Well I'm on the subcommittee, I'll make a motion for the vote. Is that appropriate?

MS. HOLIDAY: I think because you're moderating this, perhaps you'd like to ask if someone else from the subcommittee would like to put forth the motion?

VICE CHAIRMAN ZANZONICO: Thank you. Would anyone on the subcommittee care to do so?

MEMBER SUH: So this is John Suh, I put forth the motion to approve the report of the subcommittee on the hormesis linear no-threshold petition.

VICE CHAIRMAN ZANZONICO: So all on the subcommittee in favor of the motion please say aye or yes.

(Chorus of aye.)

VICE CHAIRMAN ZANZONICO: Any opposed?

(No audible response.)

VICE CHAIRMAN ZANZONICO: Any abstentions?

(No audible response.)

MEMBER COSTELLO: Excuse me, sir, this is Frank, this is just the subcommittee voting, right?

VICE CHAIRMAN ZANZONICO: No, no, this is -- this is the --

MEMBER COSTELLO: It's just the subcommittee.

VICE CHAIRMAN ZANZONICO: -- full --

MEMBER COSTELLO: It's the full committee voting?

VICE CHAIRMAN ZANZONICO: The full committee voting to accept the subcommittee's report.

MEMBER COSTELLO: Understood.

(Chorus of aye.)

VICE CHAIRMAN ZANZONICO: All right. So any -- any nays or no's from the whole committee?

(No audible response.)

VICE CHAIRMAN ZANZONICO: Any abstentions?

(No audible response.)

VICE CHAIRMAN ZANZONICO: Okay, so hearing no abstentions or nays, the subcommittee report is accepted unanimously by the ACMUI.

This has gone more quickly than we anticipated, but that's not a bad thing.

So the business of this teleconference is essentially concluded, and I will therefore turn the proceedings back over to Dr. Alderson.

CHAIRMAN ALDERSON: Thank you, Pat, for running a very nice meeting.

This concludes the meeting. Thank you to the subcommittee members for their work on this report and the Committee members for being engaged with us, and thank you to all the other attendees.

Does the NRC have any closing remarks that they would like to add?

MR. BOLLOCK: Thank you, Dr. Alderson. No, we do not. Thank you all very much for a good,

concise subcommittee meeting. We appreciate it.

CHAIRMAN ALDERSON: Thank you. Given that, this is Dr. Alderson saying that I believe we are adjourned. Thank you, everyone. Have a nice day.

(Whereupon, the meeting in the above-entitled matter went off the record at 2:47 p.m.)

COMMENTS OF PETER CRANE, NRC COUNSEL FOR SPECIAL PROJECTS (RETIRED)
ON RULEMAKING PETITIONS FROM DR. CAROL S. MARCUS, ET AL.

Re: PRM-20-28, Carol S. Marcus; PRM-20-29, Mark L. Miller; PRM-20-30, Mohan Doss et. al, "Linear No-Threshold Model and Standards for Protection Against Radiation."

ABSTRACT

Dr. Carol S. Marcus has petitioned the NRC for a rule change that would allow embryos, fetuses, children, and pregnant women to receive as much radiation as workers in a nuclear facility. She asks the NRC to scrap the cardinal principle of radiation protection – that radiation doses should be kept "as low as reasonably achievable" – in favor of "hormesis," the theory that radiation is good for you. Though mainstream science, as exemplified by the National Academies of Science, debunks hormesis as unsupported by the evidence, the Marcus petition does have one virtue: its extreme radicalism may help convince the NRC Commissioners of the grievous error that their predecessors made in granting the previous petition for rulemaking filed by Dr. Marcus, relating to nuclear medicine. The resulting rule change, in 1997, has made the United States an outlier in the world radiation protection community, with the weakest standards in the world, laxer even than those of Iran, Indonesia, and other Third World countries. It has put the American public, especially small children, pregnant women, and babies in the womb, at risk from the radiation emitted, excreted, and exhaled by patients given high doses of the radioactive isotope iodine 131 as outpatients. Therefore the Commission should **NOT** dismiss the Marcus petition out of hand, without a proceeding. Instead it should initiate a rulemaking proceeding that publicly examines not only the merits of hormesis, as Dr. Marcus requests, but also whether the NRC's rules on the release of radioactive patients should be made to comply once again with international standards and practices, so that this 18-year aberration can be corrected, and the NRC can resume its rightful place in the mainstream of the world radiation protection community.

I. Hormesis and its Advocates

The three petitions now before the NRC are from Carol S. Marcus, M.D., Ph.D., Mark L. Miller, and Mohan Doss and numerous co-signers. Mr. Miller's petition incorporates large sections of Dr. Marcus's verbatim and is similar to it, although to his credit, he does not ask, as she does, that radiation limits to fetuses, embryos, children, and pregnant women be made the same as for nuclear workers. The petition from Mohan Doss et al. states expressly that it "supports and supplements" the Marcus petition.

The Marcus petition attacks the Linear No-Dose Threshold hypothesis and the "as low as reasonably achievable" (ALARA) principle, which conservatively presume that radiation

exposure is harmful and should be minimized to the extent practicable. The petition asks the NRC to endorse instead the "hormesis" theory, which assumes that radiation is, on the contrary, beneficial. Among other things, Dr. Marcus requests that human fetuses and embryos, pregnant women, and children under 18 be allowed to receive as much radiation in a year as workers in nuclear facilities, up to 100 millisieverts or 10 rem per year.[1] Since many readers may think at this point that this cannot possibly be correct – that no medical doctor, certainly not a professor at a respected university, would ever advocate anything so extreme – they can read her proposals, verbatim and in full, in a footnote.[2]

But those who have followed these issues for years may ask: can this proposal really come from the same Dr. Carol S. Marcus, M.D., Ph.D., who wrote to the Food and Drug Administration on January 5, 2005? That letter said:

> The current RDRC regulations essentially prohibit pediatric research because of the minuscule radiation dose limits permitted (one tenth of that of an adult). This runs counter to the need to obtain pediatric-specific information. **While normal children are more radiosensitive than adults**, a factor of 10 is without scientific basis and is much too conservative. **A working limit of about one third of what a normal adult receives should be sufficient**.... [Emphasis added.]

Clearly, since 2005 **something** has changed by a factor of three. Either children have become three times more resistant to radiation than they were just ten years ago – an evolutionary marvel that the editors of *Science* and *Nature* need to hear about – or a very different developmental process has been at work. Only Dr. Marcus herself can clarify this, and I hope she will.

Mainstream science regards hormesis as pseudoscientific claptrap, to put it bluntly, and would view the idea of letting unborn children and pregnant women receive worker doses of radiation as either a joke in poor taste or, if meant seriously, frighteningly misguided. Yet

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[1] Because the two systems of measurement now in use lend themselves to confusion, it should be understood that national and international bodies call for members of the public to receive no more than 1 millisievert, or 100 millirems, per year; that the NRC allows all persons, including children and pregnant women, to receive five times this amount; and that Dr. Marcus asks that all be allowed to receive up to 100 millisieverts, or 10,000 millirems, per year.

[2] Dr. Marcus's petition requests, at p. 7, the following:
"1) Worker doses should remain at present levels, with allowance of up to 100 mSv (10 rem) effective dose per year if the doses are chronic.
2) ALARA should be removed entirely from the regulations, as it makes no sense to decrease radiation doses that are not only harmless but may be hormetic.
3) Public doses should be raised to worker doses, as these low doses may be hormetic. Why deprive the public of the benefits of low dose radiation?
4) End differential doses to pregnant women, embryos and fetuses, and children under 18 years of age."

hormesis has its ardent partisans[3], some with advanced degrees, and there are online journals to publish their writings. Foremost among these is *Dose-Response*, overseen by the current leader of the movement, Dr. Edward J. Calabrese.[4] He has already declared the NRC's docketing of the three petitions to be "a vindication of my 30-year career, in many ways."[5]

To explore the back issues of *Dose-Response* is to enter a looking-glass world, a sort of parallel universe in which conventional notions are turned upside down. Take, for example, the articles of a founding father and hero of the hormesis movement, Dr. Thomas J. Luckey, otherwise known as, "Sir Samurai T. D. Luckey, Ph.D."[6] Discussing the effects of Hiroshima in "Atomic Bomb Health Benefits," he has written that "[o]ne burst of low dose irradiation elicits a lifetime of improved health," and suggested that as part of triage, survivors of a nuclear bomb blast should be given *additional* radiation.[7] Or take "Radiation Hormesis: The Good, the Bad, and the Ugly"[8]:

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[3]Hormesis has won the support of such notable thinkers as Lyndon LaRouche, who has touted it in his publications for some 30 years, and the columnist and author Ann Coulter. For insight into LaRouche's views on hormesis, see *Executive Intelligence Review* (EIR) for March 22, 2013. (In the same issue, one can read his illuminating exposé of Queen Elizabeth II's genocidal plan to eliminate six-sevenths of the world's population.) http://larouchepub.com/eiw/public/2013/eirv40n12-20130322/eirv40n12-20130322.pdf For Ann Coulter's article, "A Glowing Report on Radiation," describing "burgeoning evidence that excess radiation operates as a sort of cancer vaccine," see http://humanevents.com/2011/03/16/a-glowing-report-on-radiation/

[4]See the July 23, 2015, press release, "Hormesis hypothesis may be acknowledged by US regulatory action,"http://www.eurekalert.org/pub_releases/2015-07/uoma-hh072315.php Dr. Calabrese continued: "From being totally marginalized to now an exciting and potentially transforming concept, it makes the possible NRC rule change more special. If something like this can happen on the radiation side with the NRC, there is possibly a whole revolution coming on the chemical side with EPA." It should be explained that in Dr. Calabrese's view, all kinds of stimuli normally thought of as harmful can have a hormetic effect, which may explain the financial support given to the movement over the years by such firms as R. J. Reynolds, Philip Morris, Lorillard, British American Tobacco, ExxonMobil, Rohm & Haas, and NiPERA, an arm of the Nickel Institute. (See: http://dose-response.org/wp-content/uploads/2014/06/www_dose_response_org_conference_2004_overview_htm.pdf)

[5]True believers in hormesis tend to declare victory on the basis of less than overpowering evidence, as we see from the efforts currently being made to persuade the editors of *Science* to retract a paper published **in 1956**, solely because the online journal *Environmental Research* has just published an article by Dr. Calabrese, revealingly titled "On the origins of the linear no-threshold (LNT) dogma by means of untruths, artful dodges and blind faith." So far, the editors of *Science* have refused. See: http://atomicinsights.com/edward-calabrese-challenges-science-magazine-to-right-a-59-year-old-case-of-scientific-misconduct/;http://atomicinsights.com/jerry-cuttler-and-mohan-doss-add-their-voices-to-calabreses-challenge-to-science-rejected-so-far/

[6]"Sir Samurai T. D. Luckey, Ph.D.," *Dose Response*, 2008; 6(1): 97–112.

[7]*Dose Response*, 2008;6(4):369-82.

[8]*Dose Response*, 2006; 4(3): 169–190.

> Premature cancer deaths are caused by insufficient radiation. ... [T]the United States has about 275,000 preventable, premature cancer deaths each year. The cause is attributed to insufficient radiation. ... [W]e live in a state of partial radiation deficiency. [W]e need radiation supplementation for more abundant health (Luckey, 1997b).

Discussing so-called "dirty bombs," Dr. Luckey wrote: "Excepting those who feel the blast, or who receive physical harm from heat or flying debris, low dose irradiation is beneficial (Luckey, 2004)." As for radon in homes, "higher residential radon levels consistently decrease the lung cancer mortality ... lowering radon in homes, as recommended by the EPA, will cause many lung cancer deaths." If cancer patients and their families ever realized the benefits of low dose irradiation, he wrote, they would not only insist on access to it, they would "want to prosecute BEIR and NCRP committee members for their decades of erroneous information causing needless suffering and deaths." He concluded:

> Considerable information indicates that we live in a partial deficiency of ionizing radiation. Nuclear wastes could provide safe radiation spas throughout the world (Luckey, 1995a, 1995b, 2004). Low dose irradiation could be provided in hospitals as a public health measure. If we had 50 times more radiation than we now receive, we would reach a new plateau of health (Luckey, 1999a, 1999b).

Attractive as the idea of the Yucca Mountain Radiation Spa may be, the reader at this point may well be thinking that this is all too goofy for words, and that neither the NRC nor any other agency of the U.S. Government would ever be taken in by it. It has even been suggested to me that to file comments on these petitions is a waste of time, as the Commission would never yield to anything so zany.

