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June 30, 2015 VIA E-MAIL:<Vladik_Dorjets@omb.eop.gov>

Mr. Vlad Dorjets, Desk Officer
Office of Information and Regulatory Affairs
(3150-XXXX), NEOB-10202
Office of Management and Budget
Washington, DC 20503

Dear Sir:

I wish to oppose NRC's proposed information collection entitled "NRC Request for Sodium Iodide I-131 Treatment and Patient Release Practices".

First, the NRC assumes that "one size fits all" advice is dispensed to patients, and it wants to see that advice. This is incorrect. Advice to patients by competent nuclear medicine physicians is generally personalized to the patient's lifestyle, socioeconomic level, and ability to understand a scientific subject. As a physician with 35 years of experience using sodium iodide I-131 in patients occupying the full gamut of socioeconomic, educational, and cultural variability, my advice to patients varies considerably. It would be impossible to get that information to the NRC, as much of it is verbal (many of my patients have been functionally illiterate). It would be a huge burden on physicians to try to do this.

Second, the NRC wants comments from patients and patient advocacy groups as well, which means that there is going to be a good deal of misinformation. What a patient remembers months or years after a sodium iodide I-131 treatment is highly likely to be incomplete and at least somewhat inaccurate.

There have been complaints from some patients that their physicians tell them nothing, and that they get poor information from nuclear medicine technologists. While I believe that this is true, we have to look at what is really going on.

The NRC is required by law to support its medical program with user fees from its medical licensees. As NRC's medical program bureaucracy has increased, the costs of supporting increased staff has increased. When NRC tried to raise its already high user fees to something higher, Congress warned it not to do so. Faced with decreasing its bureaucracy or getting more paying licensees, the NRC gutted its proposed requirements for licensure in the late 1990's, and thereby increased the number of physicians who

could easily become paying licensees. The NRC considered them "qualified", but many board certified nuclear medicine physicians find a large proportion of these minimally "qualified" physicians to be marginally competent or not competent. These are trying economic times in medicine, and hospital administrators, eager to cut costs wherever possible, tell diagnostic radiologists or radiation oncologists to do these therapies, and then get rid of their board certified nuclear medicine physicians. This drives quality way down, but that's what happens in tough economic times.

It is highly likely that the huge majority of patients who complain that they get little or no satisfying guidance are not treated by board certified nuclear medicine physicians, but by physicians with minimal training. The problem here is NRC greed. Rather than stop this practice of decreasing licensing requirements to collect more user fees, in nuclear medicine diagnostics as well as in therapy, the NRC now wants to put a burden on physicians to tell them how to give patients information so that NRC can waste a good deal of time and user fee money writing guidance to physicians about what they should tell their patients. NRC guidance documents in the medical program are basically worthless, and competent physicians do not need any of it. Poorly competent physicians do not need guidance---they need to have their NRC licenses terminated.

Would you go in for elective surgery from a physician who is not a board certified surgeon? Would you go to a urologist who isn't a board certified urologist? In a scientifically complex area like nuclear medicine, wouldn't you want a board certified nuclear medicine physician?

Therefore, rather than burden physicians with a request for information, NRC should abandon this guidance project, substantially increase the requirements for nuclear medicine therapy licensure, and start laying off staff in its medically and scientifically naïve medical program to cope with the loss of user fees. (In addition to requirements of a few cases and lectures covering some of the needed subjects, there should be a requirement to pass a comprehensive examination in basic nuclear and radiation sciences. This was in a proposed rule in the Federal Register in the mid 1990's, but suddenly disappeared without any public comment period, probably because few of the non-nuclear medicine board certified physicians would pass it.) There will be an increase in medical quality, and that's what we want, isn't it?

Thank you for your attention and consideration.

Sincerely,

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

Prof. of Molecular and Medical Pharmacology (Nuclear Medicine), of Radiation Oncology, and of Radiological Sciences, David Geffen School of Medicine at UCLA

cc: Tremaine Donnell, NRC Commissioners

CHAIRMAN Resource

From: Carol Marcus <csmarcus@ucla.edu>
Sent: Wednesday, July 01, 2015 1:03 PM
To: Vladik_Dorjets@omb.eop.gov; Schiepers Christiaan; czernin johannes
Cc: INFOCOLLECTS Resource; CHAIRMAN Resource; CMRBARAN Resource; Cmr. Kristine L. Sviniki; CMROSTENDORFF Resource
Subject: [External_Sender] Comments to OMB and NRC about I-131 Info Collection
Attachments: NRC-Patient Release Info 06-30-15.docx

July 1, 2015

Dear Mr. Dorjets:

My apologies for the blank attachment yesterday.

Please accept my comment letter about NRC's proposed information collection entitled "NRC Request for Sodium Iodide I-131 Treatment and Patient Release Practices", published in the June 23, 2015 Federal Register (pp. 35990-35991). The letter is the attachment.

Thank you.

Sincerely,

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