PATIENTS
FOR SAFER NUCLEAR MEDICINE

November 24, 2025

Dear Chairman Guthrie and Ranking Member Pallone,

As promised in our letter from earlier this month, our coalition—Patients for Safer Nuclear Medicine (PSNM)—is providing you with a point-by-point response to the inaccurate letter you received from SNMMI, ASTRO, ACR, and AAPM regarding the Nuclear Medicine Clarification Act (H.R. 2541), which has been referred to the House Committee on Energy and Commerce.

We are a group of over 30 patient advocacy organizations representing hundreds of thousands of patients and 7 corporate sponsors dedicated to bringing transparency to a nuclear medicine patient safety issue. It is important to note that our coalition includes the premier patient safety hospital grading organization, The Leapfrog Group. We are also supported by unconflicted experts like the co-inventor of the PET/CT scanner, Dr. David Townsend, and one of the top radiologists in the world, Dr. Dan Sullivan. As you will see from our response below and our included references, the positions we take are clearly supported by scientific and clinical evidence.

Myths versus Facts

The 4 medical societies have misled members of Congress in their June 27, 2025, letter.

The 4 societies intimated that the radiopharmaceutical extravasation issue is nothing to worry about because extravasations happen in all types of medical injections. What the societies failed to share with you is that the extravasations in all areas of medicine outside of Nuclear Medicine are reported to someone in a hospital or to the FDA. And because these extravasations are reported, the medical community has focused on reducing their frequency. The 4 societies failed to share with you, for example, the clinical evidence that shows only 1 in 1,000 patients being administered chemotherapeutic agents are extravasated and 2 in 1,000 patients being administered contrast agents for CT exams are extravasated[1,2]. The 4 societies failed to share with you that radiopharmaceutical extravasations are NOT REPORTED to anyone in the hospital or any regulatory or accreditation organizations. Nor did the 4 societies share with you that **172 in 1,000 nuclear medicine patients** are extravasated[3-13].

The 4 societies also suggested that the extravasation issue is nothing to worry about because adverse clinical events associated with radiopharmaceutical extravasations are exceedingly rare. The 4 societies are knowingly misleading members of Congress. The article they reference does not justify this assertion in any way. Please note that this article was drafted by clinicians from a center led by the president of SNMMI and published in JNM, SNMMI's own journal. The 4 societies did not share with you that they chose a study:

- that focused on an isotope that has uncommonly low radiation energy,

- that only referenced approximately 2% of the true number of extravasated patients and ignored completely the other 98%,
- that did not effectively follow patients for the appropriate amount of time to look for harm,
- and that did not consider the negative effects that can result from a flawed image resulting in incorrect patient care.

They also did not share with you that this article was immediately critiqued for misleading members of the medical community in a letter to the editor by a leading physicist. He provided a detailed analysis showing why the article was flawed and emphasized that it should not be used as an authoritative reference. He stated,

> **"Readers could be misled were this article to be quoted as a 'definitive reference based on large numbers,' suggesting that extravasations in nuclear medicine procedures are without consequence. It is clear that they are not."**
> *(https://jnm.snmjournals.org/content/jnumed/early/2023/06/29/jnumed.123.265717.full.pdf)*

The 4 societies also failed to share with you that they had previously communicated to the NRC that extravasations **<u>can</u>** compromise the quality and quantification of the nuclear medicine procedures that are used to help guide patient care[14]. While compromised images are not considered adverse clinical events, they can easily lead to life-threatening mistakes in a patient's care. Nor did they share with you that because radiopharmaceutical extravasations are exempt from reporting, patients and their treating physicians are not told that their images used to guide their care have been compromised.

The 4 societies also suggest that Congress need not act because the ACMUI and NRC are moving forward with a proposed rule. What the 4 societies failed to share with you is that the NRC's own Office of Inspector General reported that these ACMUI members violated federal ethics rules by providing the NRC with input when these members were leaders of the societies opposed to extravasation reporting. What the 4 societies also failed to share with you is this conflicted input led to the proposed rule that will continue to keep the extravasation issue hidden from patients and from our physicians responsible for our care. The societies also failed to share that it has been more than five years since NRC received the petition for rulemaking commencing this evaluation and nearly three years since NRC accepted the petition and agreed with its factual basis, and yet the agency is still years away from finalizing a rule and implementation guidance. That is why it is critical that Congress acts.