The flaw in that reasoning is that the last time Dr. Marcus filed a rulemaking petition, in the 1990's, the Commission not only gave her everything she had asked for but much more, with dire consequences that haunt the NRC to this day, and have caused untold harm to the thyroid cancer community, of which I have been a part for 42 years, and the public at large.[9] That grave error on the part of the Commission was described to me in 1999 by a distinguished professor and nuclear medicine physician at Penn State as "the worst decision from that agency in 40 years," a judgment hard to dispute. It would therefore be unwise to take anything for granted this time around. I hope that many other members of the public will join me in submitting comments; that former NRC Commissioners and staff, realizing that the agency's credibility and reputation are at stake, will add their voices; and also that the Nuclear Energy Institute and other representatives of the nuclear power industry will offer their views, along with representatives of the environmental community,

[9]The argument can be made that it cannot be shown that anyone's exposure to radioactive iodine, as a result of the current Patient Release Rule, has caused a case of cancer or mental retardation. But with health effects of this kind, such proof is usually impossible. There is a world of difference between no demonstrated proof of effects, on the one hand, and demonstrated proof of no effects, on the other.

EPA, FDA, OSHA, and the unions that represent hotel housekeepers.[10]

Dr. Marcus and the other petitioners acknowledge that the consensus of scientists and regulators is entirely against them, but they reject the possibility that this might stem from a good faith disagreement about the underlying science. Rather, they see it solely as the result of corrupt self-interest. Their notion is that these scientists and regulators believe that if they ever confessed what they know to be true – that radiation is beneficial – their jobs would be abolished and their organizations' funding would dry up, so they conspire to perpetuate what the petitions call "the greatest scientific scandal of the 20th century."

While recognizing that for the NRC to embrace hormesis would make it an "outlier," Dr. Marcus uses that word not with embarrassment but with a defiant pride.[11] From the agency's perspective, however, to declare that it was seceding from the international scientific consensus and raising the banner of hormesis would be ruinous for its reputation in the world radiation protection community. The NRC would not merely cease to be taken seriously as a science-based institution, it would become an international laughingstock, like Soviet biological sciences in the era of Lysenko.[12]

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[10]It may be asked why the nuclear power industry should care one way or another. The answer is that if the NRC were to grant these petitions, banish the ALARA principle from its regulations, and embrace hormesis, the backlash from the scientific mainstream would cast a shadow over every other NRC decision, including its judgments on the safety of nuclear reactors. Why should the hotel workers' unions care? Because about five percent of I-131 outpatients recover in hotels, which means that the housekeepers who clean their rooms, unaware of the presence of contamination and unequipped to deal with it in any case, may be the group most endangered by the current Patient Release Rule, as will be discussed later in these comments.

[11]Dr. Marcus recently wrote: "The NRC plan to make its radiation protection program closer to that of ICRP has no scientific basis. It is instead based upon the idea that uniformity is a good thing. Uniformity makes no sense if it makes everyone uniformly wrong. **It is better to have an outlier that is correct.** At least it sets a good example for the others." [Emphasis added.] (Letter of March 19, 2015.)

[12]For Dr. Marcus, this might be a plus, not a minus, given her frequently stated opinion of the agency. See, e.g., her letter to the Commission of January 24, 1992: "The Commission, with its oversimplifications of medical and pharmacy practice, required willing pawns to do its work. A sort of Darwinian evolution took place in which the scientifically unfit, a few individuals with very poor attitudes, and several cowards inherited the duty. ... In order to support the Commission's desires, and advance their own power agendas, the present staff uses fraud in any convenient form. Data are misrepresented, omitted, ignored, or manufactured for convenience. ... The recent humiliation of NRC by staff of OMB when NRC's fraudulent version of the 'Quality Management Rule' was uncovered is astounding but predictable. Instead of NRC's upper management retracting the material and apologizing, a delegation of NRC staff and management went into frenzied, paroxysmal 'superlying' to cover the original lying, and earned the contempt of all concerned. Some of the statements made in writing by NRC staff to justify the Rule describes actual deaths of patients caused by physicians which in fact did not occur. This would itself constitute a libel suit, but in this case has no point; no damage will be done because no one believes the NRC anyway. Pitiful, isn't it? ... I do not believe that the Medical Use Program is compatible with honesty, integrity, or even simple human decency."

The NRC is not the only agency to receive Dr. Marcus's tongue-lashings. See such postings to the RADSAFE listserv as the following, from December 22, 1998: "NRC's medical regulations are illogical, inconsistent, and completely devoid of any scientific underpinning. It's just arbitrary and capricious self-serving junk. I don't discriminate, though---I trash EPA as well, and then demolish one of FDA's Centers, CDER."

It is easy to poke fun at Dr. Marcus, Dr. Calabrese, Sir Samurai T. D. Luckey, Lyndon Larouche, Ann Coulter and all the rest. But what few Americans realize is that the United States is **already** an outlier in the world radiation protection community. Our country's radiation protection standards in the medical area are not only inadequate in comparison to those in developed nations of Europe and Asia, they are weaker by far than those in the Third World. (NRC Commissioners have been known to discover this only when they travel abroad and compare notes with foreign counterparts.) With regard to the release of radioactive patients after treatment with I-131, the regulatory standards of Iran and Indonesia put ours to shame – all because in the 1990's, under Chairmen Ivan Selin and Shirley Jackson, the Commission acceded to the demands of Dr. Marcus and her allies, for reasons that remain a mystery. The result has been higher radiation doses to the loved ones of I-131 patients and to the unsuspecting public.[13]

Dr. Marcus believes that the NRC's regulations on radiation protection are badly in need of revision. I agree completely – but not in the direction she proposes. Rather, they should be brought back into conformity with the recommendations of expert national and international institutions, so that the grievous harm done in the 1990's can at long last be repaired.

The key event in that process was the 1997 rule change that led to the current Patient Release Rule, 10 CFR 35.75, a regulation so out of step with conventional standards and practices that even its strongest defenders sometimes seem unable to credit that it really says what it does.[14] What the Commissioners undoubtedly did not realize at the time,

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[13]To give credit where due, Dr. Marcus may have done more to single-handedly change U.S. policy on a major issue of public protection than anyone except Rachel Carson and Ralph Nader. One can admire the energy, tenacity, psychological insight, and force of will behind this remarkable achievement, even while deploring her goals and tactics, and wishing that her talents had been applied to worthier purposes.

It may also be noted that Dr. Marcus's name is to be found among the signers of a 2007 petition opposing the Kyoto protocols on climate change. The petition asserts: "Research data on climate change do not show that human use of hydrocarbons is harmful. To the contrary, there is good evidence that increased atmospheric carbon dioxide is environmentally he1pful." See: www.petitionproject.org/seitz_letter.php

[14]When a subcommittee of the Advisory Committee on the Medical Uses of Isotopes reported to the Commission in October 2010 that 10 CFR 35.75 was fine as is and needed no changes, it told the Commissioners, wrongly, that the rule provided a ceiling of 100 millirems for exposures to children, pregnant women, and the public from released patients. Minutes later, the NRC staff corrected the subcommittee: the actual limit is 500 millirems. The ACMUI subcommittee members had supposedly studied the rule for five months, accepting NRC payment for their labors, and in that time, quite clearly, not one of the members had bothered to read it.

A similar mistake was made by Dr. James Sisson and 15 co-authors in an article in *Thyroid*, the journal of the American Thyroid Association, in April 2011, after a three-year study, but in their case, they were unaware that 10 CFR 35.75 existed, and thought that patient release was governed by Part 20. (A correction and apology appeared in the June 2011 issue.) At an international conference on radiation safety in medicine, held in Bonn in December 2012 under the auspices of the International Atomic Energy Agency, a doctor from Memorial Sloan-Kettering Cancer Center, presiding over a panel discussion, informed the attendees that the NRC rule included a 100 millirem ceiling for exposures to the public. I had to tell him from the floor that this was a commonly held misconception.

because this was never explained to them, was the key role of hormesis partisans in this giveaway. The rule change came about via a petition that was requested by an NRC staff member in the first place; submitted by a hormesis advocate, Dr. Marcus; and then resolved in reliance on the advice of a supposed expert who was in fact a leader of the hormesis movement, the late Dr. Myron Pollycove.[15] It was thus "an 'inside job' from the start," to quote Dr. Marcus's unforgettable description of an earlier NRC rulemaking, one that began with a petition that was nominally filed by her, but actually was solicited by the NRC staff and drafted in part by an NRC staffer.[16]

II. Analyzing the Marcus Hormesis Petition (2015)

Dr. Marcus opens her petition by attacking the Linear No-Dose Threshold Theory (LNT). So far so good, the reader may think: the LNT, like the theory of evolution, is admittedly a theory that remains to be proven. (There are certainly reasonable people who believe that there is some threshold below which radiation probably is not harmful.) She goes beyond that, however, to disparage the expertise of the many bodies that advocate the LNT – she mentions "NCRP, ICRP, IAEA, and NAS-NRC's[17] BEIR Committee" – and the integrity of the "army of regulators at NRC, EPA, FDA, as well as DOE [who] would be unbudgeted if the LNT disappeared."

Dr. Marcus endorses the view of Professor Edward Calabrese, the hormesis guru discussed earlier, that the LNT was based on "amazing misconduct by the nation's leading geneticists in mid-twentieth century." The basis for this assertion is the claim that Dr. Hermann Muller, the 1946 recipient of the Nobel Prize in chemistry, deliberately lied in his Nobel acceptance speech in Stockholm, and that a worldwide cabal of scientists and regulators has

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None of these people intended to spread misinformation. Rather, they **assumed** that 100 millirems was the NRC standard, presumably because they were so well aware that it **ought** to be the limit that they had not thought it necessary to check. Finally, NCRP Report No. 155, "Management of Radionuclide Therapy Patients"(2006), also says that 100 millirems is the standard for exposure to the public. If this was intended as a description of current standards, it too was erroneous; if it was a recommendation of what the standard **should** be, it constitutes yet another data point telling us that the NRC rules are out of step with expert thinking at home and abroad.

[15]Personally, Dr. Pollycove, who spent years at the NRC as a Medical Fellow, was an endearing gentleman, unfailingly friendly and warm, whether you agreed with his views or not. His passing in 2013, at the age of 92, saddened all who knew him.

[16]The dialogue on the subject of this rulemaking between an appalled Senator John Glenn and a contrite and apologetic Chairman Ivan Selin, in a 1993 oversight hearing, makes for amusing reading. U.S. Senate, S. Hrg. 103-61, Federal regulation of medical radiation uses: hearing before the Committee on Governmental Affairs (May 6, 1993) at 18-19. Glenn's point was that the Commission would never let this happen if nuclear power plants were involved, but seemed indifferent where medical uses were concerned. He had rightly perceived the heart of the matter: the prevalent attitude of "it's only medicine, not reactors, so who really cares?"

[17] "NRC" stands here for the National Research Council, not the Nuclear Regulatory Commission.

perpetuated this scientific deception ever since, cruelly persecuting those who dare to speak the truth.[18] She tells us that "the attitude of today's regulators is reminiscent of the Catholic Church at the time of Galileo. ... [T[he Church threatened to torture Galileo to death unless he rescinded his point of view."

Next, Dr. Marcus reviews the scientific data: the Hiroshima and Nagasaki survivors, nuclear power plant workers, tuberculosis patients given fluoroscopes, radium watch dial painters, hyperthyroidism patients treated with I-131, persons exposed to radiation from the explosion of a nuclear fuel reprocessing plant in Russia in 1957, persons exposed to radiation from accidentally recycled cobalt-60 sources in Taiwan, and Americans exposed to low levels of radon in their homes. Again and again she finds a hormetic effect.

The reader of the petition may at this point wonder how she will deal with Chernobyl, which, as is widely known, has caused over 7000 cases of thyroid cancer to date, almost entirely among persons who were children at the time of the 1986 accident. Her answer is that it did nothing of the kind. She writes, at p. 6 of her petition:

> The affected population in the former Soviet Union was followed for increased cancer incidence. According to UNSCEAR 2000b [citation omitted] and the United Nations Chernobyl Forum in 2006, except for thyroid cancers in the highly contaminated areas, there was no increased incidence of leukemias or solid tumors, and no evidence of increased genetic diseases. The increase in thyroid cancers was found in children under the age of 15 years in 1987, the year after the accident.[19] **However, the radiation doses were too low to have caused this**, and there was no dose-response relationship. In addition, the timing was off – the mean latent period for radiation induced thyroid cancer is about 28 years [citing the UNSCEAR 2000b report.] However, the increase was highly likely due to a mass screening effect [citing S. V. Jargin, "Chernobyl-Related Cancer and Precancerous Lesions: Incidence Increase vs. Late Diagnostics," Dose Response. 2014 Feb 13;12(3):404-14.]. Occult thyroid cancer is actually extremely common....[20] [Emphasis added.]

