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ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States

House of Representatives

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October 20, 2010

The Honorable Greg Jaczko
Chairman
Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

Dear Chairman Jaczko:

I am writing to inform you of several findings the Subcommittee on Energy and Environment staff have made in the investigation the Subcommittee has undertaken into the manner in which NRC has regulated and overseen the release of patients treated with radioactive materials from hospitals. Since the Nuclear Regulatory Commission (NRC) plans to hold two meetings related to the use of medical isotopes and other medical issues that are within the Commission's jurisdiction[1] today and tomorrow, I also ask for your prompt response and commitment to address these findings.

The Subcommittee's investigation, which drew from a survey of more than 1,000 thyroid cancer survivors' experiences, indicates that there is a strong likelihood that members of the public have been unwittingly exposed to radiation from patients who are discharged after being treated with radioisotopes, and that this has occurred because of weak NRC regulations, ineffective oversight of those who administer these medical treatments, and the absence of clear guidance to patients and to physicians that provide procedures to ensure that such exposures do not occur.

As you know, in 1997, the Nuclear Regulatory Commission (NRC), in response to a proposal initiated by its own staff, weakened its rules surrounding the release of patients treated with radioactive iodine. The rules were changed from the prior practice -- still followed in Europe and other countries --which requires the hospitalization of patients emitting high levels of radiation in order to protect children and other members of the public from being irradiated, to one that allows most treatments to be performed on a less expensive outpatient basis.

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[1] http://www.nrc.gov/reading-rm/doc-collections/commission/agenda/2010/agenda-20101020.pdf

NRC's weaker, current regulations depend on the ability of medical professionals to assess the living conditions of patients and use the results of this assessment to calculate the likely radiation dose to those people the patient might come into contact with. It is unclear whether such a calculation could be accurately performed for a patient choosing to recover from treatment with radioactive iodine in a hotel, since it would be impossible to characterize every hotel's layout, or know whether hotel occupants or employees included the most vulnerable populations such as pregnant women or children. Additionally, despite a commitment made by NRC in 2008 to develop guidance specifically for patients being released to recover in hotels[2] , the NRC has yet to do so. Furthermore, the NRC actually twice voted to reject proposals[3] that would have required reports of dangerous radiation doses delivered to members of the public, through exposure to released patients, to be submitted to the NRC –an active choice by the Commission to ignore the problem of unwitting and inappropriate public exposures.

On March 18, 2010 the Energy and Environment Subcommittee released a staff report[4] that discussed in detail issues related to the immediate release of patients treated with radioiodine, including the lack of enforceable regulations to ban or otherwise limit the release of treated patients from recovering in hotels. This staff report was forwarded to the NRC for review, and the NRC Inspector General is currently investigating conflicting statements made by the NRC Office of General Counsel, including a statement made in a court of law regarding NRC's policy of releasing treated patients to recover in hotels.

Since the staff report was issued, the Subcommittee on Energy and Environment has taken subsequent actions to further investigate this subject. The first was a series of letters[5] sent to all 37 NRC Agreement States to gather information about the licensees' discharge practices, and the second was a survey of more than 1,000 thyroid cancer patients. The responses from the 34 Agreement States that responded[6] indicate that:

- All but one State default to NRC regulations, with Florida being the only State that retained the more stringent pre-1997 release criteria for a large portion of its licensees (58 out of 308 Florida licensees amended their licenses to release patients under NRC's current dose based criteria (10 CFR 37.75)).
- Four Agreement States (Minnesota, Florida, Massachusetts and Washington) indicated that they have provided explicit guidance recommending against discharging patients to hotels, but only Florida attempts to ascertain whether or not licensees are following this guidance.
- One Agreement State (New Jersey) reported issues with discharged patients taking public transportation and subsequently setting off radiation alarms in

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[2] NRC June 12, 2008 Memorandum to Region 1. See U.S. NRC letter to Congressman Edward Markey, March 5,2010; Attachment 5

[3] http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment1.pdf and http://www.nrc.gov/reading-rm/doc-collections/commission/cvr/2002/2002-0111vtr.pdf

[4] http://markey.house.gov/docs/STAFF_REPORT_031810_FINAL_with_crest.pdf

[5] An example of the letter sent to the Agreement States: http://markey.house.gov/docs/lettertostate.pdf

[6] New Hampshire, Alabama and Arkansas failed to respond to the Subcommittee's letter despite numerous requests that they do so.

tunnels and bridges, and three Agreement States (Florida, New Mexico, and Illinois) indicated that they provide explicit State guidance instructing licensees to inform patients that public transportation should be avoided in the days immediately following treatment. All other States indicate that they refer their licensees to guidance NRC developed in 2008[7] which says that licensees *may* include a recommendation for patients to avoid the use of public transportation, but does not make this mandatory.

