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AUTHOR: Roy Brown
AFFILIATION: CA
ADDRESSEE: Nils Diaz
SUBJECT: Concerned with allegations that could disrupt the supply of medical isotopes

ACTION: Signature of Chairman
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*Council on Radionuclides and Radiopharmaceuticals, Inc.*

3911 Campolindo Drive
Moraga, CA 94556-1551
(925) 283-1850
Fax: (925) 283-1850
E-mail: corar@silcon.com

Henry H. Kismar, Ph.D., FACNP
Executive Director

April 23, 2004

CHAIRMAN REC'D
04 APR 27 PM 4:16

The Honorable Nils J. Diaz, Ph.D.
Chairman
Nuclear Regulatory Commission
One White Flint North Building 11555 Rockville Pike
Rockville, M.D. 20852-2738

Dear Chairman Diaz:

On behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR¹) we are concerned about the recent allegations that could potentially disrupt the supply of essential medical isotopes. The United States lacks a domestic supplier of certain medical isotopes. We are 100 percent dependent on foreign manufacturers to supply us with these drugs. These vital medical isotopes are used in 16 million procedures annually to treat and diagnose illnesses such as heart disease and cancer.

The suppliers of medical isotopes to the United States' radiopharmaceutical industry require small quantities of highly enriched uranium (HEU) to manufacture these essential drugs. The Nuclear Control Institute (NCI) has recently suggested that an excess of global capacity to produce medical isotopes exists. This is not accurate. In fact, the United States radiopharmaceutical manufacturers have experienced supply shortages when our current isotope suppliers have had a disruption in production. In addition, medical isotopes are patient specific and have extremely short half-lives, some as brief as several hours. It is not possible to manufacture and stockpile medical isotopes for future use.

In addition, NCI has contended that it would be possible to supply the United States with medical isotopes manufactured from LEU if the current United States suppliers were forced to halt production. Today, approximately two percent of the current global supply of medical isotopes is manufactured from low enriched uranium (LEU) targets. LEU produced medical isotopes are still several years from commercial viability and even further away from having sufficient production capabilities to ensure reliable supply for United States patients. In fact,


¹ CORAR is comprised of the major manufacturers and distributors of diagnostic and therapeutic radiopharmaceuticals, life science research radiochemicals, and sealed sources used in therapy, diagnostic imaging, and calibration of instrumentation used in medical imaging.

LEU produced medical isotopes are only used in the region they are produced in and are significantly subsidized by government programs. To suggest halting the export of HEU for the production of medical isotopes when LEU technology is still in the developmental phase will put the lives of patients who rely on these crucial drugs at risk.

CORAR is concerned that the politicization in tandem with mischaracterizations of the facts surrounding this issue will result in disruption of the supply of medical isotopes to patients in the United States. In order to ensure a reliable supply of medical isotopes continues, as well as to address any possible misinformation regarding the export of HEU for medical purposes, we urge the Nuclear Regulatory Commission (NRC) to undertake a comprehensive review of the current supply of medical isotopes and investigate the claim that LEU targets could sufficiently supply enough medical isotopes to meet demand in the United States. Finally, we urge the NRC to continue to balance the United States' nonproliferation concerns with the United States cancer patients' needs for a reliable supply of medical isotopes.

Thank you for your attention to this important matter. Please do not hesitate to contact Jim Massie at 202-548-2300 if you require any additional information.

Sincerely,



Roy W. Brown, Chairman
Council on Radionuclides and Radiopharmaceuticals

cc: Commissioner Edward McGaffigan, Jr.
Commissioner Jeffrey S. Merrifield