The 4 societies suggests that H.R. 2541 will impose "arbitrary, unreasonable extravasation reporting requirements without a clear, clinical link to patient safety or a credible scientific basis." What the 4 societies failed to share with you is that H.R. 2541 requires the NRC to treat the accidental radiation exposure from an extravasation no differently than any other medical event that these societies report today. What the 4 societies failed to share with you is that H.R. 2541 provides clear, objective reporting thresholds based on data that the societies supported at the last NRC revision of these regulations in 2001. What the 4 societies also failed to share with you is that the current NRC regulation for all medical events is not tied to clinical harm[15] to patients, but to reporting threshold that the SNMMI supported in 2001[16] as being indicative that a clinician potentially mishandled an isotope. H.R. 2541 is clear. It simply tasks NRC with treating extravasations like any other medical event. What the 4 societies failed to share with you is that they simply do not want to have to do the work, or as has been communicated to the NRC by a leading

society member—the 'blah, blah, blah, associated with reporting mechanisms[17], or be required to fix their processes so that they are not extravasating.

The 4 societies state: "Medical institutions have developed comprehensive protocol for the rare occurrence of radiopharmaceutical extravasations." What the 4 societies failed to share with you is that the clinical evidence does not support that statement. In a recent paper published on this exact topic, the authors could not find one center that had such a protocol[18]. Interestingly, protocols exist for reportable contrast CT extravasations, but not for radiopharmaceutical extravasations.

The 4 societies also stated that nuclear medicine patients who are extravasated are followed for days. This is simply not true. PSNM have been studying this extravasation issue for years. We are only aware of one hospital system that tracks their extravasated patients and follows them clinically. We encourage you to ask these societies to provide evidence that nuclear medicine centers across the US clinically follow patients who are extravasated. The 4 societies will NOT be able to provide that evidence.

The 4 societies stated that, "infiltrated material is rapidly absorbed by the body without causing harm to the patient." This is yet another example of the disingenuous attempt by these societies to influence you. These 4 societies failed to tell you that this "absorption" takes time, during which the healthy tissue near the injection site is being exposed to high doses of radiation from the extravasation. Nor did the 4 societies share with you that the "absorption" is the result of the body's lymphatic system moving the radiation from the healthy tissue into the lymph nodes and then back into the venous system hours later. They didn't share with you that this "absorption" also unnecessarily exposes the patient's healthy lymphatic system to accidental radiation that never should have happened.

The 4 societies also stated that the H.R. 2541 requirements are "onerous, unnecessary, and technically challenging". They also stated they are impractical – "especially in under-served settings." Like most statements in this letter, these comments are simply not true. We consulted with the world's leading expert in monitoring extravasations is Dr. Jackson Kiser. His team has monitored nearly 20,000 radiopharmaceutical administrations. Dr. Kiser is ON RECORD for saying that there is minimal financial and time burden to monitor and there is free software provided by the University of Tennessee at Knoxville that takes 5 minutes to measure the severity of large extravasations. The 4 societies also failed to share with you that just because a nuclear medicine center may be in under-served setting NRC still requires all authorized users to be capable of reporting medical events.

The 4 societies also used scare-tactics in their letter to you. They shared their concern that H.R. 2541 will "impede proper patient care and increase referring -physician and [patient fear." They added that it could also lead to repeat imaging and driving patient cost up. Dr. Kiser, noted above, addressed this nonsense in recent peer-reviewed paper[19]. Dr. Kiser points out that hiding radiation mistakes from patients and their physicians is unethical and being transparent with patients improves trust. He also has demonstrated that addressing extravasations reduces healthcare waste and improves patient care. The 4 societies also failed to share with you that reducing extravasations actually reduces repeat imaging procedures that are necessary when the quality is so bad that the image is useless. Nor did they share with you that this cost is not a patient cost.