Just three years ago, however, Dr. Marcus co-authored a practice guideline on I-131 therapy that included the statement: "A causative role for 131I in carcinogenesis, **other than for**

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[18]Dr. Calabrese's views can be found here: http://www.21stcenturysciencetech.com/Articles_2011/Fall-2011/Interview_Calabrese.pdf

[19]A note of clarification is perhaps necessary here. The cancers were not **found** in 1987, they were found years later in children who had been 15 or under (including in utero) at the time of the accident.

[20]Dr. Marcus overstates Sergei Jargin's position in the cited article. He wrote: "TC [thyroid cancer] was under-reported before the Chernobyl accident and more accurately diagnosed thereafter. This higher incidence of TC was attributed to the accident, **although it was at least partially caused by more complete detection."** [Emphasis added.] Thus Jargin did not dispute that Chernobyl was a cause of childhood thyroid cancer.

thyroid cancer in children at Chernobyl, is difficult to establish."[21] [Emphasis added.] I hope she will explain the apparent contradiction between the two statements.

Mainstream science is well aware that the post-Chernobyl childhood thyroid cancers began showing up long before any screening for cancer took place.[22] The mainstream view of the Chernobyl data is that the appearance of so many thyroid cancers so soon after the accident – the first cluster of cases showed up near Minsk around 1991 – was an indication that I-131 was far more carcinogenic, when inhaled or ingested by the young, than previously suspected. Until then, the latency period had been believed to be much longer.[23] In her petition, Dr. Marcus turns this causal relationship on its head, arguing that since the latency period for radiogenic thyroid cancer is much longer (a mean of 28 years, she says), the cancers found in 2000 and 2006 cannot have been caused by radiation. They were there all along, she tells us, and their discovery can be attributed entirely to better screening.[24]

Is that argument sound? To focus on just one part of the question, latency periods, let us consider "Latency Period of Thyroid Neoplasia After Radiation Exposure," an article

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[21]SNMMI Practice Guideline for Therapy of Thyroid Disease with 131I 3.0*,Edward B. Silberstein, Carol S. Marcus, et al. (2012), http://snmmi.files.cms-plus.com/docs/I-131_V3.0_JNM_pub_version.pdf (at p. 10).The same document said, citing BEIR VII, "No threshold for radiation-induced carcinogenesis has been firmly established."

[22]In comments filed with the NRC on October 31, 1992, when Dr. Marcus's petition for rulemaking was out for comment, I made the point that, as the *New York Times* had recently reported, a World Health Organization team visiting Belarus "had come up with wholly unexpected findings: deaths from thyroid cancer (normally a disease slow in its onset and progress, with high cure rates) among children exposed to I-131 after Chernobyl." I continued: "This is not the time for the NRC to be approving regulatory changes that will have the effect of exposing American children to more I-131." (Dr. Marcus's response was to jeer at me for citing such "superbly scientific sources as the *New York Times*.") By the time the NRC granted the petition, in 1997, there was an abundance of data confirming the earlier reports, but the NRC final rulemaking notice included no mention whatever of Chernobyl or the resulting childhood thyroid cancer. Chernobyl was more than the elephant in the room; it was a whole herd of elephants.

[23]See, e.g., NIH News for March 17, 2011: "Higher cancer risk continues after Chernobyl; NIH study finds that thyroid cancer risk for those who were children and adolescents when they were exposed to fallout has not yet begun to decline." http://www.nih.gov/news/health/mar2011/nci-17.htm

[24]It would be fascinating to know when this realization came to Dr. Marcus, for in the past, her view of the post-Chernobyl thyroid cancers was quite different. On September 16, 1999, she wrote to the internet bulletin board RADSAFE: "We don't know why young children near Chernobyl developed thyroid cancer, but we have not seen this in other children who received NaI-131 for medical reasons. We do know that babies and young children near Chernobyl received massive doses of SSKI [super-saturated potassium iodide], and it is conceivable that SSKI-induced thyroiditis led to thyroid cancer." This suggestion, incidentally, was utter nonsense. The problem in the former Soviet Union was that there was minimal distribution of potassium iodide, whereas in Poland, 97 percent of children received it promptly. If KI had been the cause of thyroid cancer, rather than the means of preventing it, we would expect to see large numbers of cancers among Polish children. They did not occur.

published in the journal *Annals of Surgery* in 2004.[25] It found, based on a relatively small sample, that the mean latency period for papillary thyroid cancer associated with external radiation was approximately 30 years, whereas the mean latency period for post-Chernobyl cancer, associated with internal radiation, was about six years. There is in fact ample scientific evidence not only that the post-Chernobyl thyroid cancers were caused by internal radiation exposure, but also that there is a linear dose-response relationship.[26]

III. The Merits of Hormesis

Over the years, I have acquired, not always of my own volition, a measure of knowledge about radiation-caused thyroid cancer, its treatment with I-131, and the rules and practices for the protection of family members and the public. But on the scientific merits of the hormesis petitions, I will defer to someone with established credentials in the field, Dr. Ian Fairlie. I am attaching his views and incorporating them by reference. http://www.ianfairlie.org/wp-content/uploads/2015/08/US-NRC-Consultation-4-1.pdf

IV. Relationship Between the Marcus Petition and the Patient Release Rule

If this petition were to be granted, it would have little effect on the average American living near a nuclear plant, because the radiation doses from them are minuscule. The people who would be most immediately and drastically affected would be nuclear medicine patients, their families and loved ones, and the members of the public with whom they come in contact. The effect of the rule change would be to further loosen the already extremely lax NRC rules on release of radioactive patients.

As noted earlier, I agree with Dr. Marcus that a revision of the Commission's radiation protection standards is in order, albeit not in the direction she wants. Eventually, the Commission will have to come to terms with the reality that the current Patient Release Rule is deeply flawed, as is the advice it has received on it from the ACMUI. The filing of the Marcus petition is an appropriate occasion for that reexamination to take place.

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[25]http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1356259/Ann Surg. 2004 Apr; 239(4): 536–543. Latency Period of Thyroid Neoplasia After Radiation Exposure Shoichi Kikuchi, MD, PhD, Nancy D. Perrier, MD, Philip Ituarte, PhD, MPH, Allan E. Siperstein, MD, Quan-Yang Duh, MD, and Orlo H. Clark, MD

[26]See, e.g., "Risk of thyroid cancer after exposure to 131I in childhood," Cardis E et al., J. Natl Cancer Inst., 2005 May 18:97(10); 724-32: "After the Chernobyl nuclear power plant accident in April 1986, a large increase in the incidence of childhood thyroid cancer was reported in contaminated areas. Most of the radiation exposure to the thyroid was from iodine isotopes, especially 131I. We carried out a population-based case-control study of thyroid cancer in Belarus and the Russian Federation to evaluate the risk of thyroid cancer after exposure to radioactive iodine in childhood and to investigate environmental and host factors that may modify this risk. ... **A strong dose-response relationship was observed between radiation dose to the thyroid received in childhood and thyroid cancer risk. ...Exposure to (131)I in childhood is associated with an increased risk of thyroid cancer**."[Emphasis added.]

Some explanatory history is necessary here. Before 1997, patient release was governed by the 30 millicurie rule, which, as the NRC had explained in codifying it a decade earlier, was a yardstick based on the hazards of I-131.[27] That isotope was chosen because it was "the most commonly used therapeutic radiopharmaceutical" and also "the most radiotoxic byproduct material used for medical use." The NRC stressed the "special contamination hazards of radiopharmaceutical therapy patients," and rejected the idea, proposed by one commenter, of basing release on the probable exposure to others. The calculations themselves were straightforward, it said, but knowing the facts on which to base them – the probable distance from others, length of time of exposure, etc. – was too "tenuous" to be relied on. It concluded that at activity limit of 30 millicuries provided an "adequate margin of safety" for exposure to both external and internal doses.[28]

That the 30 millicurie rule was intended to ensure compliance with the 500 millirem maximum permissible dose to a member of the public was well understood, and not only by the NRC. In 1997, at a time at which the rule seemed to be threatened by efforts on the part of EPA to reduce public exposures to radioactive iodine, it was strongly defended in an article in *Thyroid*, the journal of the American Thyroid Association, by Dr. Pat Zanzonico, then as now a health physicist at Memorial Sloan-Kettering Cancer Center.[29] He showed that the maximum likely dose to the family member of a patient receiving 30 millicuries of I-131 was 500 millirems. His point was that the 30 millicurie standard was adequate to protect the public, and thus that there was no need to make it stricter. To quote the abstract of the paper:

> Based on actual measurements of thyroid activity and of external absorbed dose, the total thyroid and mean extrathyroidal absorbed doses to adult family members from immediately released 131I-treated patients are approximately 0.01 and approximately 0.02 rad/mCi administered, respectively, yielding an effective dose of approximately 0.02 rem/mCi. **A maximum permissible effective dose of 0.5 rem for adults therefore is consistent with a release criterion of retained 131I. Lower-activity release criteria therefore may be unnecessarily restrictive.** [Emphasis added.]

The obvious implication of what Dr. Zanzonico wrote was that any limit looser than 30 millicuries would result in doses to others exceeding the 500 millirem maximum. He also observed, correctly, that the 30 millicurie limit only applied to external doses, from

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[27]This was an activity cap, meaning that a person leaving a treating facility could have no more than 30 millicuries of activity in his or her system. This translated to an emitted radiation dose of about 6 millirem per hour at a distance of one meter, so that if you were a patient given 150 millicuries of I-131, you would be measured at intervals by someone from the hospital's radiation safety department, and when the emissions fell below 6 millirems, it meant that the activity level had dropped below 30 millicuries, and you could be released.

[28]See 50 FR 30616 (July 26, 1985) and 51 FR 36932 (Oct. 16, 1986.)

[29] Zanzonico, P.B., "Radiation Dose to Patients and Relatives Incident to ^{131}I Therapy," *Thyroid*, Vol. 7, No. 2, 199-204 (1997).

proximity, and commented: "**Of course, the overall hazard is a combination of both the external and internal radiation hazards**." With respect to internal dose, he noted, again quite accurately, that "**saliva and urine [are] the primary sources of such contamination**." [Emphasis added.]

The article also noted that the activity threshold for hospitalization of radioactive patients ranged "from as low as 2 mCi [millicuries] in some parts of Europe **to as high as 30 mCi in the United States**." [Emphasis added.] Thus even before the 1997 deregulation, the NRC's 30 millicurie standard was as loose as any in the world. If we were already outliers then, one can imagine how far wide of the norm we are now.

Dr. Zanzonico evidently did not realize, as he was writing his article, that the NRC was on the verge of ditching the 30 millicurie rule in favor of a dose-based approach, and that outpatient treatment with I-131 in much greater amounts was about to become common. Sloan-Kettering, for example, would soon be giving outpatient treatments of up to 200 millicuries of I-131.[30]

Once the 30 millicurie rule had been abolished, the party line shifted in the blink of an eye. Now it became necessary for the partisans of the nuclear medicine industry to prove that the 30 millicurie rule had been overly restrictive, and lacking a scientific basis, rather than adequately restrictive, and well supported by scientific research, as Dr. Zanzonico had argued in *Thyroid*.

Writing to RADSAFE in 1999, Dr. Marcus claimed that an NRC staff official had confirmed to her that no one at the NRC knew the origin of the 30 millicurie rule.[31] (If he said this, he

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[30]Bath, C., How can patients who receive radioactive iodine treatment for thyroid cancer reduce the chance of radiation risks to others, ASCO POST 2:4 (March 2011).

[31]Writing to RADSAFE, Dr. Marcus explained that her initial petition to the NRC had asked that the 30-millicurie rule be eliminated for all radioisotopes except I-131, but that she had later amended it to remove that exception: "After the main petition was submitted, I went back and looked at the I-131 case and couldn't figure out where in the world the '30 mCi' had come from. **NCRP no. 37 pooh-poohs the '30 mCi' number,** but did not give its origin. (The NRC originally applied the '30 mCi' to I-131; only in 1987, I think it was, was it applied to ALL radionuclides.) Don Cool admitted that no one at NRC had any idea where it came from or what it was based on; we had a completely arbitrary and capricious standard with no scientific basis at all. It certainly had nothing to do with the 500 mrem limit." [Emphasis added.]

