PATIENTS
FOR SAFER NUCLEAR MEDICINE

February 15, 2024

Dear Chairman Hanson,

Thank you for meeting with me and other members of the Patients for Safer Nuclear Medicine (PSNM) coalition on February 7. We appreciate the opportunity to discuss our ongoing concern about the failure of the Nuclear Regulatory Commission to monitor and require reporting of large extravasations, and the concern about improper influence over NRC by the very community it is charged with regulating – in particular, the agency's relationship with the Society of Nuclear Medicine and Molecular Imaging (SNMMI).

I am writing to follow up on some of the key points discussed during the meeting. First, I want to bring to your attention a new case report published by *Frontiers in Nuclear Medicine* entitled: "Radiopharmaceutical extravasation, radiation paranoia, and chilling effect." I urge you to read the entire case report written by a nuclear medicine physician and a Radiation Safety Officer but would like to highlight a key passage from the conclusion of this timely examination of the extravasation issue, and why patient concerns are well-founded:

The SNMMI has long argued against the reporting of radiopharmaceutical extravasations. Most recently, they have stated that they are concerned that patients will forgo important nuclear medicine procedures because of "radiation paranoia" caused by misinformation. ***This statement and their past arguments are not supported by our real-world experience…****We have studied the causes of extravasations. Extravasations are almost entirely preventable. The inadvertent injection of radiation into a patient's tissue can result in unnecessary irradiation and result in doses that easily exceed current reporting requirements. These extravasations also negatively affect the diagnostic imaging procedures that guide patient care.* ***The preventability and consequences of extravasations are supported by numerous peer-reviewed publications. This is not misinformation.*** *We see no scientific justification for holding extravasations to a different standard than other medical events.* ***Providing licensees with an appropriate grace period to address the factors that lead to extravasations and then mandating reports of large extravasations will ensure that licensees are providing the radiation protection and transparency to patients that is needed. (Emphasis added)***

The points noted in the above passage have been concerns of ours since the formation of PSNM in 2021. The Mace/Kiser report places these concerns under a microscope and reaches the same conclusion: SNMMI is misleading NRC about the true scope and underlying concern around extravasation, and could easily fix the issue but steadfastly refuses to do so, instead feeding NRC misleading narratives in an effort to keep a deeply flawed, 44-year old loophole in place.

We would add that the information correction request filed by PSNM with NRC back in 2022 highlighted the same points now being made by this case report: that the SNMMI has provided information that is being used almost verbatim by NRC to make decisions and the case report is further evidence to support that fact.

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We cannot help but be struck by the parallels between NRC and another agency now under the spotlight, the Federal Aviation Administration (FAA), and the multiple deadly recent mishaps involving Boeing 737 Max 8 jets. A February 5 *New York Times* article notes years of foot-dragging from the FAA following incidents in 2018 and 2019, before moving with lightning speed to ground similar planes after a Max 9 door panel blew out in mid-flight. From the article:

[T]he door panel mishap has prompted another wave of questions from Congress about how the nation's air safety regulator exercises its oversight role. The agency has long relied on plane makers to conduct safety work on the government's behalf, a practice that came under scrutiny after the Max 8 crashes and is now drawing attention once again…the F.A.A.'s fast and aggressive response once the door plug blew out in midair was unusual for the agency. ***Considered the most influential aviation regulator in the world, it has been called the "tombstone" agency over the years for not taking action to address potential safety issues until people had died. (Emphasis added)***

This is not an overstatement of our concern. Please don't make the same mistake the FAA has made. Your job at NRC is to protect the public, not the industry. Patient safety, patient care, and with new high dose radiotherapeutics, patient lives are at risk due to extravasation. The mountain of evidence continues to grow in support of getting rid of the extravasation reporting exemption. Yet, even during our meeting on February 7, NRC continues to prolong the process: planning a proposed rule this coming August, more comment periods, and so on and so forth.

While we appreciate your willingness to hear our concerns, the fact remains: patients are still being extravasated daily in the U.S., with some patients receiving large doses of radioactive material injected into their tissue without getting so much as a notification. The potential for patient harm is both obvious and apparent.

How many more patients need to experience extravasation because the NRC is being led astray? Why is NRC prolonging this when the exemption can be erased with the stroke of a pen? You have the power to act today.

Mr. Chairman, for more than three years we have respectfully attempted to work with you in good faith to help patients while seeking ways to minimize the impact on the nuclear medicine industry, which is undeniably important to the health and well-being of countless patients. Clinicians on the ground who deal with nuclear medicine every day are telling you extravasation is a serious problem that can be - *must* be - addressed. Please heed their concerns and consider expediting a solution that includes reporting of large extravasations.

Sincerely,

Mary Ajango, Patients for Safer Nuclear Medicine Coalition Spokesperson