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(4)

December 26, 2005

Annette Vietti-Cook, Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Re: Response to Docket No. PRM-35-18, Peter G. Crane; Petition for Rulemaking

Dear Ms. Vietti-Cook:

As the author of the petition that ultimately led to the "500 mrem Patient Discharge Rule" (10 CFR 35.75), which is under attack by Mr. Crane, I wish to make a number of comments pertaining to Mr. Crane's allegations, level of understanding of medical science, and level of scientific knowledge of radiation and its effects.

My first comment has to do with the fact that the NRC has determined that Mr. Crane's petition meets the threshold sufficiency requirements for a petition for rulemaking under 10CFR 2.802. That is truly ludicrous. Mr. Crane's allegations are largely false and in a few cases, merely completely distorted. He is terrified of radiation, especially I-131, and has no appreciation of low dose effects (and lack thereof) below 500 mrem (and higher). A perusal of my letters and my petition and its addenda and ACMUI minutes, plus questioning involved staff, should have convinced a competent NRC that Mr. Crane's petition is invalid and should never have been docketed. Unfortunately, the NRC appears not to have bothered to do this, putting an unpaid burden on the public rather than a paid burden upon itself. This is shameful.

On the issue of the staff attitude regarding the Medical Program, Mr. Crane could not possibly be more in error. While a few people on the NRC staff have had a scientifically rational and reasonable attitude about the use of byproduct material for nuclear medicine, they were all fired or pushed out into other areas long ago. Those who remain, a number of whom were around when my petition for the 500 mrem Patient Discharge Rule was submitted, are at best ignorant, and at worst enemies of the scientifically rational use of byproduct material in nuclear medicine. That is why my petition took six years of war to resolve. Various members of the Medical Section staff, aided by members of the Office of General Counsel (OGC), fought it tooth and nail.

I have written two petitions to the NRC, one in 1989 that resulted in the "Radiopharmacy Rule" and one on the "500 mrem Patient Discharge Rule" written on Christmas Eve, 1990, which NRC received very early in January, 1991. The first petition was ardently requested by Richard Cunningham, who assigned Norman McElroy (the head of the

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Medical Section) to help me write it. There was no question of staff assistance here. It was freely acknowledged. The staff assistance was in encouraging me to start the petition at a far simpler level than I had conceived, due to profound NRC ignorance of medical and radiopharmaceutical everything. The other area of assistance was in crafting the regulatory language that would satisfy the changes I thought were needed. Mr. Cunningham had insisted that the petition contain recommended regulatory language, which is usually an NRC staff function. All medical and scientific material in the petition was mine. The NRC had made an unwise regulation in 1987 that was a threat to patient health, and this embarrassment needed to be fixed. Staff under McElroy and in the OGC nevertheless fought my petition furiously, which is why it took five years to resolve. My second petition was written at the urging of Hal Peterson, who had nothing to do with the Medical Section (as I recall, he was in the Chairman's office), and who provided not one shred of assistance. My second petition came about because NRC had approved the new Part 20, with a foolish requirement to obey all EPA regulations, which would have imposed the Radionuclide NESHAPS on the nuclear power industry, as well as other materials licensees. I pointed out this folly, but the rule had been approved by the Commission, and it was too late to change it (we thought). This was why Hal wanted the petition "yesterday". The medical consequences of the new Part 20 due to the change in doses permitted to the general public were not really Hal's concern. I never spoke with Hal about the petition again, and as I recall, he left some months later to take a position at the EPA. In fact, the Chairman's office simply changed the EPA part of Part 20 after the fact, no petition required, which was interesting. As to the medical part, I was on my own. As to the staff in the Medical Section, it was as though my petition had never been written. I was told that the EDO had told them to bury it under the bottom of their pile. It never came up for air until E. Gail De Planque, Ph.D. became a Commissioner, and removed it from whomever had it and directed Don Cool to get working on it. Not only did I not get any assistance from the Medical Section, but I had to assist *them*, because none of them understood how to do the math and pathophysiology (ask Don Cool about this).

