PATIENTS
FOR SAFER NUCLEAR MEDICINE

January 3, 2024

ATTN: Members of the GOP Doctors Legislative Caucus

We are writing to make you aware of just-introduced legislation impacting the administration of radiopharmaceuticals in the U.S.

We hope you will review and consider co-sponsoring the bipartisan **Nuclear Medicine Clarification Act (H.R. 6815)**, which clarifies an existing regulation and provides hospitals with the time and flexibility to address a critical patient safety issue.

We are Patients for Safer Nuclear Medicine (PSNM), a coalition comprised of 30 non-profit patient advocacy organizations, representing thousands of patients across every state, including your constituents. PSNM has one primary objective: ensure that the U.S. Nuclear Regulatory Commission (NRC) addresses the reporting of large extravasations similar to any other accidental exposure of radiation.

As you know, nuclear medicine imaging (PET/SPECT scans) and nuclear medicine therapies are indispensable components of modern healthcare. Nearly 30 million diagnostic radiopharmaceuticals are administered annually in the U.S. to help diagnose and assess effectiveness of therapies for oncology, neurology, and cardiology patients. Additionally, new high-dose, extremely expensive radiotherapeutics are now entering the market to help address neuroendocrine, prostate cancer, and many other cancers.

Millions of extravasations occur each year when radiopharmaceuticals are injected into the patient's skin tissue instead of a vein. Not all are large enough to matter clinically, but many do. Large extravasations are concerning for two primary reasons. First, a large extravasation can result in a very high absorbed radiation dose to healthy tissue. Ionizing radiation can lead to pain and damage to underlying tissue that can take weeks, months, or even years to develop. The degree of potential tissue damage depends on the depth of the extravasation and the type of isotope. Higher doses of ionizing radiation can increase the chance of developing cancer in the future. This is particularly concerning for younger patients.

Secondly, and even worse, a large extravasation can compromise the procedure and may negatively impact care. Accurate nuclear medicine images used to guide care decisions require precise knowledge of the injected radiation. Large amounts of radiation left in the arm for diagnostic procedures invalidate the images. Additionally, therapeutic radiation left in the arm exposes the lymphatic system to high radiation doses and compromise the delivery of therapy.

We were spurred to develop our coalition when we learned that clinicians currently are not required to report an extravasation to the NRC. Unlike other areas of medicine, such as contrast CT departments that focus on intravenous administrations, nuclear medicine administrations are not effectively monitored, and quality standards are utterly lacking. For example:

- Nuclear medicine administrations are not audited.
- Technologists who administer **radioactive drugs into patients** are taught how to handle radiation, but they **do not receive formal vascular access training,** nor do they undergo annual credentialling.
- Extravasation mitigation protocols do not exist.
- Technologists often use direct injections (straight sticking) to inject radiation into patients and do not routinely use vein finding tools to minimize extravasations.
- Technologists often use very small gauge needles that do not have the purchase to remain in place and that can blow the vein when they cause very high-pressure bolus injections over a period of 1-2 seconds.

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At the request of Congress, since 1980 NRC has required "medical event" reporting of medical isotope handling errors that result in patient exposure above a certain dose-based threshold. However, a loophole has exempted extravasations from any NRC reporting requirements, regardless of how high the radiation exposure.

More importantly, there is currently no requirement to notify the affected patient that they have been extravasated. Radiation inadvertently spilled ***onto*** a patient must be measured and potentially reported to NRC; if an amount of radiation hundreds of times larger is inadvertently injected ***into*** a patient's tissue, no report is required. In short, the current policy defies logic and common sense, and is actively harming patients.

In December 2022, NRC accepted a petition for rulemaking to close the regulatory loophole. But in May 2023, the NRC offered a proposed 'solution' that essentially keeps large extravasations from being reported. The NRC draft rule puts the onus on patients to report suspected extravasations to the nuclear medicine physician ultimately responsible for the extravasation, who in turn uses subjective criteria to decide whether to report or not.

The proposed rule completely fails to protect patients, who are not told at the point of care that they were extravasated, and who do not know the symptoms or that the damage can take weeks, months, or years to manifest. The NRC proposal expects patients to self-diagnose and seek independent corroboration from another medical professional before returning to the physician who administered the injection. Consider how expensive and time-consuming this is for patients, many of whom are already struggling with a debilitating illness and don't need the additional pain, stress, and cost caused by the NRC reporting process.

Furthermore, by addressing extravasation, you can help solve a longstanding healthcare inequity. Because nuclear medicine technologists choose veins primarily by sight and feel, it is believed that patients with darker skin are extravasated at a higher rate by affecting the search for a vein. Additionally, as our coalition has previously told Chairman Hanson of the NRC, any rule that puts the burden on patients to self-report will surely lead to more inequity, causing an unnecessary drain on time, resources, and emotional energy at an exceptionally difficult time.

The NRC must begin treating extravasations like any other medical event. If the extravasation results in a tissue dose greater than the threshold the NRC already uses, it should be reported. Using this standard, it is estimated that several hundred thousand extravasations each year would be large enough to merit reporting to the NRC. However, we think H.R. 6815 will ultimately minimize extravasations, by providing guidelines that nuclear medicine administrators will be able to deploy. Evidence suggests that requiring reporting could quickly reduce the number of large extravasations to fewer than 3,000 annually.

In addition, the bill would provide nuclear medicine centers with an ample 18-month reporting grace period to get up to speed on the new requirement, providing these centers with ample time to train their technologists so they can minimize the problem rather than minimize the reporting.

Millions of vulnerable patients are affected by the current extravasation policy loophole. They deserve better protection. H.R. 6815 is a targeted fix, simply requiring NRC to treat large extravasations like any other reportable medical event. This fix does not prescribe how a nuclear medicine center addresses the issue; it simply ensures that if the center is routinely mishandling medical isotopes, then they must report to the NRC and to patients.

We respectfully ask you to review and cosponsor this common-sense legislation to ensure transparency in care while protecting patients from harm. Through our various channels, including a robust social media presence, we plan to make our entire coalition membership aware of legislators who support H.R. 6815.

Thank you for considering our request. If you have any questions, please contact Mary Ajango at majango@youngsurvival.org.