Incidentally, Dr. Marcus's message grossly distorted how the authors of NCRP No. 37 saw the 30 millicurie limit. Anyone who troubles to read that slender volume, and it is well worth the small effort required, will see that the point it made, entirely correctly, was that a "one size fits all" activity limit of 30 millicuries for every radioactive isotope was not the most meaningful basis for release, "since the exposure rates and half-lives of various radionuclides differ greatly." (At p. 17.) For chromium 51, for example, 30 millicuries was unduly restrictive, while for others, such as I-131, it was not restrictive enough, in the authors' view. (At 18.) For I-131, it recommended release without restrictions only for doses of **eight millicuries or less**. Far from advocating the abolition of activity caps, it advocated limiting outpatient treatment with I-131 to 80 millicuries at the absolute maximum, and then only in exceptional situations, with prior notice to local health authorities.

should have known better, for in 1985, the NRC had cited a recommendation of the NCRP as a source.[32]) Soon this became the new orthodoxy for Dr. Marcus and her allies. Articles duly appeared making the claim that the 30 millicurie rule came out of nowhere. We see this, for example, in the articles of Dr. Marcus's allies Drs. Stabin and Siegel,[33]and in a July 2014 article in *Thyroid*, co-authored by Dr. Siegel and Dr. Edward Silberstein,"The AEC/NRC Thirty-Millicurie Rule: Regulatory Origins and Clinical Consequences for Iodine-131 Remnant Ablative Doses." They wrote:

> **Clinical and historical uncertainty exists** surrounding the issue. ... Without any data, these U.S. regulatory agencies caused significant expense, inconvenience, and fear, affecting thyroid cancer patients and their families. ... Studies on this 30 mCi ablative dose indicate that **this activity was never associated with radiation health and safety issues.** [Emphasis added.]

"Clinical and historical uncertainty"? "Never associated with radiation health and safety issues"? One wants to say, "Oh, come **on.**" The proof to the contrary is all there in black and white, in the back issues of *Thyroid*.

Let us now skip ahead to 2010. In the meantime, the following has happened:

- The International Commission on Radiation Protection has issued, in 2004, a report, ICRP 94, detailing the radiation hazard presented by patients treated with I-131;
- I have filed, in 2005, a petition for rulemaking asking for reinstatement of the 30 millicurie rule, for I-131 only[34];
- the NRC has denied the petition, in 2008;
- I have taken the NRC to court, in the Ninth Circuit Court of Appeals;

NCRP 37 was anything but casual about radiation risks to others. Appendix III, at p. 45, is highly instructive. Titled "Radiation Safety Check List for Discharged Patients Containing Radionuclides," it asks for a description of the patient's household, and "in multi-family buildings, possible proximity of neighbors." In addition, the form asks for the names, relationship, and ages of household members, and the names of regular visitors. The radiation safety issues to be discussed are listed, and there are lines for "Film badges issued" and "Identification card, or wristband issued." Sample tags and wristbands, with the trefoil radiation hazard symbol, are included in Appendix II. Appendix IV, at p. 46, provides "Instructions for Family of Released Patient." The authors of NCRP No. 37 would surely be appalled that anyone could ever cite their document as the basis for allowing radioactive patients to go home to their families, ride public transportation, go to hotels, etc., with 400 millicuries or more of I-131 in their systems.

[32]See 50 FR 30616, 30627, col. 2 (July 26, 1985).

[33]Drs. Jeffry Siegel, Carol Marcus, and Michael Stabin,"Licensee over-reliance on conservatisms in NRC guidance regarding the release of patients treated with 131I," Health Phys. 2007 Dec;93(6):667-77, http://www.ncbi.nlm.nih.gov/pubmed/17993847.

[34]I later modified my request to say that I was open to solutions that allowed I-131 outpatient doses in higher amounts than that, under limited circumstances.

- the NRC has secured dismissal of the case, in 2009, not on the merits but on jurisdictional grounds (it agrees with the NRC that my treatments with I-131 were too far in the past for me to be sufficiently affected by the rule to have legal standing;
- also in 2009, the New York City Department of Health has issued a notice warning doctors not to send radioactive patients to hotels[35];
- in 2010, Congressman Ed Markey's staff has issued a lengthy report criticizing the Patient Release Rule; and
- The NRC's Advisory Committee on the Medical Uses of Isotopes has established a subcommittee, headed by Dr. Susan Langhorst, to examine and comment on the Markey report and on the Patient Release Rule.

At a public meeting in October 2010, an NRC staff official, James Luehman, had expressed concern about one class of hotel worker exposed to radiation from I-131 patients: those who work in hotels near major cancer centers, and who may clean numerous contaminated rooms in the course of a year, accumulating a dose each time. But when the ACMUI subcommittee issued its report in December 2010 on the release of radioactive patients, the issue of the worker who cleans multiple rooms was not even addressed.[36] Looking instead at doses to housekeepers from cleaning a single room, the subcommittee found that radiation doses to hotel workers were well within acceptable limits. This conclusion was premised on the assumption that **"dose contribution of possible internal radioactive contamination is considered minor and not included**." [Emphasis added.] (At p. 23.) The ACMUI subcommittee's analysis therefore considered external dose from the urine excreted into bedsheets by radioactive patients, but not internal dose from the urine and saliva that patients leave on bathroom surfaces.[37]

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[35]It should be explained that in 1997, the possibility that some released I-131 patients might not go directly home, but to hotels instead, had not occurred to the NRC, and the Patient Release Rule was therefore silent as to whether it was permitted. As a result, about four or five percent of patients were going to hotels and motels, where their rooms were cleaned by housekeepers unaware of any radiation hazard and unequipped to deal with it even if they had known. The notice from the New York City Dept. Of Health and Mental Hygiene, Information Notice ORH 2009-01 (June 29, 2009) notice stated: "To avoid sending iodine therapy patients home, do **NOT** advise patients to go to a hotel. A hotel presents substantial probability of close contact with infants, young children, pregnant women, and of course the general public. In a serious, and not at all implausible case, a patient could have their room or dining area cleaned by a pregnant woman who could come into very close contact with radioiodine-containing-bodily fluids." [Emphasis in the original.] Similar notices have been issued by state authorities in Minnesota and Washington.

[36]See U.S.N.R.C. Advisory Committee on the Medical Uses of Isotopes (ACMUI), Patient Release Report (Dec. 13, 2010). Sadly, it is a recurrent pattern that if there is no good answer for a troublesome question, the response often is to behave as though it had never been asked.

[37]In response to the criticism that the subcommittee should have considered doses from urine, Dr. Zanzonico replied that it **had** in fact considered urine: the external dose to housekeepers who handle bedsheets in which patients have deposited urine. It takes no advanced degree, however, to realize that the toilet (and in men, its surroundings as well) is a more likely place to look for radioactive urine than the sheets. The failure of

The health physicist whose calculations formed the basis for the subcommittee's report was none other than Dr. Pat Zanzonico, by now a member of the ACMUI. The report's findings directly contradicted what he had written in *Thyroid* in 1997, namely that internal dose mattered, and that the principal sources of it were urine and saliva.[38] Referring to the former 30 millicurie rule, the ACMUI report declared: "The Subcommittee finds no scientific merit in returning to such activity-based release criteria, which have **no identifiable scientific basis."**[39] [Emphasis added.] This too was completely contrary to what Dr. Zanzonico had written in *Thyroid* in 1997. The only person who can explain these apparent inconsistencies is Dr. Zanzonico himself, and I hope he will do so.

My intention is raising these matters is not to cause gratuitous embarrassment to anyone, but for the light they shed on the critical question of whether the NRC was wise or unwise to abolish the activity limit for I-131 patients, and whether the current Patient Release Rule affords the adequate protection to the public that the Atomic Energy Act requires. For the Commission, this is not optional. It is a matter of legal obligation, as much so as the Commission's duties on the reactor side, and at least as important, given that the radiation doses to the public are vastly higher.

Today, the Commission has no idea whether its rules on patient release provide adequate protection or not. The NRC staff wanted to tell the Commissioners that in SECY-12-0011, "Data Collection Regarding Patient Release," in 2012. The draft of that memorandum said, **"It is not known whether members of the public are, in fact, receiving doses that are less than 5 mSv [500 millirems] from the released patients."** [Emphasis added.] Leaving aside the fact that the NCRP and ICRP believe that the standard should be a fifth of that 500 millirem limit, this was highly significant, as it meant that the staff was unsure whether the

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the subcommittee to consider the doses that might be received in cleaning the bathroom speaks volumes, as does its refusal, year after year, to explain or even discuss its reasons for ignoring them, as we see in the transcript of the ACMUI meeting of April 16, 2012:

MR. CRANE: But as far as the bed sheets, it seems to me that the amount of urine that is going to be deposited in the bed sheet is trifling compared to the amount of urine that is going to be put into a toilet. And if you grant that urine is taken into account, why not count the toilet and why not count the sink? We know about saliva. We know also that a lot of common household products cause radioiodine to volatilize, so people can be inhaling. What is the reason for not taking into consideration toilets?

ACTING CHAIR THOMADSEN: Thank you very much, Mr. Crane, but we are not going to have a debate on this right now. (Transcript at 122.) Dr. Thomadsen might have added,"nor at any other time," for the question remains unanswered to this day.

[38]This is confirmed by data showing that in hospital rooms used by I-131 patients, the highest level of contamination is on the toilet, followed by the pillow (the latter presumably reflecting in part contamination by saliva). Tuncel, N., Karayalcin, B., Koca, G., Budak, E.S., "The environmental dose measurements of high dose iodine-131 treated thyroid cancer patients during hospitalization period" [paper presented at IAEA conference in Bonn, Germany, December, 2012]

[39]Here the subcommittee cited an article by Jeffry Siegel in the Journal of Nuclear Medicine, "Tracking the Origin of the NRC 30-mCi Rule," J. Nucl. Med. 2000;41:10-16N.

regulatory requirements were being met. But the ACMUI subcommittee, like a goalie guarding the net, intervened to keep this information from reaching the Commissioners. Making the specious argument that the Commission's Staff Requirements Memorandum forbade the staff to say this, the ACMUI demanded that the statement be deleted from the paper, and regrettably, the staff gave in.[40] (I will discuss this SECY paper further below.)

In a parallel situation, can anyone imagine the Advisory Committee on Reactor Safeguards trying to block the NRC staff from alerting the Commission to a possible gap in reactor safety? The idea seems beyond belief, but if ever such an attempt were made, it would be shot down in an instant. Why then should it be tolerated on the medical side? The unspoken message seems to be, just as Senator John Glenn had realized nearly 20 years before: it's only medicine and people, not reactors, so it doesn't really matter.[41]

The rulemaking that brought us the Patient Release Rule in 1997 was, in colloquial terms, a scam, or something very close to it. As mentioned earlier, the final rule published by the NRC said not a word about Chernobyl and the upsurge of thyroid cancer in children in the former Soviet Union, even as countries and organizations all over the world, realizing that this meant that I-131 was more dangerous to the very young than previously suspected, were tightening their regulations. This was, however, just one of a great many issues that the Commission never heard about in the package sent to them for approval by the NRC

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[40]In reality, the Commission had not instructed the staff to tell it that everything was working like a charm; rather, the Commission wanted to know where it needed more information, and of what kind, in order to judge whether the current system was working as it should. Attachments to that staff paper make it possible to see the changes insisted on by the ACMUI subcommittee and the staff's response to them.

[41]The question may be asked: where was the Patients' Rights Advocate when all this was happening? Thereby hangs a tale. In 1990, in an effort to achieve greater balance on the ACMUI, which was heavily weighted to the licensee side, the Commission decided to create the position of Patients' Rights Advocate. The first person named to the post was Judith Brown, a highly competent and conscientious nurse, who sometimes posed pertinent questions that the staff would have preferred not to be asked. Thus in October 1992, when a senior staffer was making the case to ACMUI for granting the Marcus petition and allowing therapy doses of I-131 to be given on an outpatient basis, on the basis of the "emotional benefits" to the patient, she asked, as a point of information, how patients felt **physically** at the time of treatment. This was a question that my own children, then eight and six, could have answered without difficulty, but the staff official had to admit ignorance, which raised the question: how can the NRC staff purport to make judgments on the psychological state of patients when it has not bothered to learn how they are feeling physically?