- Two states (Maryland and Massachusetts) acknowledged one of the compounding problems of outpatient treatment with I-131 is the contamination of household waste that is being picked up and transferred to waste management facilities such as landfills. The vehicles hauling this waste often set off radiation alarms requiring the dismantling of the trash load and the examining and sampling of the contents-- exposing sanitation workers and investigators to biological as well as radiological hazards.
- All States with the exception of Illinois were unaware of any releases of patients to hotels. In Illinois, a patient was released to a hotel in 2007 and contaminated the bed, linens and other items in both her room and throughout the hotel - but this was only discovered because two nuclear power plant workers who were equipped with radiation monitors subsequently stayed in the same hotel and set off alarms when reporting to work[8].
- There have been several cases in the last 10 years in Arizona, California, Illinois, Maryland, New Jersey, New Mexico, Ohio and Pennsylvania in which State inspections have revealed that licensees were not performing the required individualized dose calculation to ensure that they would not contaminate those they came into proximity to with radiation, but the destination of these patients after release from the hospital was never recorded.

The Subcommittee on Energy and Environment staff also developed an online survey (Attachment 1) which was taken by 1,080 thyroid cancer survivors, 781 of whom were treated as outpatients after 1997, in order to better understand how these patients have been educated and cared for by the doctors and facilities where their treatment has occurred. The staff's analysis of this survey indicates that:

Most I-131 treatments are now performed on an outpatient basis, and insurance providers deny inpatient stays to some who request it

- Only 27.0% (292) of survey responders indicated that they were treated with I-131 as inpatients and therefore were allowed to stay overnight in a hospital or other medical facility. Insurance companies denied requests for inpatient stays associated with 10.4% of the treatments received after 1997.
- In only 6.8% of treatments with I-131 were patients given a choice as to whether their treatment should occur on an inpatient or outpatient basis.
- Although most treatments with radioactive iodine occurred on an outpatient basis, only 10.7% (102) of these treatments involved quantities of I-131 below 33

[7] Appendix U of NUREG 1556 Vol. 9 Rev. 2 http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/sr1556v9r2-final-appendices-i-w.pdf
[8] http://markey.house.gov/index.php?option=com_content&task=view&id=4109&Itemid=25

millicuries, meaning that before the NRC changed its regulations in 1997, the vast majority of these treatments would have occurred on an in-patient basis.

Some patients choose to recover in hotels or other similar facilities, usually after informing their physicians they plan to do so. Patients acknowledge that they shared bathrooms or bedrooms with pregnant women or children, or that they may have exposed these vulnerable populations through their use of taxis or public transportation upon discharge.

- 52 patients (6.7 % of outpatients) who received 67 treatments with I-131 on an outpatient basis since 1997 in 28 States (5 NRC States and 23 Agreement States) left the hospital to go directly to a hotel, motel, inn or similar facility.
- While 65.0% of all outpatient releases were reported to have occurred after informing the physician about where the patient would be housed during recovery, an even higher percentage – 74.6% - of treatments involving recovery in a hotel, motel, inn, or similar facility occurred with the physician's knowledge.
- 56 treatments that occurred on an outpatient basis after 1997 involved a patient who shared a bathroom or bedroom with a pregnant woman or child, or otherwise came into close contact with members of this vulnerable segment of the population. Another 16 treatments involved patients who were unaware or can't remember whether they came into close contact with a pregnant woman or child. 10 treatments involved patients who took public transportation like a crowded train or bus to get to their place of recovery, while 496 treatments (51.9%) involved patients who indicated that they either took a taxi or were driven by someone who picked them up from the hospital and brought them to their final destination.

Many patients say they were not informed about the dangers of exposing vulnerable populations to radiation.

- For 26.4% of treatments that occurred on an outpatient basis, patients reported that medical providers never discussed procedures by which patients could ensure that they would not expose pregnant women and children to dangerous radiation that they were emitting after treatment.
- For 19.5% of treatments that occurred on an outpatient basis, patients reported that they were never provided with written procedures to follow to ensure they didn't expose pregnant women and children to dangerous radiation.
- For 10.6 % of treatments, patients reported that they were neither verbally informed nor did they receive written instructions about the dangers of exposing pregnant women and children to radiation, or the procedures to follow to ensure that pregnant women and children were not exposed to dangerous radiation.

