

July 10, 2023

Dear Dr. Helen Nadel,

Patients for Safer Nuclear Medicine (PSNM) is a growing coalition of 29 patient advocacy organizations representing tens of thousands of patients, one nonprofit watchdog patient safety organization, and seven healthcare corporations. Our organization is also actively supported by individual patients and many physicians, technologists, and physicists who are also members of the Society of Nuclear Medicine and Molecular Imaging (SNMMI), and the Health Physics Society (HPS). All of us are focused on ensuring safe, transparent, and effective nuclear medicine care.

PSNM deeply values the benefits of nuclear medicine procedures. We understand that these procedures are critical to our lives, and we appreciate the efforts of you and your members. We are also excited by the new possibilities that nuclear medicine therapies can provide to patients.

But we are concerned that SNMMI does not share our focus on ensuring safer and transparent care. While SNMMI claims to have an “Eye on the Patient,” public comments, on-line discussions by your members, publications from your medical journal, and activities during your recent annual meeting do not match your words. We are asking you, as the new president of SNMMI, to critically evaluate the SNMMI position and actions regarding radiopharmaceutical extravasations.

#### **Public Comments by SNMMI and Members**

In a press release, in meetings with the Nuclear Regulatory Commission (NRC), and through public comments to the NRC, SNMMI and your members dispute that extravasations occur, state that technologists follow best practices (and therefore cannot reduce extravasations), suggest that diagnostic extravasations could never result in a dose that exceeds 50 rem, swear that harm is not possible because they have never seen it (even though the effects are latent and below the skin), claim that patients’ anatomy or “passive interventions” are to blame for extravasations, state that active monitoring will not reduce extravasation frequency, and suggest that monitoring for extravasations will put centers out of business—just to name a few of the objections raised.

During an NRC/ACMUI meeting in September 2021, SNMMI actively lobbied the NRC to continue the 1980 policy of exempting all extravasations from reporting, but also suggested that if NRC were to make certain extravasations reportable, then the reporting burden should be put on patients. SNMMI suggested that patients who are injured should seek medical attention and confirmation of a radiation injury from the authorized user at the center where the extravasation occurred.

We have reviewed the public statements made by SNMMI (and HPS and the American College of Radiology) and other than the SNMMI admission that an extravasation can affect the quality and quantification of images, we find a lack of any clinical evidence to support these statements. The proposal for patient reporting is particularly disturbing. Recommending that the NRC should wait for patients to be injured, when your members could use existing technology to identify and assess

extravasations and immediately begin mitigation, provides a clear picture of the priorities of your organization. The SNMMI patient reporting proposal is disingenuous since, as you know, most patients are not fully educated by the authorized user about the properties of the radiopharmaceutical injection or the symptoms and latent effects of ionizing radiation on healthy tissue and are not able to schedule and pay for follow-up visits to authorized users.

The SNMMI proposal also shows that your organization fails to account for the issues facing patients of color, who are more likely to be extravasated based on current vascular access practices used in nuclear medicine. Expecting those who already have a fraught relationship with the health care system to understand the nuances of nuclear medicine, self-diagnose, then seek a medical professional to concur before further action occurs is an excessive burden. At a time when every effort is being made to reduce healthcare inequities, SNMMI's proposal perpetuates inequity.

### **Online Discussions**

After the NRC initiated rulemaking based on the SNMMI patient reporting proposal, your members have been vociferously complaining about patient interest in extravasations. On LinkedIn and on your own online Community Forum, your members have minimized the importance of extravasations, emphasized their expertise in administering radiopharmaceuticals, and described PSNM as a nefarious organization led by vascular access nurses who are intent on stealing patients and business from nuclear medicine. Furthermore, one of your leading members suggested that SNMMI was "fostering" future publications to counter existing peer-reviewed literature on the topic.