Clearly, Judith Brown was an inconvenient sort of Patients' Rights Advocate to have around. When her term expired, the person chosen to replace her was someone who, like Dr. Marcus, was a Southern Californian involved in the effort to promote creation of a dump for low-level nuclear waste in the Mojave Desert. She had spent 20 years doing public relations work for the nuclear isotope industry. Her successor came from a lifetime in isotope production at Hanford, and when he left the ACMUI to take a position in the isotope industry, his successor was someone whose name was sent to the Commission for approval in 2006 with no CV attached and no indication of what he did for a living. It was only after his appointment was announced that the Commissioners learned that their new Patients' Rights Advocate was the head of the DOE isotope program. That pattern was broken, thankfully, with the appointment of the current Patients' Rights Advocate, the admirable Laura Weil.

staff. Among other matters that commenters raised during the two comment periods (1992 and 1994), but that the Commissioners seem never to have learned about, were:

- six U.S. states had warned the NRC that iodine 131 was a special case, requiring special protections and standards;
- NCRP Report No. 37, the supposed analytic basis of the rule, had placed an activity cap of 80 millicuries on outpatient treatments;
- the rule change would put the NRC in violation of the IAEA's International Basic Safety Standards, to which the U.S. was a signatory;
- the NRC had rejected the premises of the proposed new rule just 11 years earlier, in 1986, for reasons set forth persuasively in Federal Register notices at the time;
- the importance of internal doses of I-131 from contamination;
- the concerns expressed by commenters about the likely economic pressures it would create;
- the warning from the National Institutes of Health about foreign patients who, disregarding instructions to avoid close contact with others after I-131 treatment, go directly from NIH to the airport to board long transoceanic flights, where they irradiate nearby passengers; and
- the emotional benefits to many patients of knowing that, by being treated as inpatients, they are protecting their families from harm.[42]

From all this, the Commissioners remained largely insulated. (Perhaps they wanted to be; at this point it is hard to know.) The Office of Inspector General made a valiant effort to enlighten the Commissioners as to the magnitude of the changes they were being asked to approve, the issues that were going unaddressed, and the defects in the way the proposal was being packaged and sold. In a brilliant and devastating March 18, 1994, memorandum from the IG to the Executive Director for Operations, Maryann Grodin, then OIG counsel and now General Counsel to the IG, wrote:

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[42]To make very clear, I am not saying, and have never said, that **every** patient finds inpatient treatment to be emotionally beneficial, compared to outpatient treatment. I would be lying if I said so, for I am personally acquainted with a couple in Seattle who feel very strongly that for them, outpatient treatment is preferable, and that the husband, who is by profession a radiation safety officer, is fully capable of ensuring that everyone's safety is assured. Rather, I am saying that **many** patients find it so. Why? Because, for example, it means (1) not having to worry about exposing their loved ones; (2) if they experience nausea or other ill effects, there will be hospital staff to take care of them; (3) meals will be provided; and (4) they do not have to worry about exposing others while traveling home. Since 1992, the NRC has repeatedly touted the "emotional benefits" of outpatient treatment, even going so far as to claim that it contributes to "better patient outcomes," without so much as once in 23 years acknowledging that there are some patients who take the opposite view. "Emotional benefits" is an argument that cuts both ways. My position is that you cannot, with any intellectual honesty, talk about the emotional benefits of early release to some people without also talking about the emotional benefits to others of being kept in radiological isolation until it is safe to be released to the general population. And by the same token, it would be wrong for me to promote the benefits of hospitalization without acknowledging that there are persons for whom this may not be the ideal option, and for whom exceptions need to be possible, as NCRP No. 37 recognized in 1970.

> Another concern is that the significance of the proposed rule change is not clearly conveyed in the Draft Public Announcement. Enc. 6. While the announcement sets forth the proposed revision, it fails to state that the proposed rule will increase the amount of radiation exposure to some members of the public. Further, the change from an activity-based exposure limit to a dose-based limit is not elaborated on. Instead, the language used in the announcement could mislead a reader to interpret the proposed revision to be merely a regulatory clarification, as opposed to a substantive change.
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> **As an additional matter we note that the choice of a dose-based vs. activity-based limit was not presented as an issue for comment in the agency's petitions. Enc. 2, p. 16. By not raising the issue in the petitions, an opportunity for full comment on the matter was missed. [at p. 4.]** [Emphasis added.]

Ms. Grodin's memorandum did not use the term "hiding the ball," but the message was clear enough. It was all in vain, however. The staff blew off the OIG analysis, and the IG chose not to press the matter.[43]

V. Do Contamination and Internal Dose Matter?

For a perfect example of why the Commission needs to revisit its regulations in the medical area, let us take the treatment of contamination by I-131 patients and the risk it presents of internal dose to family members and others. On a subject that should be stable scientific fact, we see instead an oscillation, with a return period of approximately 11 years.

For decades, everyone knew that the most dangerous medical isotope was I-131, and that patients were hazardous not only from proximity (external dose), but also from contamination (internal dose), since the isotope is given by mouth, and the patient is thus a "leaky source," as one expert put it:

> It should be realized that the calculation system utilized in NCRP no. 37 assumes that the patient is a "sealed source." It is important to consider situations in which the patient is a "leaky source." In such situations, more conservative considerations need to apply. It is important to consider the patient given NaI-131 in this context.
>
> I-131 appears in urine, feces, sweat, saliva, lacrimal fluid, nasal fluid, and emitted gases. **The radiation absorbed dose to the thyroid in individuals who share households with patients can be much more significant from contaminant I-131 than from the patient as a sealed source. Therefore, the limiting factor in deciding when a patient can go home should be contaminant levels of I-131 that can reasonably be expected to occur.** [Emphasis added.]

[43]The OIG analysis was forwarded to the Commission in SECY-94-054A, a publicly available document which is an attachment to these comments. The cover memo from the EDO to the Commissioners stated that the staff had no intention of making any changes or modifications in the proposed rule, and that the IG did not intend to press the matter.

The expert in question was Dr. Carol S. Marcus, and the quotation is from her amended petition of 1992. Every single word of it was correct and on point, and remains so today.[44]

In highlighting the risk of contamination, Dr. Marcus was not saying anything novel. As early as 1978, Dr. Dade Moeller of Harvard, later to chair the NRC's Advisory Committee on Reactor Safeguards, and a Harvard colleague wrote an article in the *American Journal of Public Health* in which they made the point that I-131 patients were boarding airplanes with amounts of radioactivity in their systems that would make it contrary to NRC rules to ride in the baggage compartment as packages. (This was, moreover, in the days of the 30 millicurie rule.) They wrote:

> The quantity of radioiodine discharged in body wastes treated at a major medical center can substantially exceed that released from a large commercial nuclear power plant. … A person who is treated on an outpatient basis can become an avenue of transport for radionuclides through contamination within the home and through person-to-person contact.[45]

Let us now review the history of the NRC's evolutions on the subject of internal dose.

1985-1986.

In 1985, in proposing a codification of its rules on radioactive patients, the NRC stresses "the special contamination hazards of radiopharmaceutical therapy patients."[46] Its explanation of the 30 millicurie activity standard, 10 CFR 35.75, begins: "A patient whose body contains byproduct material is a source of external radiation and can be a source of

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[44]In the same year, at the ACMUI meeting of October 22, 1992, we find Dr. Marcus commenting, at p. 505 of the transcript, that it is acceptable for family members of released patients to receive radiation doses of 500 millirems from them, because "they have some benefit to go with the risk." Today, she would probably take issue with anyone who suggested that a radiation dose in that amount carried any risk at all.

[45]"Population exposures from radionuclides in medicine--as low as reasonably achievable?" J Shapiro and D W Moeller Am J Public Health. 1978 March; 68(3): 219–220. Professor Moeller and his co-author, Dr. Jacob Shapiro, a radiation protection officer at Harvard, were responding in part to a study by Jacobson, Plato, and Toeroek, published in the same March 1978 issue of the AJPH, which found significant internal doses in young children of thyroid patients given I-131: 612 millirems in a three-year-old, 1330 millirems in a four-month-old baby. That their comparison to emissions from nuclear plants was on target would be confirmed in 2006, when a draft report by the ICRP included the observation that **a single I-131 patient may give off more radiation than a nuclear power plant emits in an entire year**. But in a June 12, 2006, letter to the ICRP, an NRC staffer asserted that it was "inappropriate" to compare nuclear power plant emissions with "medically authorized discharges," and complained that though the ICRP was asking member nations to revisit their regulations on patients, *i.e.*, with a view to tightening them,"no discussion is provided concerning the benefits, both financially and emotionally, associated with discharging patients." (He did not dispute the accuracy of the statement, however.) The offending sentence was, as the NRC requested, deleted from the final report, ICRP 104, "Scope of Radiological Protection,"issued in 2007. For the NRC comment, see: http://www.icrp.org/consultation_viewitem.asp?guid={6D5B1740-3D6A-4487-A3B4-A324C80531C1}. .

[46]50 FR 30616, 30629 (July 26, 1985.)

radioactive contamination."[47] The proposed rules become final in 1986, with a notice describing I-131 as "the most radiotoxic byproduct material used for medical use," and explaining why the 30 millicurie rule, which was based on the hazards of I-131, provides "an adequate measure of public health and safety."[48]

1997.

We now jump ahead 11 years to 1997, and we have the new Patient Release Rule, based above all on the views of just one expert, Dr. Myron Pollycove, who as noted earlier is a passionate advocate of hormesis. He believes that I-131 is not carcinogenic[49] and that if a nuclear accident occurred, any health effects would be beneficial.[50] Suddenly, internal dose from contamination has gone from being a significant hazard to a non-issue, as we will discover shortly from the NRC's so-called "Regulatory Analysis," NUREG-1492.

Is vomiting by I-131 patients an issue? Anyone who knows the least thing about thyroid cancer and its treatment, including every patient and Dr. Marcus herself, knows that I-131 can produce nausea and vomiting.[51] Not the authors of NUREG-1492, however. They write:

> Vomitus. The occurrence of vomiting is not related to the administration of iodine-131 or any other radiopharmaceutical (personal communication, M. Pollycove, August 1995). (At p. 15.)

And so NUREG-1492 concludes, at p. 16:

> [I]nternal doses from intake of contamination are likely to be much smaller than doses from external radiation and much smaller than the public dose limit. Therefore, **internal exposures will not be considered in this analysis** other than for the breast-feeding infant. [Emphasis added.]

It is not my wish to deprecate the memory of Dr. Pollycove, but it must be said that he was

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[47] *Id.* at 30627.

[48] 51 FR 36932 (Oct. 16, 1986.)

[49] Memorandum, Myron Pollycove, Visting Medical Fellow, to L. Joseph Callan, EDO, Sep. 3, 1998.

[50] ."If a nuclear accident occurred, the radiation exposure would not be harmful and might even be beneficial." M. Pollycove and J. Cuttler, "Nuclear Energy and Health: And the Benefits of Low-Dose Radiation Hormesis," *Dose-Response* 2009; 7(1): 52–89; http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2664640/.)

[51] Dr. Marcus is a co-author of guidelines that say, of I-131 treatments: "Early side effects may include oral mucositis, nausea, occasional vomiting, sialadenitis, loss of taste, or unusual, often metal-like, alterations in taste. ... Vomiting can be prevented by prophylactic administration of oral antiemetics...." SNMMI Practice Guideline for Therapy of Thyroid Disease with 131I 3.0*,Edward B. Silberstein, Carol S. Marcus, et al. (2012) ,http://snmmi.files.cms-plus.com/docs/I-131_V3.0_JNM_pub_version.pdf

almost the last person on whom the NRC should have been depending for expert advice in that rulemaking. The result of that misplaced reliance was a deregulation, still very much in place, that may be the most radical ever by a federal agency charged with protecting health and safety.

2004.

We move on in time to 2004. The ICRP has issued a report, ICRP 94, warning of the danger to children from patients made radioactive by treatment with I-131. It states, among other things, that one kiss from a radioactive parent can transfer enough I-131 to double a child's risk of developing thyroid cancer.[52] Do the staff and/or the ACMUI pass this information on to the Commissioners, and explain that the dismissal of contamination and resultant internal dose in 1997 might have been a mistake? Regrettably, they do not.

2008.

Fast forward to 2008, and the NRC staff is denying a petition for rulemaking, filed by me in 2005, asking the Commission to revisit its regulations on patient release. (The matter is considered too unimportant to require Commission involvement.) One of the commenters has happened to mention ICRP 94, and the NRC staff has therefore felt obliged to address it. In a *Federal Register* notice, the staff explains that it has decided to deny the petition and "**revise the guidance in NUREG-1556, Volume 9, to include the ICRP Publication 94 recommendations** and issue a Regulatory Issue Summary (RIS) to medical licensees to make them aware of the ICRP recommendations."[53] [Emphasis added.] The notice says: "NRC believes that enhancing the guidance is a more efficient way of protecting children and infants than amending the regulations."

