



October 18, 2024

Dr. Cutler,

On behalf of Patients for Safer Nuclear Medicine (PSNM) – a national coalition of 30+ non-profit organizations – we wish to congratulate you on your new role as President of the Society of Nuclear Medicine and Molecular Imaging (SNMMI). We are writing to ask for your help.

Since 2021 PSNM has been committed to one priority: improving transparency and patient safety in nuclear medicine. Most of our patients rely on nuclear medicine to guide their care, but the current NRC reporting exemption for all extravasations is unacceptable. We have approached each of your predecessors since 2021 and SNMMI has refused to meet with us to hear patient concerns directly. It is our sincere hope that with you as the new SNMMI president, we can work together to give patients confidence in the safety, effectiveness, and transparency of their nuclear medicine procedure.

We believe that a dialogue will help us better understand why SNMMI believes that patients “need not be concerned” with an extravasation of a diagnostic radiopharmaceutical. Why does SNMMI discourage assessing the severity of these extravasations, when diagnostic procedures help diagnose our disease and assess our treatment? We would like to understand why SNMMI believes that patients should not be informed when radiation is accidentally injected into our tissue instead of our veins as prescribed by *your physicians*. We would be happy to meet with you at your convenience to discuss our concerns.

The NRC recently issued Draft Regulatory Guide DG-8062 for radiopharmaceutical extravasation reporting. While we are thrilled the NRC has finally agreed after 44 years with the scientific evidence that shows extravasations are not virtually impossible to avoid and the reporting exemption is incorrect, we think DG-8062 will not meet your needs or patients’ needs.

The draft requires providers to effectively identify extravasations but fails to require that providers use dosimetry to assess large extravasations. Even worse, the draft provides a subjective criteria, “potential radiation injury” as a criterion, rather than using the objective, dose-based, and risk-informed standards used to determine whether all other accidents warrant medical event reporting. Without dosimetry, providers cannot effectively assess how much radiation was left in the patient’s arm, cannot assess the true effect to the procedure, and cannot know if the dose exceeds a reporting threshold or intelligently assess the potential for radiation injury and the need to follow up with patients. One physician may report, while another might decide to forego reporting of an event ten times more serious. This is not good for patients or nuclear medicine.

These shortcomings are why several members of Congress introduced the Nuclear Medicine Clarification Act (H.R. 6815), which PSNM and its members strongly support.

SNMMI plays a critical role in guiding nuclear medicine policy. It is a responsibility that cannot be taken lightly. We were deeply troubled by the report released by the NRC Office of the Inspector General (OIG) in March 2024, which found two NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI) members were also leading members of SNMMI. The OIG stated that the two violated federal ethics rules by advising NRC on the petition for rulemaking regarding extravasations. For your reference, you can find the published report at this link: <https://bit.ly/NRCOIG>.

We raise this issue because the power of medical societies to impact the health of future generations is enormous. As an example, we would point to a *New York Times* opinion piece by Pamela Paul on “several episodes of medical authorities sticking to erroneous positions despite countervailing evidence.” You can read the full article [here](#), but this passage illustrates the degree of power you now hold:

"Rather than remaining open to dissent, the medical profession frequently closes ranks, leaning toward established practice, consensus and groupthink...In this kind of environment, what begins as opinion can quickly become dogma, especially once the profession has become wed to an idea."

We believe the SNMMI, HPS, ACR, and several other organizations are making the same mistakes regarding extravasations as those societies highlighted by Ms. Paul. Several of our members have reached out to Ms. Paul to provide specific examples for her consideration. With you in place as the new President of SNMMI, we can reset the discussion. The PSNM coalition understands that nuclear medicine is important to our lives. We are not afraid of radiation. We know it is needed to provide insight into our conditions. We know that the complete delivery of the radiopharmaceutical provides the highest quality image and improves the quantitative capabilities of the image. We are deeply concerned by efforts of the nuclear medicine community to inhibit commonsense patient safety and transparency. Let's work together to eliminate extravasations. Several of our patients along with a few scientific and clinical experts in nuclear medicine, physics, and vascular access would appreciate an audience with you.

Dr. Cutler, thank you in advance for considering our concerns. Patients across the US are counting on all of us to protect them from the harm of extravasation. With your engagement, we can arrive at a solution that improves patient care, sets up nuclear medicine to thrive, and drives positive systemic change.

Sincerely,

Simon Davies, Executive Director
Teen Cancer America
PSNM Spokesperson

CC:
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