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Dr. Leon S. Malmud
Chairman, Advisory Committee on the Medical Uses of Isotopes
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Dr. Malmud:

First, let me say that I am sorry that illness has kept you away from the past two meetings of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), and that we therefore have not yet had the chance to meet. I hope this letter finds you restored to good health, and that we will get to see each other at the Committee's May 2011 meeting.

The ACMUI, of which you are Chairman, often admonishes the Nuclear Regulatory Commission how improper it would be for the NRC to "interfere with the practice of medicine." Many times, the Committee has made the point that no one but doctors and patients should be deciding the kind of care that patients receive.

Today, there is grave interference taking place in the practice of medicine, specifically in the treatment of thyroid cancer with radioactive iodine 131, but it is not, except very indirectly, coming from the NRC. Rather, it is coming from insurance companies which have taken advantage of the NRC's patient release rule to deny coverage for inpatient treatment with radioiodine. As a result, doctors are handcuffed: they find themselves forced to treat all or nearly all patients on an outpatient basis, even when patients' home situations make this unwise. Insurance companies have thus snatched medical decisionmaking out of the hands of physicians.

No one in the medical community has publicly the stated the dimensions of the problem better than you yourself, at the October 2007 ACMUI meeting.[1] The transcript of that

[1] 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....

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

meeting, specifically the colloquy between you and Dr. Eggli, is the best evidence on the public record for the proposition that the present system is broken and desperately in need of fixing.

The ACMUI subcommittee that recently examined the patient release issue did what was expected of it, namely to report that everything is fine with the current rule. But you yourself plainly know better.

All the problems that you and Dr. Eggli so vividly described are the result, as the transcript makes clear, of the NRC's 1997 rule change, which has had consequences wholly unforeseen by both the regulators and the licensee community. The price for this is being paid by cancer patients and their families, as well as other members of the public exposed to radioactive patients, including the housekeepers in the hotels where many patients go after treatment, either at the direction of doctors or by their own choice, to protect their families from exposure to radiation. We can expect that years from now, there will be more cases of thyroid cancer and other thyroid damage as a result.

Of course, no one will ever be able to establish that a specific cancer resulted from a specific exposure to radiation. And if a housekeeper at a hotel near the Mayo Clinic, which gives outpatient radioiodine treatment to patients from around the country and around the world, cleans 20 radioactively contaminated rooms in the course of her pregnancy, and her baby is born with an under-functioning thyroid, who will ever connect the medical condition and its cause?

I recently read the comments that you, as President of the Society of Nuclear Medicine

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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. The hospital doesn't want the patient in the hospital. More than one room has to be reserved for the patient. It's an impossibility.

... 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.

(SNM), together with the then President of the American College of Nuclear Physicians (ACNP), Robert J. Lull, M.D., submitted to the NRC on April 24, 1992, in response to the petition for rulemaking filed by the American College of Nuclear Medicine (ACNM), and docketed on January 14, 1992. They are extremely illuminating, for they suggest that the NRC, in its deregulation of I-131 treatments, went far beyond what you were advocating.[2] The situation faced by doctors and patients today is therefore radically at odds with what you yourself supported in 1992.

In those comments, you proposed that the NRC substitute NCRP No. 37, published in 1970, for the standards then appearing in 10 CFR Part 35.72(a)(2). NCRP 37 should be required reading for anyone involved in this controversy, and in particular for the NRC Commissioners. Anyone who reviews it will see that it never for a moment contemplated that patients would be sent home, as sometimes occurs today, with several hundred millicuries of I-131 in their systems.

To be sure, the report led the way in suggesting that dose rate to others might be preferable to activity rate in the patient as a basis for determining when patients can be released. It said, at p. 17: "Since the exposure rates and half-lives of various radionuclides differ greatly, a more meaningful basis for release from the hospital is the possible exposure to other individuals with whom the patients are likely to associate." However, it did not propose disregarding all activity limits. Rather, as New York State's Department of Health pointed out in its comments of May 7, 1992, NCRP 37 envisioned 80 millicuries as the maximum permissible amount for outpatient treatment with I-131.[3]

NCRP 37 was anything but casual about radiation risks to others. It said that while there were "some relatively rare and unusual situations where it would be necessary, or highly desirable, to send a patient home in spite of his carrying a burden that could result in a

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[2] It is worth stressing that the original petition, filed by Dr. Carol Marcus, was intended not to revamp the NRC's approach to outpatient treatment but to preserve it. An NRC staff member had urgently requested the petition under the misconception that newly adopted NRC regulations in 10 CFR Part 20, on permissible radiation doses to members of the public from NRC-licensed activities, could override the regulatory provisions of10 CFR Part 35 on nuclear medicine. (The NRC subsequently clarified that Part 20 had no such intent or effect.) In short, the whole NRC deregulation of nuclear medicine was set in motion by one NRC employee's mistake, and by his decision to solicit a petition for rulemaking from outside the agency, rather than go through bureaucratic channels to address his concerns.

