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March 18, 2015

Ms. Sophie Holiday
ACMUI Coordinator
Medical Radiation Safety Team
Office of Nuclear Material Safety and Safeguards
United States Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Sophie:

Would you kindly circulate the attached statement to the members of the ACMUI? Thanks as always for your unfailing helpfulness and consideration.

Best regards,

/s/

Peter Crane

STATEMENT OF PETER CRANE TO THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

MEETING OF MARCH 19, 2015, NRC HEADQUARTERS, ROCKVILLE, MARYLAND

March 18, 2015

To the Committee:

I appreciate the opportunity to submit this statement to the Committee, as it prepares for its meetings on March 19 and 20, 2015. I look forward to hearing the staff's report on the progress of the continuing studies, under contract to NRC, on radiation doses attributable to patients released under 10 CFR 35.75, the Patient Release Rule.

Through the RADSAFE online bulletin board, I recently learned that Dr. Carol S. Marcus, a former member of this Committee, filed a petition for rulemaking with the NRC on February 9, 2015.[1] I urge the members of the Committee and other concerned persons in the NRC community to give this document close attention. Not only is it of interest in and of itself, its extremism serves to illuminate the intellectual underpinnings of the Patient Release Rule, which derives from an earlier petition for rulemaking from Dr. Marcus, filed in 1990 and later amended. Regrettably, the Commission did not then appreciate the extent to which Dr. Marcus's views deviated from the mainstream.

Dr. Marcus begins by attacking the Linear No-Dose Threshold Theory (LNT). So far so good, one might say; the LNT is admittedly a theory which remains to be proven. Dr. Marcus goes beyond that, however, to disparage the expertise of bodies that advocate the LNT (she mentions "NCRP, ICRP, IAEA, and NAS-NRC's BEIR Committee"[2]) and the integrity of the "army of regulators at NRC, EPA, FDA, as well as DOE [who] would be unbudgeted if the LNT disappeared." She reveals herself as a passionate advocate of the "hormesis" theory, and cites with approval the claims of Professor Edward Calabrese that the LNT was based on "amazing misconduct by the nation's leading geneticists in mid-twentieth century."[3] She informs us that "the attitude of today's regulators is reminiscent of the Catholic Church at the time of Galileo. ... [T[he Church threatened to torture Galileo to death unless he rescinded his point of view. ... [W]hile today's regulators do not have the tools of torture available that the Catholic Church used, today's regulators will certainly destroy careers for regulatory violations of questionable importance."

I will leave it to those currently employed by NRC to decide whether they deserve comparison to

[1] It can be found online at:
http://radiationeffects.org/wp-content/uploads/2015/03/Hormesis-Petition-to-NRC-02-09-15.pdf

[2] "NRC" in this context stands for the National Research Council.

[3] Anyone with an interest in unusual conspiracy theories can read Dr. Calabrese's views in an interview in which he asserts that the LNT was a deliberate lie, launched in the 1946 Nobel Prize acceptance speech of Dr. Hermann Muller.
http://www.21stcenturysciencetech.com/Articles_2011/Fall-2011/Interview_Calabrese.pdf

torturers. I certainly didn't feel that way in my 23 years at the agency.

Next, Dr. Marcus reviews the scientific data: the Hiroshima and Nagasaki survivors, nuclear power plant workers, tuberculosis patients given fluoroscopes, radium watch dial painters, hyperthyroidism patients treated with I-131, persons exposed to radiation from the explosion of a nuclear fuel reprocessing plant in Russia in 1957, persons exposed to radiation from accidentally recycled cobalt-60 sources in Taiwan, and Americans exposed to low levels of radon in their homes. Again and again she finds a hormetic effect.

This reader of the petition immediately wondered, how will she deal with Chernobyl, which has caused over 7000 cases of thyroid cancer to date? The answer: it didn't happen. She writes:

> The affected population in the former Soviet Union was followed for increased cancer incidence. According to UNSCEAR 2000b [citation omitted] and the United Nations Chernobyl Forum in 2006, except for thyroid cancers in the highly contaminated areas, there was no increased incidence of leukemias or solid tumors, and no evidence of increased genetic diseases. The increase in thyroid cancers was found in children under the age of 15 years in 1987, the year after the accident. However, the radiation doses were too low to have caused this, and there was no dose-response relationship. In addition, the timing was off – the mean latent period for radiation induced thyroid cancer is about 28 years [citing the UNSCEAR 2000b report.] However, the increase was highly likely due to a mass screening effect [citation omitted]. Occult thyroid cancer is actually extremely common.... [petition at p. 6.]

