PATIENTS
FOR SAFER NUCLEAR MEDICINE

January 30, 2025

Dear Representative Joyce and Representative Murphy,

Congratulations on your co-chairmanship of the GOP Doctors Caucus. We are writing to seek your support for a critical patient safety issue that has been inadequately addressed by the U.S. Nuclear Regulatory Commission (NRC).

Bureaucratic inaction and mismanagement are failing Americans by leaving them vulnerable to safety risks that require your immediate attention. We ask you to support the bipartisan **Nuclear Medicine Clarification Act**, which will soon be reintroduced in the 119th Congress.

Patients for Safer Nuclear Medicine (PSNM) is a coalition of 30 non-profit patient advocacy organizations and the nation's premier advocate for patient safety/transparency in healthcare, the Leapfrog Group. We represent thousands of patients across every state, including your constituents. We are fortunate to be advised by leading global experts in radiology, nuclear medicine, physics, radiation protection, and vascular access. PSNM has one primary objective: ensure that NRC requires transparency regarding large extravasations, just like any other accidental exposure of radiation.

As healthcare professionals and legislators, your leadership is critical to correcting NRC's longstanding policy oversight, which negatively affects patient safety and care.

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, expensive radiotherapeutics are now entering the market to help address neuroendocrine and prostate cancer, and with hope to treat many other cancers very soon.

Millions of extravasations occur each year when radiopharmaceuticals are mistakenly injected into the patient's tissue instead of a vein and almost all go undetected. And while not all extravasations are large enough to matter clinically, many 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, but which rarely creates visible symptoms on the skin. Furthermore, higher doses of ionizing radiation can increase the **chance of developing cancer in the future**. This is particularly concerning for younger patients.

Second, a large extravasation can negatively impact patient care—hundreds of peer-reviewed articles and our global experts support this statement. Accurate nuclear medicine images used to guide care decisions require precise knowledge of the injected amount of radiation. Large amounts of radiation left in the arm for diagnostic procedures **invalidate the images**, which can result in an ineffective course of treatment. Therapeutic radiation left in the arm compromises the delivery of therapy and unnecessarily exposes the lymphatic system to high radiation doses. These issues

have patient and economic costs that are far greater than the cost for providers to address the underlying issues that lead to extravasations.

We were spurred to develop our coalition when we learned that clinicians currently are not required to report a large extravasation to the NRC. Conversely, other large accidental radiation exposures are required to be reported.

The historical lack of reporting of large extravasations to any regulatory body has ramifications. With no oversight requirements, providers are not effectively monitoring radiopharmaceutical administrations. No one identifies extravasations or tracks them. Extravasations are not reported to the radiation safety officer, the nuclear medicine physician, or the provider's chief medical officer. Furthermore, they are not documented as an adverse event nor documented in the patient record. The vast majority of extravasations remain hidden. And when an extravasation is suspected or known, less than 5 percent of these are even documented in the radiology report, according to two recent studies.

Despite nearly identical procedures for administration, extravasations of radiopharmaceuticals are far more common than contrast CT and chemotherapy extravasations for several reasons:

- Technologists don't see swelling since the volume injected is ~1cc. Patients don't feel pain, because ionizing radiation causes latent effects and does not initially result in a burning sensation at the injection site.
- Radiopharmaceutical administrations are not audited by any accreditation organizations.
- There are no CMS quality measurements for radiopharmaceutical administrations.
- Technologists who administer **radioactive drugs into patients** are trained to handle radiation, but they **do not receive formal training on how to gain venous access,** nor do they undergo annual credentialing.
- Nuclear medicine departments do not create and enforce extravasation prevention and mitigation protocols.
- 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 inappropriate and very small gauge needles that do not have the purchase to remain in place and can cause very high-pressure that "blows" a vein during rapid bolus injections.

At the request of Congress and since 1980, NRC has required "medical event" reporting of medical isotope handling errors that result in patient exposure above a certain dose-based and risk-informed threshold. This is not excessive regulation. It is appropriate regulation that requires accidents that exceed a risk-informed threshold be investigated and reported and thus helps NRC meet its mission to protect public health and safety. However, an incorrect loophole has always exempted nuclear medicine 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's skin 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 instead of into the vein as intended, no measurement or report is required.

The current policy defies logic and is actively harming patients. Additionally, it results in NRC failing to report Abnormal Occurrences to Congress as required by the Energy Reorganization Act of 1974.

In December 2022, NRC accepted a petition for rulemaking to close the regulatory loophole, but essentially proposed a new loophole at the request of the industry the NRC regulates. The NRC initial proposal expected untrained patients to self-diagnose an extravasation 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.

At the same time, a recent NRC Office of Inspector General (OIG) report found NRC-paid advisers violated federal ethics rules in advising NRC on the extravasation topic. The published report can be found at this link: https://bit.ly/NRCOIG.

To assuage our coalition and attempt to address the bombshell OIG report, the NRC has proposed adding another nonsensical new criterion. Now centers would also have to report those extravasations that may *potentially cause injury*. Once again, the NRC is abdicating their role in protecting patients. This criterion is purely subjective, and the reporting decision-makers are the same physicians who are lobbying to not report extravasations at all. This proposed rule is insufficient; the reporting criterion needs to be an objective threshold.

The Nuclear Medicine Clarification Act proposes to **add just 23 new words** specifically ensuring extravasations are added to the existing medical event reporting rule. In essence, the legislation requires that 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 for other accidental exposures, it should be reported. Unlike NRC's proposed conflicted rule which adds new, complex, subjective regulation, the Nuclear Medicine Clarification Act simply adds large extravasations to the existing risk-informed threshold regulation.

To ease implementation, the **Nuclear Medicine Clarification Act** allows total flexibility about how a nuclear medicine center addresses the issue, and it provides 18 months of a reporting grace period after enactment, enough time to make this preventable patient safety issue almost entirely disappear.

By requiring that extravasations be reported like any other current medical event, NRC will drive centers to take actions that minimize their extravasations rather than minimizing reporting. The bill is also consistent with a Project 2025 goal of setting clear radiation safety standards based on risk rather than arbitrary objectives.

Millions of vulnerable patients are affected by the current extravasation policy loophole. They deserve better protection. The **Nuclear Medicine Clarification Act** is a targeted fix, simply requiring NRC to treat large extravasations like any other reportable medical event. If a center is routinely mishandling medical isotopes, then NRC and patients should be made aware. And if some of those

Trade associations who want to avoid transparency are lobbying hard to convince Congress not to act. They hide the fact that these generally safe procedures can negatively affect patients and their care if an injection is misadministered, and falsely claim the bill transfers regulatory responsibilities to Congress or will limit access to nuclear medicine procedures. This is nonsense.

Finally, these trade groups demand total deference to their policy views, despite the OIG report identifying improper conflicts of interest in their lobbying of NRC and Congress, and a pattern of providing misleading information.

We respectfully ask you to take action to protect patients. We can provide you with unconflicted experts who will tell you the truth on this issue. We ask you to review and cosponsor this common-sense legislation to ensure transparency in care while protecting patients from harm.

Thank you for considering our request. If you have any questions, please don't hesitate to contact me at simon@teencanceramerica.org.

Respectfully,

Simon Davies
Executive Director, Teen Cancer America
Representing the membership of the Patients for Safer Nuclear Medicine Coalition