[3] See NCRP 37, p. 18, Table 4. The NRC, however, brushed aside New York's comments, as it did all those that differed from its predetermined course. It did not even acknowledge them in their memoranda to the Commission. As a result, the Commissioners proceeded with the deregulatory rulemaking with little or no understanding of the actual safety issues involved.

dose to other persons in excess of 0.5 rem[4]," such cases required not only documentation of the reasons for making an exception, but also something more: "The local health authorities *shall* be notified of the action." [Emphasis in the original.]

Appendix III, at p. 45, is also highly instructive. Titled "Radiation Safety Check List for Discharged Patients Containing Radionuclides," it asked for a description of the patient's household, and "in multi-family buildings, possible proximity of neighbors." (One can imagine would the authors would have said to a patient proposing to go a hotel.) In addition, the form asked for the names, relationship, and ages of household members, and for the names of regular visitors. The radiation safety issues to be discussed were listed, and there were lines for "Film badges issued" and "Identification card, or wristband issued." Sample tags and wristbands, with the trefoil radiation hazard symbol, were included in Appendix II. Appendix IV, at p. 46, provided "Instructions for Family of Released Patient."

Consider also the September 26, 1983, letter from J. A. Spahn, an NCRP staff scientist, to Edmond E. Griffin of the American Heart Association, who had inquired about exemptions from the 30-millicurie rule. Saying that he was writing on behalf of NCRP President Warren K. Sinclair, Spahn forwarded Griffin a copy of NCRP 37 and explained the organization's position:

> The NCRP would recommend against "exemptions" from the standard 30 mCi body content prior to release from the hospital. If anything, in the case of Iodine-131, we would recommend that in the majority of cases the patient should not be released until the total amount in the body is 8 mCi.[5]

What does NCRP 37 have to say about the appropriate instructions for someone

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[4] By the time the NCRP updated the report, with NCRP 155 (2005), it had come to realize that for children and pregnant women, the 0.5 rem standard was insufficiently protective, and needed to be revised to 0.1 rem. The NRC has rejected this approach, however, a fact which Dr. Langhorst evidently missed when preparing her presentation to the Commission on October 20, 2010. She was promptly contradicted by Jim Luehman of the NRC staff.

[5] The Spahn letter, which is further support for the proposition that I-131 is in a class by itself, owing to the special hazards it poses to others, may be found in the NRC docket as an attachment to a comment from the Texas Department of Health, dated May 8, 1992. Texas warned strongly against relaxing the 30-millicurie rule, noting that it was aware of a case in which a patient had been released with more than that amount of a radiopharmaceutical in his system and caused "widespread contamination of a private residence." As with New York's comments of the previous day, the NRC ignored Texas's warnings, and did not even acknowledge that they had been made.

discharged with an activity level of just *50* millicuries of I-131? At pages 20 and 21 of the report we read that in the first *week*, if there is anyone under the age of 45 in the household, no child or person under 45 shall be allowed in the same room, or at a distance of less than 9 feet, for more than a few minutes a day.[6] Lesser precautions are appropriate for the second and third weeks after treatment, but only after eight weeks is unrestricted contact with others permitted.

In sum, what the authors of NCRP 37 envisioned was not the present sky's-the-limit approach to I-131 treatment, but a tightly regulated system under which exceptional patients would be allowed to leave the hospital with at most 80 millicuries of I-131 in their system, after a careful evaluation of their living situation, and wearing tags or wristbands identifying them as a radiation hazard.

You surely also recall that the first petition for rulemaking on the subject of patient release was filed by Dr. Carol Marcus, who originally asked that the 30 millicurie release limit be eliminated *for all radioisotopes except one*: I-131. She too evidently recognized, at least initially, that I-131 was in a class by itself.

