PATIENTS
FOR SAFER NUCLEAR MEDICINE

March 25, 2025

Dear Representative Bera:

Congratulations on the formation of the Democrat 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).

Regulatory capture, 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 by Rep. Don Davis (D-NC).

Patients for Safer Nuclear Medicine (PSNM) is a coalition of 30 non-profit patient advocacy organizations, representing 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 the NRC requires reporting of large extravasations, just like any other accidental exposure of radiation.

As healthcare professionals and legislators, your leadership is critical to correcting this longstanding policy oversight, which endangers patient safety.

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.

Data shows that millions of extravasations occur each year when radiopharmaceuticals are mistakenly injected into the patient's tissue instead of a vein. The nuclear medicine community is four decades behind vascular access skills and without a concerted effort to decrease extravasations as has been accomplished in contrast CT and chemotherapy injections, the extravasation rate in nuclear medicine is 172/1,000 patients. Not all extravasations are large enough to matter clinically, but 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 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 exposes the lymphatic system to high radiation

doses and compromises the delivery of therapy. 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. 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 zero CMS quality measurements for radiopharmaceutical administrations.
- 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 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 small gauge needles that do not have the purchase to remain in place and can cause high-pressure that "blows" a vein during rapid bolus injections.

At the request of Congress and since 1980, the 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. 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 the 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 report is required.

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

In December 2022, the 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 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 NRC Office of Inspector General (OIG) report found NRC-paid advisers violated federal ethics rules in advising NRC on the extravasation topic.

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 unacceptable - the reporting criterion needs to be an objective threshold.

The Nuclear Medicine Clarification Act proposes to **add just 23 new words to the existing medical event reporting rule**. In essence, the legislation requires that 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 for other accidental exposures, it should be reported.

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, the NRC will drive centers to take actions that minimize their extravasations rather than minimizing reporting. The bill is also consistent with the existing objective, risk-informed threshold that exists for every other radiation exposure that NRC requires to be reported. The only reason that the NRC is proposing a subjective criterion is because they are captured by the industry they regulate.

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 the NRC and patients should be made aware.

Trade associations who want to avoid transparency are lobbying hard to convince Congress not to act. They hide the fact that these safe procedures can be highly dangerous if an injection is

misadministered, and falsely claim the bill transfers regulatory responsibilities to Congress or will limit access.

Finally, these trade groups demand total deference to their policy views, despite the OIG report identifying improper conflicts of interest in their lobbying of the 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.

Sincerely,

Simon Davies, Executive Advisor
Teen Cancer America
Member of the Patients for Safer Nuclear Medicine Coalition