The May 16, 2008, press release accompanying the RIS explains that it tells physicians to "consider hospitalizing patients whose living conditions may result in the contamination of infants and young children." (Contamination, in this context, translates to internal dose.) The press release continues:

> These regulations were based on the assumption that internal doses to family members or others from a patient released following iodine therapy would be small compared to external doses received from being near the patient. **However, concern has increased in recent years that contamination of infants and young children with saliva from a patient in the first few days following treatment may result in**

[52] International Commission on Radiological Protection, "Release of Patients after Therapy with Unsealed Radionuclides," ICRP Publication 94, Annals of the ICRP 34(2), Pergamon Press, Oxford (2004). The reference to the doubled risk of thyroid cancer is found at p. 30.

[53] 73 FR 29445, 448 (May 21, 2008.)

significant doses to the child's thyroid. [Emphasis added.]

So the NRC once again accepts that internal doses from contamination are significant, and is revising the NUREG-1556 guidance to include the ICRP 94 recommendations. Surely this means that the aberration of 1997 has been corrected, finally and definitively? So one might think. But at the NRC there can be many slips between the cup and the lip. As of this writing, more than seven years after the NRC's 2008 *Federal Register* notice, the reference to ICRP 94 has yet to be included in NUREG-1556.

2010.

Now it is 2010, and the ACMUI subcommittee is presenting its report on the Patient Release Rule to the Commission. Just the year before, the IAEA, assisted by the ICRP, has issued Safety Report No. 63, "Release of Patients After Radionuclide Therapy." It has reiterated, at p. 7, that treated patients can cause exposure of other persons to radiation in two ways:

> (a) External irradiation of persons close to the patient;
> (b) Internal contamination of persons as a result of excreted or inhaled radionuclides.

IAEA No. 63 has also stressed the importance of appropriate measures to control doses to others, stating: "Without precautions, it is possible to envisage doses up to a number of orders of magnitude higher than the dose limits or dose constraints." (At p. 8.) "This can be controlled and minimized so that dose limits and constraints are not generally breached in practice,"it says, but a "key element in achieving this is the information and instruction provided for the patient and their family." *Id.* Among its conclusions are:

> Thyroid cancer as a result of radiation exposure is a significant risk for unborn children, infants, and younger persons. Particular care should be taken to avoid contamination of pregnant women, infants and children. (At p. 38.) ...
>
> The success of a patient release programme is critically dependent on the quality and specificity of the information provided to the patient, the skill with which it is communicated, and whether or not the patient believes the information provided.
>
> There is a lack of audit data on the behaviour of patients and the consequences of early release programmes. There is some evidence of unanticipated consequences of early release programmes in the USA that requires assessment and evaluation. (At p. 39.)[54]

[54]What the authors might have meant by "unanticipated consequences of early release programmes in the USA" is suggested by SECY-02-0111, in which the NRC staff, evidently at the instigation of Chairman Richard Meserve, proposed amending the NRC's rules to require the agency to be notified if a member of the public received a radiation dose exceeding 5 rems (10 times the permissible dose) from a released patient. The

IAEA No. 63 identifies – just as the NRC had in 1986, when it rejected the idea of a dose-based standard – the "many methodological issues that can compromise external dose calculations." (At p. 8.) It cites studies indicating that external dose from patients far exceeds internal dose from contamination, "with the exception of contact with a patient's urine," and it notes that "removable activity from toilet rims during the first 48 hours post-treatment was much greater for men than for women."[55] (At p. 9.) It says:

> Wellner et al. [citation to 1998 article in *Nuklearmedizin*] calculated that **the effective dose, from air contamination, for relatives of cancer patients treated on an ambulatory basis could be up to 6.5 mSv** and could, thus, exceed the 1 mSv public dose limit. ... The ICRP concludes that, in general, contamination of adults is less important than internal exposure. Notwithstanding this, it is very important to avoid contamination (particularly from saliva) of pregnant women, infants, and young children, owing to the sensitivity of foetal and paediatric thyroids to cancer induction. [Emphasis added.] (At p. 10.)

Note that patients treated with I-131 can, **from exhaled breath alone**, deliver doses to family members of as much as 650 millirems. This is entirely internal dose, and not only does it exceed the internationally accepted dose limit of 100 millirems, it also exceeds the 500 millirems permitted by NRC. Doesn't this seem like something the Commissioners should know about? But the ACMUI report on patient release, while it cites IAEA No. 63, says not a word about internal dose from exhaled breath.[56]

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proposal was prompted by a July 24, 2001, letter from Joseph Klinger of the Illinois Department of Nuclear Safety, who wrote:

> "The Department would question the basis, including supporting data, for NRC's statements regarding the low frequency of known events associated with patient release. Simply because NRC does not keep records on such events, does not mean that such events are not occurring. Such Events have occurred in Agreement States and means of addressing them have been problematic because hospitals will accept no responsibility for them."

The proposal was voted down, 3-2. Chairman Meserve, in dissent, observed that "members of the public who have received involuntary doses from the release of patients will never be informed of their exposure." He noted that though the NRC had solicited the views of the medical community on the proposal – they were strongly opposed to it – no comparable effort had been made to seek the views of the public: "We have thus ignored the very individuals who have the greatest stake in assuring that there is a reporting and notification process."

[55]This point has special relevance to the hotel workers, possibly pregnant or nursing, who clean the toilets of I-131 patients treated as outpatients and then released to hotels.

[56]There is a great deal of literature, especially in European medical journals, on the subject of the I-131 exhaled by treated patients. See, for example, M. Gründel et al., "^{131}I Exhalation by Patients Undergoing Therapy of Thyroid Diseases," *Rad. Prot. Dosimetry* (2008), Vol. 129, No. 4, pp. 435-438; A. P. Stefanoyannis et al., "Radiation Exposure to Caregivers from Patients Undergoing Common Radionuclide Therapies: A Review," *Rad. Prot. Dosimetry* (2014), pp. 1-10; and K. Schomäcker et al., "Exhalation of ^{131}I after radioiodine therapy: measurements in exhaled air," *Eur. J. Nucl. Med. Mol. Imaging* (2011) 38:2165-2172. See also E. Westcott et al., "Benefits of Automated Surface Decontamination of a Radioiodine Ward," *Health Phys.* 102 (Supplement 1):S4-S7; 2012. The last of these describes the use of robots to clean contaminated surfaces of isolation rooms in Australia, where patients receiving more that 600 MBq [16.2 mCi] of I-131 are hospitalized. The use of robots, it reports, provides "occupational health and safety benefits," since "decontamination with a mop and bucked

Let us put this into practical, real-world terms. A young mother is sent home after I-131 treatment and told to keep at a safe distance from her young child. Fine, she thinks, the playpen will be on the other side of the room, I'll keep an eye on the baby but I will stay 15 feet away. Does anyone tell her that she may be delivering a significant radiation dose to her child simply by being in the same room and breathing? Not, it seems, if the ACMUI subcommittee can prevent it.

The ACMUI report criticizes the NRC staff's 2008 RIS for having repeated the ICRP's warning about the thyroid cancer risk to the children of radioactive patients without also having provided "details regarding the assumptions." (At p. 11.) It "commends the NRC for adopting the current-risk-based [*sic*] criteria," and declares, "Change from the 30-mCi rule to the current 10 CFR 35.75 patient release criteria in no way weakened the NRC rules." (At p. 16.) It says this notwithstanding that the NRC in 1997 frankly acknowledged that "even though released patients are given instructions on how to limit the hazard from contamination, contamination control in a hospital can be more effective than contamination control out of the hospital."[57]

2012.

In late 2011, the staff is preparing a memorandum, "Data Collection Regarding Patient Release,"which will go to the Commissioners in early 2012 as SECY-12-011. The staff wants to include a reference to the fact that I-131 patients can contaminate their children by kissing them – a central point of the 2008 RIS, since reinforced by the 2009 IAEA report. But the ACMUI subcommittee on patient release demands that this be deleted from the paper, claiming that the terms of the of the Commission's Staff Requirements Memo prohibit the staff from mentioning this. Regrettably, the staff gives in and allows itself to be silenced. The paper never mentions the RIS at all. It is as though all trace of it had been wiped from history.

SECY-12-011 says, at page 3-4:

> **The staff determined it may be beneficial to re-examine one of the assumptions in NUREGs-1492 and 1556 guidance which underlies current release practices, specifically that internal dose to members of the public is negligible compared**

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presents several possible routes of exposure." If the NRC desires copies of these articles, I will be happy to provide them. I myself first raised the issue of exposure to patients' exhalations of I-131 in comments to the docket dated August 25, 1994.

[57] 62 FR 4120, 4123 (January 29, 1997.) The NRC explained that the other side of the coin is that having these patients in the hospital means that there is the potential to contaminate "people who frequent the hospital (e.g. clergy or a hospital orderly)." Thus it is a tradeoff: babies, with no say in the matter, may get more contamination, but clergy members who voluntarily visit a hospital where radioisotopes are used will get less.

> **with external dose.** This re-examination may be warranted because current release practices permit patients to be released with much higher activity than was the case when this assumption was made in promulgating the patient release rule. Accounting for internal dose is particularly important in the case of children and women. [Emphasis added.]

It is to the staff's credit that it is at least trying to alert the Commission to the fact that internal dose matters, especially for children and women. Likewise, it is highly significant that the staff is explaining that patients are being released with far more I-131 in them than had been foreseen in 1997. What is troubling, however, is the suggestion that current release practices treat internal dose as negligible. Wasn't that error acknowledged in 2008, in the RIS and the accompanying press release? It is as though the calendar been turned back to 1997. Radiation biology is not like economic policy, where higher interest rates may be a good idea one year, a bad one the next, and a good one the year after that. This is science, where some kinds of facts are expected to have some staying power, and when new information suggests a change in approach, the reasons for rejecting the earlier position have to be explained.

For all my criticisms of the ACMUI, it sometimes has its uses. For example, the best description of the damage wrought by the 1997 deregulation is to be found in the transcript of an October 23, 2007, ACMUI meeting. There, the longtime chairman, Dr. Leon Malmud, a former head of the Society of Nuclear Medicine, and another member, Dr. Douglas Eggli, discuss how insurance companies have taken advantage of the new rule, and how this in turn has transformed medical practice:

> Dr. Eggli: "We can't get a preceptor to admit most patients to the hospital anymore from the insurance companies since the release rule went into effect. ... If I am admitting somebody [with] less than 200 millicuries, the chances that I can get an insurance authorization for a hospitalization to isolate them, **even when I have family situations that require it**, it's fighting tooth and nail with the insurance companies...."
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> Dr. Malmud: "It is not now possible to treat a patient at our hospital and many hospitals in the Philadelphia area with I-131 in high doses for thyroid cancer because in order to do that a patient has to be isolated in a room which itself is isolated from the rooms next door. Therefore, **all patients are discharged upon treatment. We whisk them out the doors as fast as possible**. They are given outpatient doses between 100 and 200 millicuries of I-131, depending upon the extent of their thyroid cancer and occasionally, even higher doses. ... There's also an impossibility of keeping the patient in the hospital since the insurer will not cover it. The insurer will not cover it, will not cover the inpatient stay. It will cover the treatment, but not the inpatient stay. ... Being in the hospital today in most situations is an absolute impossibility. The nursing staff won't care for the patient. The other personnel in the hospital don't want to be near the patient. ... Within the hospital, this patient is an unwelcome guest currently. **Uninsured, their wonderful insurance stops because it's no longer necessary for them to be an inpatient**."[Emphasis added.] [Transcript

at pp. 126-130.]

Given that Dr. Malmud was a strong supporter of the 1997 rule, it would be easy to view this as demonstrating a callous disregard for the consequences of discharging patients whose family situations demand that they be hospitalized. But that may be a misreading of what he is saying. His words are also susceptible to the interpretation that he and other nuclear medicine doctors are merely trying to cope with a situation that they had not asked for, and that was imposed on them by the NRC and the insurance companies. If that is what he meant – and only he can clarify this point – one can feel some sympathy, because in fact, Dr. Malmud had **not** asked for this result. In 1992, he had filed comments on the Marcus petition on behalf of the Society of Nuclear Medicine, of which he was then President, offering a simple solution: incorporate NCRP No. 37 into the NRC's regulations in place of the rule then in force.[58] The NRC could have averted a great deal of harm by taking his advice. Had it done so, we would still have a firm activity cap for patient release, set at 80 millicuries (and that much only in the rare case); inpatient treatment, paid for by insurance, would still be the norm, although exceptions would be possible where conditions warranted; and patients' family members and the public would be far better protected than they are now. Perhaps it is not too late to take that suggestion even today, albeit with some modifications.