However, the American College of Nuclear Medicine (ACNM) then filed its own petition, in which it asserted that I-131 treatments up to 400 millicuries could safely be given on an outpatient basis. Dr. Marcus then amended her petition to omit the exemption for I-131, but in a subsequent letter to the NRC, she jeered at the ACNM for its "ludicrous" idea that patients could safely be released with 400 millicuries of I-131 in their systems.[7] Ludicrous or not, patients today are sometimes being sent home after receiving doses of that magnitude, and some of them are parents with small children at home. Nowhere else in the world but in this country would this be possible.

I am well aware of Dr. Perry Grigsby and his study, published in 2000, of exposures to the family members of I-131 patients. But that study involved just 30 patients, who were, according to a contemporary press release issued by Washington University's School of Medicine, "told to minimize time spent with household members and to stay far

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[6]Incidentally, NCRP 37 makes clear that exposure limits are to be based on a per year, rather than a per treatment, basis.

[7]In a letter to NRC Secretary Samuel Chilk, dated November 9, 1992, and docketed on November 17, 1992, she wrote: "The concept of sending patients home with 400 mCi of NaI-131 was ludicrous. Although I could theoretically concoct a situation where it could possibly be justified, there are not too many patients who would qualify as hermits in isolated areas."

away from them for two days," as well as to "take several showers a day." Surely that is not representative of the advice given to the thousands of Americans treated with I-131 ever year.

Jim Luehman of the NRC staff was present at a meeting in Danvers, Massachusetts, in October 2009, where a young woman, sent home after a dose of 125 millicuries of I-131, made the point that when you have two children, six months and three years old, it is not that easy to keep them at a distance. For that mother, it was not an option to "stay far away from them for two days," and there are far too many other patients in her position.

In sum, the authors of NCRP 37 would surely be appalled to see how the NRC, in concert with the licensee community, has dismantled the radiation protection system described in that report, with the result that the United States has become an outlier in the world radiation protection community. I am sure they would be asking how the Advisory Committee on the Medical Uses of Isotopes could have allowed this to happen.

We are all accountable for our actions, sooner or later, whether we view that accountability as being before God, history, our children's opinions of us when we are gone, or the face that confronts us in the mirror in the morning. At the October 2008 ACMUI meeting, you made your own philosophy of life crystal clear when you talked about the patients who had been harmed by medical errors at the Veterans Administration hospital in Philadelphia:

> [I]f it hadn't come before the NRC, it wouldn't have been an issue to the NRC, but having been brought to the NRC, can we turn our backs on this for fear of additional paperwork, which we all are generally opposed to, and abandon that patient? That's the moral question. It's a moral question that is raised. We're not a moral group, we're a legal group, but we're still moral human beings. What do we do about that patient, having been brought to our attention? (Transcript at 125-26.)[8]

In 1992, you had no way to foresee that the NRC Chairman and Commissioners, desperately eager to appease the most strident and irresponsible elements in the licensee community, would go quite so far in abandoning established radiation standards, both domestic and international. Nor could you have foreseen that insurance companies

[8]As you no doubt remember, one of your ACMUI colleagues objected at that point that for you to worry about the individual patients, instead of focusing on the benefits of the technology used in their treatment, was to get "way down in the weeds."

would take advantage of the rule change in the way they have, thereby usurping the physician's role in making medical decisions. Neither you nor anyone else could have imagined, in 1992, that it would be left to individual state and city health departments to warn doctors not to send highly radioactive patients to hotels, because the NRC had chosen to look the other way and say nothing.

But today, in 2010, it is a different story. You now know what is happening. Already in October 2007, you knew that doctors had been deprived of the capacity to do right by their patients. You said so at the time, in forceful and pungent words that will continue to be central to this debate for many years to come, and will doubtless be quoted when the history of this remarkable chapter in regulatory misfeasance is written. You surely also know, as well as anyone, that people are being exposed to radiation from released patients in levels that cannot be squared with responsible radiation protection. What is at issue here is thus the first and most important tenet of the Hippocratic Oath, to "do no harm."

To quote your own words, "It's a moral question that is raised." I urge you to use your authority as Chairman of the Advisory Committee on the Medical Uses of Isotopes to explain to the Chairman and Commissioners that the current situation is not tenable and urgently needs to be corrected.

Sincerely,

Peter Crane
Counsel for Special Projects, USNRC (retired)

cc: ACMUI Members
NRC Chairman and Commissioners
Rep. Ed Markey

Attachments:
Selections from NCRP 37
Letter of April 24, 1992, from Leon S. Malmud, M.D., and Robert J. Lull, M.D.
Letter of September 26, 1983, from J. A. Spahn, NCRP