Mr. Crane is correct in that my original petition did not include therapeutic I-131, but he does not understand the reason. The "30 mCi Rule" goes back to Atomic Energy Commission (AEC) days, and they had some good scientific talent. I naively assumed that the AEC had a scientifically valid reason for that regulation. Later, as I played with the numbers, I realized that the 30 mCi Rule was scientific garbage, and I tried, without success, to find out where it came from. I couldn't find its origin, and Don told me he had no idea where it came from, either. I then extended my petition to include I-131. Members of the NRC may be interested in reading Siegel JA: Tracking the origin of the NRC 30 mCi Rule. J Nucl Med 41:10N-16N, 2000.

Mr. Crane's allegation that I was a shill for the NRC staff, and an indiscrete one at that, is an insulting and vicious lie. Mr. Crane produced not one shred of evidence to support his claim, and none of course exists in any case. How could the NRC accept a baseless allegation like this for publication and comment? The idea that staff cooked up the idea for the petition, and got me to sign my name to their work, is preposterous. Other than

the fact that none of them was even capable of doing this, there is the record of the six year war against the staff to get it approved. A rational person, looking at the facts, would conclude that the staff was fighting all the way, not colluding with me. Indeed, the first thing the OGC did was to try to discard my petition. Some of you may recall that the new Part 20 originally used the same numbers for the regulations that the old Part 20 used. Due to the fact that the new Part 20 would go into effect in NRC states and among NRC licensees very quickly, but that Agreement State licensees would have up to three years before compliance was required, the OMB pointed out that having two different regulations in simultaneous use in the United States that had the same number would be very confusing, and forced NRC to change the numbering system in the new Part 20. This OMB directive came about *after* my petition was submitted. The number changes took the NRC about five months to complete. OGC then "reasoned" that as my petition referred to numbers that were no longer in use for the new Part 20, that my petition was invalid and would be discarded. Mike Lesar called to tell me this. I told Mike to tell the OGC that if they really tried to pull that stunt I would go directly to the Commissioners. I was on the ACMUI from 1990-1994, and I knew them all. Apparently OGC was sufficiently intimidated that it backed down. I don't know which lawyers were involved in this nasty little episode, but perhaps Mike Lesar remembers. If he doesn't, perhaps Marge Rothschild would know. This hardly smacks of collusion with the NRC.

The six year staff war not only concerned the rule, but the Regulatory Guide (8.39) that accompanied it. The Regulatory Guide was mathematical, physical, and pathophysiological trash. I tried to get changes, and under Chairman Selin met with some success, but after he left, the quality of the document became unacceptably poor. The change sleazed into NUREG 1556 Vol. 9 with the recent redo of Part 35 turned it into even more fraudulent NRC junk. It is astounding not only that someone could write this and not be fired, but that the whole food chain of management who is responsible for approving the guidance was too lazy and/or incompetent to fix it. This, in Peter Crane's mind, constitutes collusion between me and the staff? This is completely irrational.

The above comments cover Mr. Crane's "legal" points. Now I will comment upon his claim that the 500 mrem Patient Discharge Rule is against NRC policy.

It is the policy of the NRC to keep radiation absorbed doses to the general public from licensed activities at a very low level. For many years, this level was a maximum of 500 mrem/year. In 1991, the new Part 20 lowered this limit fivefold, not based on documented hazard, but based on the fact that it was achievable. Due to the fact that some valuable activities might find achievability difficult, NRC included 10 CFR 20.1301(c). This permits a licensee to retain the prior dose limit of 500 mrem in certain circumstances, after describing such and obtaining NRC permission. My petition was based upon this regulation and the need to end the 30 mCi Rule.

Mr. Crane presents anecdotal information strongly suggesting grave hazards to family members and members of the general public from the 500 mrem Patient Discharge Rule. However, he presents no data, no measurements, no dose calculations, no examples of