The 4 societies also tried to use an unsupported NRC financial analysis to show that addressing this issue will be extremely costly. This is utter nonsense. We are aware that monitoring for extravasations may cost a few dollars per patient. Providing a center with the right tools for training and staff use may

approach $5,000. These costs are nothing compared to the cost of one therapeutic radiopharmaceutical dose that is extravasated - $50,000. The costs to stop extravasations from happening are nothing compared to the costs associated with the hundreds of thousands of dollars that can be spent on expensive therapies that are incorrectly provided based on compromised nuclear medicine images affected by unknown extravasations.

Ironically, the 4 societies stated that imaging and therapeutic professionals dedicate themselves to treating patients by providing the best care possible and that this care always comes first. While as patients, we always want to believe that our care comes first, there is absolutely no evidence that this statement by these 4 societies is true. Many of these societies are on record for stating that,

- they know extravasations happen frequently in nuclear medicine,
- that extravasations can negatively affect the quality and quantification of the images that guide patient care, yet patients 'need to be concerned,'
- and to their members that they should not take the steps to look for or measure extravasations when they happen.

Additionally, members of these societies have also admitted to the NRC behind closed doors that improved training and tools can reduce extravasations[17,20].

These society positions **do not** put patient care first, they are simply saying and doing anything they can to avoid taking accountability for these preventable medical errors. This must stop.

Our Ask

Our coalition is comprised of over 100,000 patients who rely on nuclear medicine. We know how important nuclear medicine is to our care and our lives. And we can tell you that as patients, none of us want to be extravasated. We can also tell you that SNMMI, ACR, ASTRO, and AAPM have provided you as members of Congress with misleading statements to try and convince you that as doctors and physicists they know better than you.

PSNM have the following requests:

- Ask these medical societies to send you a signed letter from their presidents stating that their members would agree that they would be comfortable if they:
    - had a family member unknowingly receive a large extravasation during their cardiovascular, oncologic, or neurological care,
    - and no one on their family member's care team was aware of the large extravasation.
- We ask you to invite the presidents of these 4 societies to meet in person with you and several patient advocate experts who we will ask to represent our coalition and address the points we have made above. If you let these presidents know that they will have to support their statements in person and in front of Dr. David Townsend, Dr. Darrell Fisher, Dr. Dan Sullivan, Dr. Jackson Kiser, and Ms. Leah Binder of The Leapfrog Group, we would be surprised if any accept your invitation.
- We ask that you advance and pass H.R. 2541 as soon as possible. NRC has known at least since 2008 that their extravasation reporting exemption is incorrect. Meanwhile, every year in the US, at least 500,000 patients are unknowingly experiencing large extravasations. NRC has failed to protect patients. They are complicit with the providers they oversee. H.R. 2541 will immediately cause

providers to address the underlying causes of extravasations. Their frequency and severity will plummet. We estimate within 2 years of passing H.R. 2541, that less than 3,000 patients every year will experience large extravasations. And these patients will know and will be appropriately cared for. We also believe improvements will continue to drive that number even lower.

In the mid-1990s, Congress became aware that women were often experiencing substandard quality of care at mammogram centers across the US. This led to the Mammography Quality Standards Act, legislation which forced providers to increase the quality of their services to an improved standard. This act has saved hundreds of thousands of women's lives from ending prematurely. Congress can do the right thing again, by passing H.R. 2541. All of us are going to need a nuclear medicine procedure one day. None of us would want to experience a large extravasation and not be told that it happened. And not have it measured to see the effect on our care and on our healthy tissue. We look forward to hearing back from you on this important patient safety issue.