### **Recent Misleading Publications**

Two papers that deal with the topic of extravasation have recently been accepted for publication in the SNMMI Journal of Nuclear Medicine. We have read these papers and sent them to independent experts in dosimetry and nuclear medicine. Both papers appear to take experiences at one center or a limited number of centers and suggest that these experiences represent all of nuclear medicine. They attempt to suggest that extravasations are rare, don't cause injury, and seldom result in high doses of radiation to healthy tissue. We are aware of the limitations of these papers and know from our own experiences that these papers are not representative of nuclear medicine across the US.

### **Annual Meeting Activities**

A few patients and several SNMMI members who support PSNM attended this year's annual meeting in Chicago. Although your theme was "Eye on the Patient," the meetings and conversations suggest otherwise.

In a talk presented by NRC staff, the outgoing president of SNMMI insisted that extravasations do not happen frequently. How can he know the extravasation rate when centers do not effectively monitor their extravasations? Others suggested that radiation doses are not high. If extravasations truly are rare and do not result in high doses, why the concern regarding reporting?

In a presentation on vascular access, we learned from a vascular access nurse that nuclear medicine technologists are not using best practices, are not certified in vascular access, and do not participate in annual credentialing. Medical professionals responsible for administering radiation into a patient's veins should be trained and should use the most current, evidence-based, vascular access practices.

At the Marriott Marquis lobby bar, one of your members loudly stated for all to hear, "I'm a medical professional and I don't care if a patient has 5 Gray or 50 Gray in their arm tissue." Well, patients care! We want to know when a large amount of radiation has been accidentally injected into our tissue instead of our vein. It affects our images, maybe our care, and maybe our tissue.

These experiences have left patients wondering if your members really care about patients and certainly made your meeting theme, "Eye on the Patient," ring hollow. Most of your members still accept that extravasations are not an issue of concern. Why do they think that it is ok to deliver these radioactive drugs into tissue rather than into the vein as intended? Why do they think that if the radiation does enter the tissue, they should not measure it as best they can and report the large ones to the patient, their doctor, and the NRC? It appears that SNMMI doesn't want to measure these accidental exposures. Is SNMMI aware of the growing importance of tracking lifelong radiation exposures?

### **Harm and Medical Event Reporting**

SNMMI and individual members continue to view the extravasation issue through a "patient tissue harm" lens. They do not appear to understand the purpose of the regulation. NRC regulations are designed to ensure that misadministrations/medical events that are the result of human error, lack of training, or lack of quality procedures and cause radiation dose greater than 50 rem to skin or tissue are reported to the NRC, to patients, and to their referring physician. ***The 50 rem threshold is a threshold that does not necessarily indicate patient harm but does indicate the potential that a medical isotope has not been handled appropriately.*** And it was this more risk-informed threshold that SNMMI lobbied the NRC to implement in 2001 and 2002. We understand that no one likes to report, but that is not an acceptable reason to avoid reporting.

### **Future Direction**

PSNM is asking you, the new president of SNMMI, to critically assess this issue.

You stated at the annual meeting that "Everything we do in nuclear medicine is to improve care." If you really mean that, then we ask you to do the following:

- Publicly communicate to the NRC that you have revisited the issue from the patient perspective and that this burden should not be put on the patients.
- Encourage centers to train their technologists, invest in the proper tools, and establish vascular access and mitigation protocols.
- Incent technologists to train on vascular access practices and receive annual credentialing.
- Encourage centers to effectively monitor and characterize extravasations when they happen.
- Adopt a patient-centric policy that includes telling patients, their physicians, and regulators when doses exceed the current reporting limits.

# PATIENTS

FOR SAFER NUCLEAR MEDICINE

We understand that SNMMI has stridently opposed reporting of extravasations, but we have studied this issue and science does not support your position. Neither do patients. Neither do some of the world's top experts in the field. We ask you to redirect your energies and activities from opposing reporting to ensuring that extravasations are reduced to the level that other areas of medicine have achieved.

Let's work together to make nuclear medicine as safe and as transparent as possible. Then let's work together to get the word out to as many patients as possible how nuclear medicine can change their lives.

Sincerely,

*Mary Ajango*

Mary Ajango, Director of Advocacy  
Young Survival Coalition  
PSNM Spokesperson

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