actual adverse effects, and no data showing why adverse effects would probably occur in the future. This is classical anti-nuke nonsense. One would expect the NRC to disallow a petition with nothing but innuendo and wild claims of harm. The situations described by Mr. Crane, and numerous other situations, were all considered during the rulemaking. They were considered by the petitioner, the ACMUI, the Chairman of the ACMUI, Barry Siegel, the regulated community, the NRC staff and management, and an NRC contractor, S. Cohen & Associates (Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material, NUREG-1492, Draft Report published May, 1994). Dr. Siegel and the ACMUI favored the 500 mrem Patient Discharge Rule and the rescinding of the 30 mCi Rule. *They did not oppose the 500 mrem Patient Discharge Rule, as claimed by Mr. Crane in his petition.* (There was a "patient advocate" planted on the ACMUI by the NRC staff in order to oppose the opinion of the medical, radiopharmaceutical, and medical physics experts. She had zero expertise in medicine, radiopharmaceuticals, radiation, physics, and math. She was an irrational "anti-nuke". Her opinion was emotional and uninformed in general. While she said some things in opposition to the 500 mrem Patient Discharge Rule, I do not recall how she voted. She never, however, had any influence on the Committee. Her existence on the Advisory Committee was another example of how the NRC staff opposed the medical community's efforts, and this situation was certainly the opposite of complicity.) All parties except for some NRC staff (but not the management) supported the safety of the 500 mrem Patient Discharge Rule. Mr. Crane quotes some "veteran professor of health physics" but did that professor submit scientifically rational comments to the NRC? I don't recall reading any, and I read every comment letter. While a few state radiation regulators opposed the 500 mrem Patient Discharge Rule, others supported it. What really counts is the science. Many of those who opposed the rule really did so because the 30 mCi Rule was easy---one didn't have to think---but the 500 mrem Rule meant pharmacokinetic models and calculations which many state radiation regulators and health physicists didn't know how to do (and still don't). This reflects badly on the quality of some people who go into health physics and state radiation programs, but in no way detracts from the scientific quality and safety of the 500 mrem Patient Discharge Rule itself.

Mr. Crane misrepresents the 500 mrem Patient Discharge Rule, giving the clear impression that sick patients with decreased mentation are unceremoniously thrown out of hospitals or clinics and left to fend for themselves. In fact, 35.75 requires the licensee to make the determination that no other person is likely to receive greater than 500 mrem from the released patient. This requires measurements or calculations, and also requires knowledge of the patient's plans and living and working arrangements. Radiation safety instructions, while they may be verbal, also must be written, so that a forgetful patient, or members of the patient's household, may review them. **Many patients are *not* released,** because of licensee doubts as to compliance, the inability of patients to understand instructions in the first place, or the patient's living conditions. Many patients are treated with antiemetics prior to dosing as a matter of course, and given pills to take at home to avoid any vomiting. Many patients are given instructions on how to clean up any spills of contaminated body fluids, and even pairs of latex gloves if they don't have any and are poor. Some patients are being treated with recombinant human thyroid stimulating

hormone before treatment, and aren't even hypothyroid. There are many considerations in assessing the ability of patients to comply with instructions, and many actions and instructions that will aid in compliance with the dose limit. Traveling home by bus or airplane is not an absolute contraindication to being released, but the licensee needs to know when the transportation will begin and how long the patient will be close to others, so that appropriate dose calculations may be performed.

In my experience, vomiting by patients, if it happens at all (and it is much reduced with compazine pretreatment), occurs hours after oral administration, well after the initial dose has been completely absorbed. Some radioiodine is concentrated from the blood into gastric juice; if this is vomited the vomitus is certainly radioactive, but does not represent a significant portion of the initial dose. I have had occasion to estimate the radioactivity of vomitus twice in my career and have confirmed that the activity present was not a significant fraction of the administered activity. I don't have the actual data any more, but in neither case was it significant enough to merit extra dosing, as expected. The case mentioned by Mr. Crane might be true, but the licensee may have calculated the absorbed dose to others from the public transportation and decided it was acceptable, instructed the wife and/or husband on how to clean up a spill and what to do with it, and given the wife antiemetic pills which were not taken. We do not know any of these details. If in fact the patient was dosed and sent home with no questions about transportation, no prophylactic antiemetics, and no oral and written instructions were given, then the problem is that the licensee was not in compliance with the regulations. The problem is the licensee. *The problem is not the regulations themselves.*

It is also important to realize that even if a patient is not released after a therapy dose, nothing can stop the patient from leaving the hospital against medical advice. The patient may agree to stay in the hospital, and then change his mind at any time. The licensee may try to change the patient's mind, but if it fails to do so, there is no legal recourse. He leaves. The police will do nothing about it. The patient is not an *actual* hazard to anyone. When police are being told that incurring a radiation absorbed dose of 50,000 or 75,000 mrem in order to save a life during an emergency response situation is acceptable, as they are being told now, how does the NRC expect them to get upset about a radiation dose equal to background radiation levels in Colorado? This is especially absurd as Colorado has the third *lowest* cancer death rate in the United States!