The mainstream view of the Chernobyl data, of course, is that the appearance of so many thyroid cancers so soon after the accident (the first cluster of cases showed up near Minsk, Belarus, in about 1991, as I recall) was an indication that I-131 was more carcinogenic, when inhaled or ingested by the young, than previously suspected. Previously, the latency period was believed to be much longer. Dr. Marcus turns this on its head, however, arguing that since the latency period is much longer (a mean of 28 years, she says), the cancers found in 2000 and 2006 had to have some cause other than radiation, and can be attributed to better screening. Does that argument hold up? I will focus on just one part of the question: latency periods. Let us look, for example, at "Latency Period of Thyroid Neoplasia After Radiation Exposure," an article published in the journal Annals of Surgery in 2004.[4] It found, based on a relatively small sample, that the mean latency period for papillary thyroid cancer associated with external radiation was approximately 30 years, whereas the mean latency period for post-Chernobyl cancer, associated with internal radiation, was about six years.

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[4] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1356259/
Ann Surg. 2004 Apr; 239(4): 536–543.
Latency Period of Thyroid Neoplasia After Radiation Exposure
Shoichi Kikuchi, MD, PhD, Nancy D. Perrier, MD, Philip Ituarte, PhD, MPH, Allan E. Siperstein, MD, Quan-Yang Duh, MD, and Orlo H. Clark, MD

This is not the place for a detailed discussion of the Chernobyl data – I only learned of Dr. Marcus's petition yesterday, and the Committee's meeting is tomorrow – but there is ample scientific evidence that the post-Chernobyl thyroid cancers were caused by internal radiation exposure, and that there is a linear dose-response relationship. See, e.g., Risk of thyroid cancer after exposure to 131I in childhood, Cardis E et al., J. Natl Cancer Inst., 2005 May 18:97(10);: 724-32.[5]

Finally, we come to Dr. Marcus's proposed solution. Rather than characterize it, I will reproduce it in full:

> 1) Worker doses should remain at present levels, with allowance of up to 100 mSv (10 rem) effective dose per year if the doses are chronic.
> 2) ALARA should be removed entirely from the regulations, as it makes no sense to decrease radiation doses that are not only harmless but may be hormetic.
> 3) Public doses should be raised to worker doses, as these low doses may be hormetic. Why deprive the public of the benefits of low dose radiation?
> 4) End differential doses to pregnant women, embryos and fetuses, and children under 18 years of age.

It is safe to say that if the United States of America were to change its radiation protection

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[5] Abstract

BACKGROUND:

After the Chernobyl nuclear power plant accident in April 1986, a large increase in the incidence of childhood thyroid cancer was reported in contaminated areas. Most of the radiation exposure to the thyroid was from iodine isotopes, especially 131I. We carried out a population-based case-control study of thyroid cancer in Belarus and the Russian Federation to evaluate the risk of thyroid cancer after exposure to radioactive iodine in childhood and to investigate environmental and host factors that may modify this risk.

METHODS:

We studied 276 case patients with thyroid cancer through 1998 and 1300 matched control subjects, all aged younger than 15 years at the time of the accident. Individual doses were estimated for each subject based on their whereabouts and dietary habits at the time of the accident and in following days, weeks, and years; their likely stable iodine status at the time of the accident was also evaluated. Data were analyzed by conditional logistic regression using several different models. All statistical tests were two-sided.

RESULTS:

A strong dose-response relationship was observed between radiation dose to the thyroid received in childhood and thyroid cancer risk (P<.001). For a dose of 1 Gy, the estimated odds ratio of thyroid cancer varied from 5.5 (95% confidence interval [CI] = 3.1 to 9.5) to 8.4 (95% CI = 4.1 to 17.3), depending on the risk model. A linear dose-response relationship was observed up to 1.5-2 Gy. The risk of radiation-related thyroid cancer was three times higher in iodine-deficient areas (relative risk [RR]= 3.2, 95% CI = 1.9 to 5.5) than elsewhere. Administration of potassium iodide as a dietary supplement reduced this risk of radiation-related thyroid cancer by a factor of 3 (RR = 0.34, 95% CI = 0.1 to 0.9, for consumption of potassium iodide versus no consumption).

CONCLUSION:

Exposure to (131)I in childhood is associated with an increased risk of thyroid cancer. Both iodine deficiency and iodine supplementation appear to modify this risk. These results have important public health implications: stable iodine supplementation in iodine-deficient populations may substantially reduce the risk of thyroid cancer related to radioactive iodines in case of exposure to radioactive iodines in childhood that may occur after radiation accidents or during medical diagnostic and therapeutic procedures.

regulations to allow children, fetuses, and pregnant woman to receive as much radiation as a worker in a nuclear facility, on grounds that we do not want to deprive them of the hormetic benefits of radiation, this country and the NRC in particular would, in the world radiation community, be laughingstocks.

Thank you.

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1356259/