VI. Radioactive Patients in Hotels

Since January 2006, I have been urging the NRC that the problem of radioactive patients in hotels, after treatment with I-131 on an outpatient basis, is both a medical and a moral issue. It was wholly unforeseen, and therefore not addressed, at the time that the Patient Release Rule was enacted in 1997. Once the problem came to light, the NRC had a choice between two possible approaches. Either:

> (1) The Commission's intention was that patients would be hospitalized unless they met the criteria to go home, since at home, they would be in a position to protect family members and others from exposure to radiation. Thus a patient who for one reason or another cannot go home (or to a private residence put at his or her disposal) must remain isolated in the hospital.

Or:

> (2) The rule only specified the conditions under which patients must be hospitalized (that is, a likely dose of 500 millirems or more to any other person). If that criterion can be met, it does not matter where the patient goes, whether home, to a hotel, to an airplane, or anywhere else.

[58]The suggestion came in a letter written jointly by Dr. Malmud and the then President of the American College of Nuclear Physicians (ACNP), Robert J. Lull, M.D., dated April 24, 1992.

Put another way, is the issue (1) under what circumstances can patients be allowed to go home, or (2) under what circumstances can they be allowed to leave the hospital, and go where they like?

The NRC opted for the second approach, which I believe is both legally erroneous and contrary to sound policy. The patient who goes home does so, at least theoretically, with instructions that minimize radiation doses to others. (In reality, those instructions are often non-existent or inadequate.) The patient who goes to a hotel, on the other hand, will be putting others at risk without their knowledge. I do not wish to go into detail on these matters, which I addressed in a paper submitted to an IAEA conference on radiation safety in medicine, held in Bonn, Germany, in December 2012. A copy of it is attached and incorporated by reference. Suffice it to say that it was the unwitting exposure of hotel workers, in violation of the most basis principle of radiation protection in the workplace – informed consent – that most shocked and dismayed the delegates to the conference.

A commentary from 2011 in the journal *Clinical Nuclear Medicine* on a study of patients treated with I-131 on an outpatient basis in Brazil offers what is for the most part an excellent summary of where we stand today in the United States:

> The patients in this series were selected because they could read instructions, were willing to follow instructions, and lived in a place where the patient could have a private bedroom and where there is an adequate sewage and water supply system. There were no children or pregnant women present in the household.... The therapeutic doses [100 to 200 millicuries] were administered under the supervision of a nuclear medicine physician, with significant health physics support. The physicians prescribed drugs to prevent stomach acid formation for 3 days from the time of therapy (presumably to cut down on gastric irritation, nausea, and vomiting), as well as antiemetics. The patients left the hospital in personal cars, and were dissuaded against using public transportation. The physician and the radiation safety officer talked to the patients about radiation protection of others and the environment. Not only do they inform the patient of how to behave, but it allays fears that the patients may be harming members of his/her family. This is more or less the way the system should work in the United States, but unfortunately this is not always the case.
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> Occasionally, patients in the United States are treated and given no personalized radiation protection information, or are given advice only by a technologist, instead of the physician or a radiation protection professional. Some patients are not given antiemetics, and gastric acid suppression is not the standard of practice in the United States. Some patients go home with public transportation, and some are told to go to hotels. Reports of these problems have been taken to the NRC, which is looking into the outpatient treatment issue. After much consideration, I have come to the conclusion that the problems in the United States are partly due to inadequate requirements for physician licensure to perform I-131 NaI therapy, partly due to irrational and expensive NRC requirements for inpatient therapy, and partly due to insurance companies not wishing to reimburse for unnecessarily expensive inpatient therapies. Until these 3 issues are resolved, we will likely continue to have some

> problems in the United States. While the data in this research from Brazil will be very useful for convincing regulators, patients, and their families of the safety of outpatient I-131 NaI therapy when it is performed correctly, we in the United States will still see the perception of radiation safety problems if it is performed incorrectly.

In these two succinct paragraphs, one can find so many of the points that I have tried to make over the past ten years, including:

- patients given inadequate instructions,
- patients on public transportation,
- patients sent to hotels,
- patients vomiting,
- risk to pregnant family members,
- risks to children, and
- patient care dictated by the mercenary interests of insurance companies.

These issues are real, no matter how strenuously the efforts to deny them, whether by the ACMUI subcommittee or anyone else. But if the question is whether these paragraphs were written by me or someone allied with me, the answer is no, they were written by Dr. Carol S. Marcus.[59]

VII. Conclusion

There is a great deal more that could be said about these subjects, citing chapter and verse, but to offer particulars here would only make these comments even longer than they already are. Suffice it to say that if Dr. Marcus or the SNMMI or the ACMUI or anyone else wishes to challenge me on any or all of these points, I will be more than happy to have it out with them, including in an open Commission meeting, if the Commissioners agree.

These comments have been lengthy in part because my institutional memory of the NRC goes back to the agency's first weeks, 40 years ago, and I am therefore in a position to provide today's Commissioners with historical background that they may not learn elsewhere.[60] But as always, my mantra is, "Don't take my word for it, check it out, find out for yourselves." I am confident that the more Commissioners explore, the more they will

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[59] "Commentary on Willegaignon et al.: Outpatient Radioiodine Therapy for Thyroid Cancer: A Safe Nuclear Medicine Procedure, *Clinical Nuclear Medicine,* Vol. 36(6), June 2011, p. 446.

[60] When I joined the NRC in the spring of 1975, there were various checks and balances built into the system to ensure that the Commissioners got independent technical and policy advice and that institutional memory was preserved. Most important of these was the Office of Policy Evaluation. It was abolished in the early 1980's, a change that unfortunately starved the Commission of information that it badly needed. The present Commissioners, except Chairman Burns, probably know nothing of this.

come to the conclusion that the regulatory problems in the medical area are genuine and demand correction.

In 1975, the NRC was fully in harmony with international radiation protection standards. By 1997, the U.S. was already an outlier, as its 30 millicurie standard was at the edge of the spectrum of what was acceptable. Then the 30 millicurie standard was junked, and we saw patients being sent home to their families, to hotels, public transportation, etc., sometimes with 200 or even 400 millicuries or more of I-131 in their systems. Until Dr. Marcus filed her petition this year, one might have thought that it could not get any worse. But if the Commission embraces hormesis, and makes the rule changes that she asks for, it will be a great deal worse, and this time, it will not merely be the affected thyroid cancer patients and their doctors who are aware of it, the whole scientific world will decide that the NRC has gone off the deep end.

When supposed experts preach that internal doses of I-131 are insignificant, that I-131 is not carcinogenic, that there never was a scientific basis for the 30 millicurie rule, that the health effects of nuclear accidents will be beneficial, and that the post-Chernobyl thyroid cancers were not caused by radiation – this is not expert advice, it is quackery and charlatanism. Whether the hormesis backers are sincere in their beliefs is completely immaterial. Some of them surely are. But what of it? When people are peddling a nostrum, the question for the regulators is not the sincerity of the seller but the safety and effectiveness of the product.

In sum, I strongly urge the Commission **not** to deny Dr. Marcus's request for a rulemaking proceeding. On the contrary, they should grant it, provided that this proceeding is not limited to whether the Commission should embrace hormesis, but instead also considers whether and how the Patient Release Rule should be revised. Organizations, like individuals, sometimes need to find the strength to say, "We made a mistake, we recognize that, but now we are going to do what it takes to set things right." For the NRC, that time should have arrived a decade ago, but regrettably, the opportunity was missed. Today we can only say, better late than never.[61]

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[61] Although this is not a rulemaking petition, I would be remiss if I did not state, at least in general terms, the kinds of changes I think necessary in the NRC's approach to I-131 therapy. First, inpatient treatment for therapy doses should be the norm, and outpatient treatment the rare exception, as envisioned by NCRP No. 37 some 45 years ago. (M.D. Anderson in Houston, a justly world-famous cancer center, takes this approach, and its guidelines should be a model for others.) Second, doctors should be able to prescribe inpatient treatment in appropriate cases and have it covered by insurance without having to spend their precious time fighting with insurance companies on the telephone, rather than caring for patients and earning a living. Third, limits on radiation doses to family members and the public should be in accordance with international and national recommendations, i.e., 100 millirems (one millisievert) under normal circumstances, with an appropriate activity maximum. Fourth, provision should be made for the unusual exception. (For example, if – God forbid – any grandniece or grandnephew of mine needed I-131 treatment, I would say, "Send her or him to me, to recover at our house. I am old, I have no thyroid, and I am in no danger. I can give informed consent and take my chances with the radiation I receive. I will pick him or her up at the hospital." I would infinitely prefer that to having a

Respectfully submitted,

/s/

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child shut away in the loneliness and fear of radiological isolation.) Fifth, whenever exceptions are made, it should be on the basis of a genuine case-specific analysis, and with an activity ceiling, as contemplated by NCRP No. 37. Sixth, under no circumstances should highly radioactive patients ever be sent to hotels, or leave the treating facility by public transportation, crowded against other passengers in a subway or bus, or go directly to an airplane.

RADIATION PROTECTION ISSUES ASSOCIATED WITH OUTPATIENT TREATMENT OF THYROID CANCER USING HIGH DOSES OF IODINE-131: THE U.S. EXPERIENCE

[IAEA Conference on Radiation Safety in Medicine, Bonn, Germany, December, 2012]

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ABSTRACT

The United States Nuclear Regulatory Commission (NRC) sets no maximum activity level for the release of patients treated with radioactive iodine 131 (I-131). For decades, NRC used an activity-based standard, 1110 MBq, but since 1997, it has allowed medical licensees to use a dose-based standard by which patients can be released without regard to activity level, provided that the probable dose to any other person will not exceed 5 mSv. This limit, applicable even to infants and nursing mothers, far exceeds ICRP, IAEA, and NCRP standards. Outpatient treatment has become the norm in the U.S., even for doses of 7400 MBq and above, as insurance companies refuse to pay for inpatient care. Radioactive patients are frequently released to hotels, where they are a hazard to other guests and above all to housekeepers, who are typically women of childbearing age and may be pregnant or nursing. The dose to unsuspecting hotel workers violates a cardinal principle of radiation protection, informed consent. The NRC has also failed to ensure that practitioners and patients receive appropriate guidance about limiting exposure to others. The 15-year U.S. experience with dose-based standards for I-131 suggests that a major revision of the NRC's rules on radioactive patients is overdue.

1. INTRODUCTION

United States law gives the Nuclear Regulatory Commission (NRC), the agency which oversees nuclear power plants, the incidental duty of regulating the use of radioactive materials in medicine [1]. For decades, the NRC and its predecessor, the Atomic Energy Commission (AEC), required hospitalization for all patients administered 1110 MBq or more of iodine 131 (I-131) [2]. In 1997, however, in response to requests from medical licensees, the NRC changed its rules and began allowing doctors to administer high doses of I-131 on an outpatient basis [3]. The NRC's current rules, unchanged since 1997, present safety issues with respect to therapy doses of I-131 for thyroid cancer, therapy doses for hyperthyroidism, and diagnostic doses for thyroid cancer. This paper focuses exclusively on therapy doses for thyroid cancer.

2. DISCUSSION

2.1 The NRC rule change of 1997

Under the NRC rules in place since 1997, medical licensees treating patients with I-131 can choose between using the 1110 MBq activity standard as a default value and using a dose-based standard, under which patients can be released regardless of activity level if they are found unlikely to expose any other person to 5 mSv in a year [4]. This 5 mSv dose limit applies equally to all persons, irrespective of age, pregnancy status, and relationship to the patient. Only if the external dose to others is likely to exceed 1 mSv do the NRC's rules require licensees to provide patients with guidance on precautions for reducing radiation exposure to others.

In 1985, the NRC stated, accurately, that patients treated with I-131 are "a source of external radiation and can be a source of radioactive contamination" [5]. In 1997, however, the NRC declared that internal dose from contamination was insignificant, except for babies and nursing mothers, and

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stated: "[I]nternal exposures will not be considered in this analysis other than for the breast-feeding infant" [6]. The NRC conceded that exposure to patients' family members could be better controlled in a hospital setting, but pointed out that sending patients home would mean lower radiation doses to frequent hospital visitors, such as members of the clergy, and hospital orderlies [7].

