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3RD DISTRICT, NEVADA

COMMITTEE ON
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THE WORKFORCE COMMITTEE

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79 FR 42409

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Congress of the United States
House of Representatives
Washington, DC 20515–2803

March 2, 2015

The Honorable Stephen G. Burns
Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Chairman Burns:

The Nuclear Regulatory Commission (NRC) regulates the medical use of radiolabeled products to treat cancer and other life threatening diseases. The NRC's regulations require that a physician treating patients with a therapeutic radiopharmaceutical must be licensed as an "Authorized User." My office has heard from patient advocates and physicians about the shortage of Authorized Users and the barriers to patient access to these life-saving cancer treatments such as Zevalin, a beta-emitter treatment for patients with non-hodgkins lymphoma.

The NRC is currently in the process of finalizing its rulemaking process on the "Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments" intended to address related issues, including shortages of authorized users, the classification of radiopharmaceuticals and associated work experience requirements. In this rulemaking, the NRC has specifically requested comments on whether its regulations "*discourage licensees from using certain therapy options or otherwise adversely impact clinical practice, and if so, how.*" We understand that the NRC heard testimony at a recent public meeting from a variety of stakeholders organizations representing patients and community oncologists. I would like to offer my comments as a physician and as someone trained in the Medical Effects of Ionizing Radiation by the Armed Forces Radiology Research Institute.

The NRC's current regulatory framework requires that most hematologists and oncologists who want to become AUs must complete 700 hours of training and experience, including a minimum of 200 hours of classroom / laboratory training in radionuclide handling techniques. This training requirement has created a shortage of Authorized Users able to administer therapeutic radiopharmaceuticals, particularly in the community oncology setting. Outside of major academic medical centers, patients sometimes have to travel great distances in order to find Authorized Users able to administer these products. For patients living in rural areas, especially elderly patients with mobility difficulties, these barriers can be insurmountable. The regulations have the effect of limiting the treatment options available to these cancer patients.

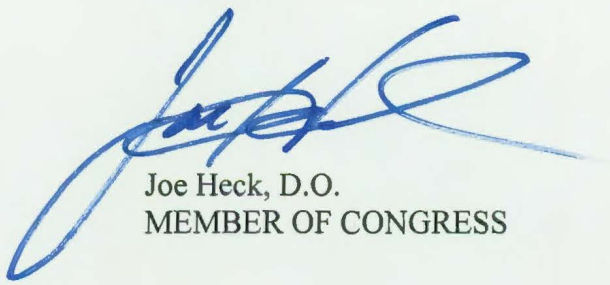
This rulemaking presents an opportunity for the NRC to address the current shortage of Authorized Users able to administer these anti-cancer therapies. By creating a training requirement commensurate with the precautions necessary to administer these products, the NRC can ensure that products are handled safely and appropriately, while ensuring all patients can

access these treatment options. I understand that there is precedent in the NRC regulations for reduced training and experience requirements for products that pose minimal safety and handling risks prior to and after administration. For example, the regulations require only 80 hours of classroom and laboratory training in order to administer oral sodium iodide I-131.

I urge the Commission in its final rule making to seriously consider the information provided regarding the shortage of Authorized Users able to administer alpha- and beta-emitting products and consider making modifications to the regulations to reduce the training and experience requirements to a level appropriate for these lower risk products. In doing so, the Commission will increase access to critical, life-saving therapies without exposing patients or providers to any significant risk.

I would appreciate being updated as the process moves forward.

Sincerely,



Joe Heck, D.O.
MEMBER OF CONGRESS

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