STATEMENT OF PETER CRANE
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before the
Advisory Committee on the Medical Uses of Isotopes
Meeting of May 8-9, 2014

My name is Peter Crane, and I appreciate the opportunity to submit a statement to this May 2014 meeting of the Advisory Committee on the Medical Uses of Isotopes. I am a retired NRC lawyer who spent 23 years with the agency, and my interest in the regulation of medical isotopes is both professional and personal. As a survivor of thyroid cancer, treated successfully for a recurrence with radioactive iodine 131, I probably have as great an appreciation as anyone here for the vital and life-saving role of these isotopes in diagnosing and curing cancer. Where I have sometimes differed with members of this Committee is on the appropriate precautions to be taken when I-131 is used, so that in treating the cancer patients of today, we do not unintentionally create the patients of tomorrow.

This meeting takes place against the backdrop of the excellent Staff Requirements Memorandum issued by the Commissioners on April 28 – the most positive step that the Commission has taken in this area since a previous Commission, quite possibly without realizing it, radically deregulated nuclear medicine treatments in 1997. Working within the framework of the existing patient release rule, the new SRM does a great deal both to address well-understood current problems and to obtain the information that might support further reforms. If it doesn't do 100 percent of what I would like to see, particularly with respect to radioactive patients in hotels, it nevertheless represents enormous progress, for which the Commission deserves great credit.

Laura Weil, the Patients' Rights Advocate on this Committee, has done a fine job of studying and documenting the inadequate and inconsistent safety guidance that released I-131 patients commonly receive. Clearly that message has got through. We have also had two Commissioners go to the horse's mouth, meeting with small groups of patients to learn first-hand about their experiences. The Commission has now acted to remedy the deficiencies in this area through the development of standardized guidelines for licensees to use in instructing patients about safety measures, and a form to make sure that patients receive and understand those instructions. It has also directed the staff to create a website where patients can get clear and consistent information.

Dr. Zanzonico of this Committee will confirm, I am sure, that over the past few years, I have repeatedly praised the model guidelines for I-131 patients that he wrote and that appear in NCRP Report No. 155, published in 2006.[1] Dr. Zanzonico is one of five co-authors of that excellent report, which belongs in the office of every Commissioner. His instructions are detailed and crystal clear, and I hope they serve as a starting point as the new model guidelines are prepared in response to the SRM.

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[1]National Council on Radiation Protection, Report No. 155, *Management of Radionuclide Therapy Patients* (2006). The guidelines appear at pages 166-168. That report incorporated and updated an earlier NCRP report, No. 37, issued in 1970, which created the analytic framework for outpatient treatments above the 30-millicurie limit, while making clear that this was to be a rare exception, with a maximum I-131 dose of 80 millicuries, mandatory notification of local health departments, and yellow wristbands with the trefoil symbol to mark such patients as radiation hazards.

Going back to those instructions and that report in the last few days, I find a great deal to recommend, including the following five points:

1. An instruction that in the first day after treatment, the bed linens of the I-131 patient should be laundered separately and put through the rinse cycle twice. Quite obviously, that precludes sending radioactive I-131 patients to hotels, where their bed linens will be washed along with everyone else's. (p. 167)

2. An instruction that patients should flush the toilet twice after using it, should "rins[e] the shower stall, tub, or sink thoroughly after use," and should "wipe up any spills of urine, saliva and/or mucus" with tissues or disposable toweling and flush them down the toilet. *Id.* That makes perfect sense, but it also makes it all the more inexplicable that when the ACMUI subcommittee estimated radiation doses to hotel housekeepers who clean contaminated rooms, no consideration was given to the doses received while cleaning sinks and toilets. The entire bathroom was off limits. The obvious contradiction there needs to be addressed.

3. The report confirms that the release limits are on an annual, not a per-release basis. It says, at p. 145: "the foregoing limits are annual totals and, therefore, do not apply to individual treatments but collectively to all treatments a patient may receive in a given year." Quite right, and it's time we heard the last of the notion that NRC standards, unlike all national and international radiation standards, are on a per-release basis.

4. The maximum allowable radiation dose to members of the public – defined as "persons who have no familial connections to the patient and for whom there is no emotional benefit" – is one millisievert, or 100 millirems, per year. (At p. 19.) Given that the NRC rule says that anyone, regardless of age, sex, and pregnancy or nursing status, can receive **five times** that amount, I take this to mean that the authors of the report want the rule to be revised, presumably in favor of the kind of split standard we see in Part 20, with a 500 millirem limit for some persons and 100 millirems for others. I couldn't agree more. That definition also makes clear that both the hotel housekeeper and the hotel guest staying in the room adjoining the patient's are members of the public, subject to the 100 millirem per year standard.

5. Through-the-wall exposures are problematic and must be taken into account. Here's what the report says on that, in the hospital context: "Other patients confined in the medical facility may be unintentionally exposed to patients receiving radionuclide therapy. The usual source of this exposure is occupancy of a room immediately adjacent to a patient receiving therapy." (At p. 19.) If this is true in the hospital, it plainly applies also to persons staying in hotels or multi-family dwellings.

So I want to commend Dr. Zanzonico and his co-authors for a very sensible and clear-sighted approach to these issues, and I hope that the rest of this Committee agrees on all five points. All of this goes to show, incidentally, just how very mainstream my own views are.

Finally, I would like to return to a concern that Jim Luehman of the NRC staff raised as long ago as 2010: cumulative radiation doses to hotel workers who work in hotels that receive many I-131 patients from nearby cancer centers, and who may therefore clean a number of contaminated rooms in the course of a year. The ACMUI subcommittee did not address that issue, however, and though the question has repeatedly been put to Dr. Zanzonico, as the Committee's foremost expert on these matters – most recently by Commissioner Magwood, at the thyroid patients' conference in Philadelphia last fall – I have yet to hear a responsive answer. I would urge Dr. Zanzonico to give us the benefit of his expertise and judgment on this point. If the answer is that this is a non-problem, tell us why. If, on the other hand (and I hope this is not the case), the answer is that the repeated exposure of chambermaids to I-131 contamination, even without their knowledge, is an acceptable price to pay for keeping down the cost of health care, then say so, and at least we will have a basis for discussing the issue openly.

I myself can see no medical, legal, or moral justification for exposing a hotel housekeeper, possibly pregnant or nursing, to radiation in the workplace with neither her informed consent nor appropriate training and gear. My views are informed by the fact that my daughter once had a job making beds and cleaning bathrooms in a Seattle hostel. I know how I would have felt if I had learned that with only a pair of rubber gloves to protect her, she had unwittingly cleaned a room and bathroom contaminated with high levels of I-131. I cannot believe that anyone here would feel at all differently if it were their own daughter or granddaughter. Sooner or later, this grave wrong will surely be righted, and when that happens, I hope it will be with the support and assistance of this Committee.

Thank you.

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