The NRC's decision that its limits on I-131 should be made less stringent came just as international and national bodies were moving in the opposite direction, toward **more** stringent controls on the isotope. ICRP 60 (1991) had reduced dose limits to the public to 1 mSv per year, and the IAEA's Basic Safety Standards (1996) prescribed hospitalization for any I-131 treatment of more than 1110 MBq [8, 9]. For many nations, moreover, the 1110 MBq activity limit of the BSS was **insufficiently** strict. As of 1998, activity limits in the EU Member States ranged from 95 to 800 MBq, with most between 400 and 600 MBq [10].

2.2 Effects of the NRC rule change

Once the new rule was in place, many physicians found that insurance companies were refusing to pay for inpatient treatment with I-131 on the grounds that it was no longer necessary. For a doctor to insist on hospitalization was, therefore, to risk not being reimbursed. At a meeting of the NRC's Advisory Committee on the Medical Uses of Isotopes in 2007, two doctors (both supporters of the current rule, it should be stressed) candidly acknowledged the dominant role of insurers in the decision whether to hospitalize patients for I-131 therapy[1] [11].

A recent survey of 311 health professionals found that 15% **never** hospitalized patients for I-131 doses below 7363 MBq; 6% **never** hospitalized for doses below 11,063 MBq; and only 22% **invariably** hospitalized for doses between 7363 and 11,063 MBq [12]. In 2002, after receiving reports that released I-131 patients were exposing members of the public to radiation, the NRC Commissioners considered and rejected a proposal to require a report to the NRC if a patient caused a dose to another person of 50 mSv or more [13]. If hard data pointing to the rule's adverse effects is sparse, it is in part because the NRC has chosen not to receive it.

2.3 Radioactive patients in hotels

In changing its rules, the NRC assumed that patients would either meet the criteria for release, in which case they would go directly home, or remain hospitalized. It had not foreseen a third possibility: that some patients, either because the criteria for home release could not be met or because they lived far away, might be sent to hotels. This presents serious risks to hotel

[1] Dr. Douglas Eggli: "We can't get a preceptor to admit most patients to the hospital anymore from the insurance companies since the release rule went into effect. ... If I am admitting somebody [with] less than 200 millicuries [7400 MBq], the chances that I can get an insurance authorization for a hospitalization to isolate them, **even when I have family situations that require it**, it's fighting tooth and nail with the insurance companies...."

Dr. Leon Malmud: "It is not now possible to treat a patient at our hospital and many hospitals in the Philadelphia area with I-131 in high doses for thyroid cancer because in order to do that a patient has to be isolated in a room which itself is isolated from the rooms next door. Therefore, **all patients are discharged upon treatment. We whisk them out the doors as fast as possible**. They are given outpatient doses between 100 and 200 millicuries [3700 MBq and 7400 MBq] of I-131, depending upon the extent of their thyroid cancer and occasionally, even higher doses. ... There's also an impossibility of keeping the patient in the hospital since the insurer will not cover it. The insurer will not cover it, will not cover the inpatient stay. It will cover the treatment, but not the inpatient stay. ... Being in the hospital today in most situations is an absolute impossibility. The nursing staff won't care for the patient. The other personnel in the hospital don't want to be near the patient. ... Within the hospital, this patient is an unwelcome guest currently. **Uninsured, their wonderful insurance stops because it's no longer necessary for them to be an inpatient**. The health care workers are concerned and the hospital will not allow them to stay." [Emphasis added.] [Transcript at pp. 126-130.]

chambermaids, who in the U.S. are typically women of childbearing age. These workers do not "knowingly and willingly" accept their exposure to radiation. Unlike hospital staff and the families of patients sent home, they are unaware of the contamination and cannot take even basic precautions. A chambermaid may receive a substantial internal dose, and if she is pregnant or nursing, her baby's thyroid may also be affected. If the hotel is near a cancer center, moreover, she may clean numerous contaminated rooms in a year. Guests in adjoining rooms may also receive external radiation doses through the walls. Current estimates are that between 4 and 5 percent of patients go to hotels after receiving therapeutic doses of I-131 [14].

In 2009, the New York City Department of Health issued a directive to medical licensees warning in forceful terms against sending radioactive patients to hotels [15]. In 2011, the NRC published a non-binding notice that "strongly discouraged" licensees from doing so [16]. The practice nevertheless continues, and even has defenders. In a March 2011 article in an online medical journal, *ASCO Post,* Dr. R. Michael Tuttle, a distinguished thyroidologist at Memorial Sloan-Kettering Cancer Center in New York, was quoted as saying that Sloan-Kettering gives outpatient doses of up to 7400 MBq of I-131 [17]. "We are absolutely comfortable that it is safe for these patients to be in a hotel," Dr. Tuttle reportedly said, adding, "Many patients don't have a choice, because they are flying in for their treatments." In context, the implication was that if they returned home to countries with stricter standards, airport radiation detectors would identify them. Currently, the chance that a radioactive patient will be identified in a hotel or motel is virtually nil, unless, as happened in Illinois in 2007, the person occupying a room just vacated by an I-131 patient happens to work in a nuclear power plant, and the contamination on his skin sets off the plant's radiation alarms [18].

2.4 The NRC reaffirms the 1997 rule

In 2005, the present writer, a retired NRC lawyer who had in the past received I-131 treatments totaling over 28,000 MBq, filed a petition asking the NRC to revisit its rules on release of radioactive patients [18]. A supplementary filing in 2006 raised the issue of radioactive patients in hotels and the resulting risk to chambermaids [19]. The NRC denied the petition in 2008, in a decision that rejected the idea of adopting a 1mSv limit for infants and children, and made no mention of hotels [20]. (In 2009, a federal court dismissed the resulting appeal on procedural grounds, accepting the NRC's argument that because the petitioner's I-131 treatments had occurred long in the past, he was insufficiently affected by the NRC's rule to be allowed to challenge it in court [21].) At the same time that it denied the petition, the NRC issued a "Regulatory Issue Summary" [22] that drew medical licensees' attention to ICRP 94 [23] and ICRP 103 [24] and their warnings about the hazard to infants and children from I-131 patients. Acknowledging that the 1997 rule had been based on the assumption that internal dose presented insignificant risks, the NRC notice asked doctors to "consider" hospitalizing patients with children at home. It made clear, however, that the request was not binding.

2.5 The current situation

Not only is U.S. practice regarding radioactive patients unconservative by comparison with world practice, it has failed to provide appropriate safety guidance to aid licensees and patients in minimizing radiation doses to others. Although NCRP 155 [25] (a report which reaffirms earlier NCRP recommendations of a 1 mSv dose limit for children, pregnant women, and the public) includes sample precautions for thyroid patients treated with I-131, the NRC has not recommended their use. Instead, current NRC guidance suggests that licensees obtain and use a pamphlet issued in **1987**, when the 1110 MBq activity standard still applied [26]. The NRC's approach to human I-131 patients contrasts with its stringent rules for cats treated with I-131 for feline hyperthyroidism Typically administered doses of 111 to 222 MBq, they must be hospitalized for a minimum of 72 hours [27].

3. CONCLUSION

The IAEA has recently revised the BSS to eliminate the 1110 MBq activity limit on I-131, and endorsed the dose-based approach to protecting the public from treated patients [28]. In its February 23, 2010 "Position statement on release of patients after radionuclide therapy" [29], the IAEA implied that "global harmonization" had been achieved among ICRP 94, SRS 63 [30], EC publication Radiation Protection 97 [10], and the NRC's 1997 guidelines. Any such apparent harmonization is purely illusory, however, so long as the IAEA adheres to the 1 mSv dose standard for exposure to the public, while the NRC's standard is 5 mSv, even for infants and pregnant women. The IAEA and ICRP have yet to address the pressing issue of highly radioactive patients sent to hotels. The exposure of unsuspecting and unprotected hotel chambermaids to I-131 contamination is medically and ethically unacceptable and deserves condemnation. A revision of the NRC's regulations to bring them into conformity with international norms is overdue.

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Comments on ACMUI Sub-Committee Report on Hormesis/Linear No-Threshold PRMs

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I read with interest the ACMUI report addressing the PRMs, ending in a recommendation that, “for the time being and subject to reconsideration as additional scientific evidence becomes available, the NRC continue to base the formulation of radiation protection standards on the LNT model.”

I offer the following brief comments on some of the information the sub-committee selected to reach its decision as contained in the Discussion section of the report. This section presents a balanced but not necessarily fair picture, since balance between truth and falsehood is not a goal to be ardently pursued.

1. Linear no-threshold versus alternative dose-response models

The report notes with respect to the LNT model that, “… a mathematical extrapolation model remains the only practical approach to estimating the presumed excess cancer risk from low-dose radiation, and the dose-response data derived from epidemiological studies of human cohorts, such as the A-bomb survivors, exposed to high-dose radiation are largely consistent with an LNT model.” However, it must be emphasized that linearity at low doses does not exist; rather, it is forced by the high-dose extrapolation of the LNT model. In addition, LNT is not the only model the A-bomb survivor data are “consistent with,” but more importantly, since there are different bodily responses, damage control/repair and recovery mechanisms at play at high and low doses, the assumption of linearity is erroneous (1).

Considerations of biology and physics should be the source of scientific hypotheses about ionizing radiation, not assumptions designed to yield mathematically convenient relationships. If epidemiological studies indicate no significant radiation-related excess cancer at low doses (<100–200 mSv), it may not simply be because the expected effect is likely too small to be detected. Statistical invisibility is a straw-man argument since, rather than being invisible, the increased cancer risk more likely *does not exist* - as many studies have demonstrated (2).

2. Low-dose protracted or intermittent radiation exposure

The report discusses the INWORKS study authored by Leuraud et al. to presumably indicate the LNT model is justified. However, this study is full of erroneous assumptions and mathematical manipulations imposed on the data, too numerous to discuss here, that render the conclusion misleading and false.

Briefly, this study was restricted to consideration of occupational exposures only, which neglects the much greater contribution of natural background radiation and medical exposure to total cumulative exposure. The Leuraud et al. study further assumes a priori that the linear no-threshold (LNT) model is applicable and notes that this model is "generally used in studies of radiation effects." The "origin" is artificially constrained as d = 0, RR= 1 (ERR = 0), but since this corresponds to a wide dispersion of actual cumulative radiation exposures, any correlation with cancer mortality has limited meaning. According to the authors, the trend in the ERR of leukaemia was "well described by a linear function of cumulative dose," but this is not entirely correct. The 200-300 mGy dose category influences the upward slope significantly and is mostly responsible for the reported ERR/Gy of 2.96; a linear fit to these data exhibits a poor correlation coefficient. A careful review of their Table A2 reveals the 200-300 mGy category is the only one with an average ERR >1 with a 90% CI that does not include zero.

3. Radiation exposure from CT scans in childhood

The report seemingly "cherry picks" the Pearce study to presumably indicate support for the LNT model. But, again, this study has significant flaws, such as failure to consider the existence of reverse causation and inadequate dosimetry and the credibility of its conclusions has been questioned based on a rigorous statistical analysis (3). The ACMUI report does not mention the more recent Journy et al. study (4) demonstrating that indication for CT exams should be considered to avoid overestimation of cancer risk. This study indicated no significant excess cancer risk in French children associated with CT exposures when adjustments were made for cancer-predisposing factors.

4. Mechanistic considerations and epidemiologic studies of background radiation and of nuclear accidents

Bravo to the ACMUI sub-committee for recognizing that "Mechanistic studies and epidemiologic studies of background radiation and recent nuclear accidents (Fukushima and Chernobyl) suggest that LNT may not be the correct model" and that "data from nuclear accidents suggest that low-dose radiation does not increase the cancer risk among exposed residents."

The huge cost in human suffering imposed on the public as a result of applying the LNT model following these nuclear accidents cannot be ignored in any discussion endorsing the LNT model. Despite the real-world observations of no harm, increased radiation-induced cancer risks at low doses are often still derived using the LNT model, but these risk estimates are only theoretical and,

as yet, have never been conclusively demonstrated by empirical evidence. Nevertheless, use of the LNT model is often justified as being 'conservative' so that any LNT model-derived regulation or policy must at least be protective. But this is now demonstrably false (2).

In conclusion, I was very encouraged by the sub-committee's recognition that there is a vast and ever-growing body of scientific literature refuting the LNT model and its recommendation that "while strongly encouraging continued investigation critically comparing alternative models, regulatory authorities should exercise prudent (though not excessive) conservatism in formulating radiation protection standards." I look forward to the day, which will indeed come, when the LNT model is definitively refuted. Until that day, we should remain vigilant as scientific evidence continues to accumulate and further advances our understanding to the point where the need for significant changes in radiation protection standards will be evident.

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