Sincerely,

Mary Ajango

Mary Ajango, Executive Director
Young Survival Coalition (YSC)
PSNM Spokesperson

CC: Rep. Bob Latta
Rep. Kathy Castor

1. Dykes TM, Bhargavan-Chatfield M, Dyer RB. Intravenous contrast extravasation during CT: a national data registry and practice quality improvement initiative. *J Am Coll Radiol*. 2015;12:183-191.
2. Jackson-Rose J, Del Monte J, Groman A, et al. Chemotherapy Extravasation: Establishing a National Benchmark for Incidence Among Cancer Centers. *Clin J Oncol Nurs*. 2017;21:438-445.
3. Osman MM, Muzaffar R, Altinyay ME, Teymouri C. FDG Dose Extravasations in PET/CT: Frequency and Impact on SUV Measurements. *Front Oncol*. 2011;1:41.
4. Hall N, Zhang J, Reid R, Hurley D, Knopp M. Impact of FDG extravasation on SUV measurements in clinical PET/CT. Should we routinely scan the injection site? *J Nucl Med*. 2006;47:115P.
5. Bains A, Botkin C, Oliver D, Nguyen N, Osman M. Contamination in 18F-FDG PET/CT: an initial experience. *J Nucl Med*. 2009;50:2222.
6. Krumrey S, Frye R, Tran I, Yost P, Nguyen N, Osman M. FDG manual injection verses infusion system: a comparison of dose precision and extravasation. *J Nucl Med*. 2009;50:2031.
7. Silva-Rodriguez J, Aguiar P, Sanchez M, et al. Correction for FDG PET dose extravasations: Monte Carlo validation and quantitative evaluation of patient studies. *Med Phys*. 2014;41:052502.
8. Muzaffar R, Frye SA, McMunn A, Ryan K, Lattanze R, Osman MM. Novel Method to Detect and Characterize (18)F-FDG Infiltration at the Injection Site: A Single-Institution Experience. *J Nucl Med Technol*. 2017;45:267-271.
9. Wong TZ, Benefield T, Masters S, et al. Quality Improvement Initiatives to Assess and Improve PET/CT Injection Infiltration Rates at Multiple Centers. *J Nucl Med Technol*. 2019;47:326-331.
10. Sunderland JJ, Graves SA, York DM, Mundt CA, Bartel TB. Multicenter Evaluation of Frequency and Impact of Activity Infiltration in PET Imaging, Including Microscale Modeling of Skin-Absorbed Dose. *J Nucl Med*. 2023.
11. McIntosh C, Abele J. Frequency of Interstitial Radiotracer Injection for Patients Undergoing Bone Scan. *The 79th Annual Scientific Meeting of the Canadian Association of Radiologists*. Montreal, Quebec; 2016.
12. Meyer A, Higgins Z, Packard AT, Johnson DR. Importance of Injection Site Image in DaTscans. *Journal of Nuclear Medicine*. 2021;62:156.
13. Fernandes D, Santos M, Pinheiro M, Duarte H, Fontes F. Radiopharmaceutical extravasation in bone scintigraphy: a cross-sectional study. *Nucl Med Commun*. 2023.
14. Packard AB, Buehner TM, Lu Y, Dorbala S. SNMMI, ACNM, ASNC Statement RE NRC Petition Docket ID PRM-35-22. 2020.
15. Backgrounder on Risks Associated with Medical Events. U.S. Nuclear Regulatory Commission; 2022. https://www.nrc.gov/docs/ML0609/ML060930582.pdf
16. Siegel JA. *Guide for Diagnostic Nuclear Medicine*: Society of Nuclear Medicine; 2002.
17. Official Transcript of Proceedings, Advisory Comittee on the Medical Use of Isotopes. US Nuclear Regulatory Commission; 2009. https://www.nrc.gov/docs/ML0920/ML092090025.pdf
18. Harris S, Crowley JR, Warden N. Radiopharmaceutical administration practices—Are they best practice? *Frontiers in Nuclear Medicine*. 2023;3.
19. Mace J, Kiser JW. Case Report: Radiopharmaceutical extravasation, radiation paranoia, and chilling effect. *Front Nucl Med*. 2024;4:1349527.
20. Official Transcript of Proceedings, Advisory Committee on the Medical Uses of Isotopes. US Nuclear Regulatory Commission; 2008.