As you know, NRC previously[9] provided me with only two known examples of licensees who released a total of four patients to hotels in Virginia and Washington, DC. The Subcommittee staff's analysis shows there are many more examples that are not

[9] http://markey.house.gov/docs/NRC_Ltr_to_Markey_030510_attachments.pdf

being identified by NRC or State inspections, even though doctors frequently know about their patients' post-treatment recovery choices. Moreover, although it is possible that neither the NRC nor the Agreement States were aware of the extent to which patients were recovering from their treatments in hotels, taking taxis or public transportation or otherwise exposing vulnerable populations to radiation (despite the fact that this concern has been repeatedly brought to the NRC's attention[10]), this is not because such exposures were not occurring. Rather, the Subcommittee's investigation demonstrates that this is likely because NRC has failed to address these practices through the provision of clear guidance to Agreement States or to licensees. As a result, physicians fail to properly instruct patients, and these patients are then left with the impossible choice of exposing their family members or exposing strangers since inpatient stays are simply no longer viable options for most.

In previous correspondence[11], you stated your belief that NRC's regulations adequately protect the public provided that "adequate instructions are given at discharge to patients and family members." It is difficult to conclude based on the survey results that this belief is justified.

I am also concerned that the NRC has compounded this problem by voting in 2000 and again in 2002 [12] not to even be informed when its licensees learn that a member of the public has received or is estimated to have received a dose exceeding 5 rem – a dose that is 10 times as high as NRC's own safe dose limits for released patients - from a patient who has been discharged from treatment with radioisotopes. This decision to not require reporting of such exposures is, in my view, inconsistent with the NRC's responsibility to protect public health and safety.

Given the Commission's plan to host meetings today and tomorrow to discuss the medical policy issues associated with NRC's regulations, I call on you and the entire Commission to take all necessary steps to appropriately revise and modernize the patient release criteria to ensure the protection of public health. I provide to you the following recommendations for immediate consideration and discussion at today's meeting.

1) The NRC should immediately commence a rulemaking to revise its 1997 regulations surrounding the treatment of patients with radionuclides, and ensure that these regulations are made to be consistent with and as protective of the most vulnerable populations as policies that are in place in other developed countries. Hospitalization should be mandatory for those patients who are treated with doses of I-131 above internationally accepted threshold limits.

2) The new regulations should ensure that patients who are released from the hospital after treatment are prohibited from recovering from such treatments in

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[10] See for example Docket ID: NRC-2005-0020 Comment (11) submitted by Peter G. Crane on Petition for Rulemaking PRM-35-18, Regarding Partial Revocation of the Patient Release Criteria Rule

[11] http://markey.house.gov/docs/nrcltomarkeyisotopes.pdf

[12] http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment1.pdf and http://www.nrc.gov/reading-rm/doc-collections/commission/cvr/2002/2002-0111vtr.pdf

hotels or taking taxis or public transportation in the days that immediately follow treatment, and that specific written and verbal guidance prohibiting such activities is provided both to medical licensees and to patients. Enforcement actions should be taken against medical licensees who fail to provide such guidance to patients, or otherwise fail to advise a patient planning to violate the prohibitions that the regulations do not permit such activities. In cases where the patients cannot identify a suitable outpatient facility in which to recover, NRC regulations should mandate in-patient stays.

3) The NRC should aggressively enhance its oversight of both its medical licensees and the Agreement States to better identify, track and respond to potential regulatory violations. NRC should pay particular attention to whether New Hampshire, Arkansas and Alabama are capable of implementing NRC regulations in this area, in light of these states' failure to respond to requests for information.

4) NRC should immediately implement a reporting requirement for incidents that could have resulted in unintended radiation exposures from patients treated with radioactive isotopes, and ensure that data related to reports of such incidents are promptly made public in a centralized location such as the NRC website.

Please provide me with the Commission's view on each of the above recommendations as well as the Commission's plan and timeline for evaluating, discussing and implementing each of the above recommendations. I request that you provide me with your response no later than Friday November 5, 2010. Thank you very much for your prompt attention to this important matter. If you have any questions or concerns please have your staff contact Dr. Avenel Joseph of my staff of Dr. Michal Freedhoff of the Energy and Environment Subcommittee Staff at 202-225-2836.

Sincerely,

Edward J. Markey
Chairman
Energy and Environment Subcommittee

Cc: Honorable Henry Waxman, Chairman,
Committee on Energy and Commerce
Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce
Honorable Fred Upton, Ranking Member
Energy and Environment Subcommittee