Mr. Crane would have us believe that the reason NRC granted this petition was to decrease radiation absorbed dose to clergy visiting the sick in hospitals. I never heard that argument. The reasons we always discussed had to do with superior patient comfort, less disruption in the patient's life, occasionally better care of the patient by household caregivers than the patient would receive in the hospital, huge decreases in cost to the patient or his third party payer, and the fact that these benefits would accrue with perfectly adequate radiation safety provisions. The adequacy of the radiation safety provisions was shown in part in a study published in 2000 in which family members and pets in households with patients released after thyroid cancer I-131 therapy were monitored. I-131 absorbed doses to household members were well below the 500 mrem

limit mandated by 10 CFR 35.75. (Grigsby, Perry W, Siegel, Barry A., Baker, Susan, and Eichling, John O.: Radiation exposure from outpatient radioactive iodine (I-131) therapy for thyroid carcinoma. Jour. American Medical Assn. 283:2272-2274, 2000.)

It certainly appears that after six years of consideration, with careful study and comment analysis, that the NRC unquestionably upheld its radiation safety policy in the crafting of the 500 mrem Patient Discharge Rule (10 CFR 35.75).

I therefore conclude that Peter Crane's petition completely lacks merit, his main points consisting merely of lies, distortions, and antinuclear hysteria. His "legal" aspect is completely flawed and his insistence that NRC has gone against its policy is not only not documented, but as I have shown, completely in error.

I do not believe that Mr. Crane's petition should have been judged to meet the sufficiency requirements of an acceptable NRC petition.

Thank you for your attention and consideration.

Sincerely,

Carol S. Marcus, Ph.D., M.D.

Prof. of Radiation Oncology and of Radiological Sciences, UCLA
President, American College of Nuclear Physicians, California Chapter
President, Carol S. Marcus, Ph.D., M.D., a Consulting Company

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From: Carol Marcus <csmarcus@ucla.edu>
To: <SECY@nrc.gov>
Date: Tue, Dec 27, 2005 10:47 PM
Subject: Response to Docket No. PRM-35-18, Peter Crane Petition

Dec. 27, 2005

Dear All:

Attached is my response to an outrageous petition submitted by Peter Crane to exterminate the "500 mrem Patient Discharge Rule" (10 CFR 35-75). Peter is a retired lawyer who used to work at NRC. His petition is announced in the Federal Register of Dec. 21, 2005, vol. 70, No. 244, pp.75752-3. Electronic copies of the petition are available from Mike Lesar at <mtl@nrc.gov>.

Happy New Year to all.

Ciao, Carol

CC: <njd@nrc.gov>, <jmer@nrc.gov>, <exm@nrc.gov>, <PBL@NRC.GOV>, <GBJ@NRC.GOV>, <ratcher@aol.com>, <Tbeven1957@aol.com>, <CLARKEM@MIR.WUSTL.EDU>, <roywbrown@sbcglobal.net>, <Mathew.Thakur@jefferson.edu>, <jlinks@jhsph.edu>, <Volkertw@health.missouri.edu>, <hcannon@snm.org>, <csmarcus@ucla.edu>, <mhrotman@aol.com>, <robert.carretta@tycohealthcare.com>, <swansondp@msx.upmc.edu>, <dpodoloff@di.mdacc.tmc.edu>, <pconti@hsc.usc.edu>, <woolfend@radiology.arizona.edu>, <nutech@tyler.net>, <jkuperus@anazaohealth.com>, <nukephysics@comcast.net>, <royal@mir.wustl.edu>, <RR68@gunet.georgetown.edu>, <wmoore@sleh.com>, <mpeters@snm.org>, <siegelb@mir.wustl.edu>, <pgrigsby@radonc.wustl.edu>, <Duffy@duffysmail.com>, <csmarcus@ucla.edu>, <roy@csmc.edu>, <joemt@earthlink.net>, <massullo@aol.com>, <Raskubic@radiological.com>, <PharmaRxRazmik@aol.com>, <mtl@nrc.gov>, <james-ponto@uiowa.edu>, <laura-ponto@uiowa.edu>

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