PATIENTS
FOR SAFER NUCLEAR MEDICINE

July 17, 2025

The Honorable Robert F. Kennedy Jr.
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
ASH@hhs.gov

Subject: Urgent Request for Action on Radiopharmaceutical Extravasations and Patient Safety

Dear Secretary Kennedy,

I'm writing on behalf of the Patients for Safer Nuclear Medicine Coalition (PSNM), a collaboration of 30 patient advocacy organizations dedicated to promoting safer nuclear medicine practices. Our coalition proudly includes the Leapfrog Group, which advocates for safer and higher-quality care in hospitals across the United States. Together, we are deeply committed to ensuring radiopharmaceutical administration errors receive the attention and oversight they deserve.

We find it abhorrent that radioactive material accidentally spilled onto a patient's skin is being treated more seriously than radioactive material accidentally injected into a patient's skin.

Your long-standing commitment to wellness, prevention, patient safety, environmental health, and medical transparency uniquely positions you to address the ongoing issue of radiopharmaceutical extravasations. A radiopharmaceutical extravasation occurs when a radioactive drug intended for intravenous injection unintentionally leaks into surrounding tissues instead of fully entering the bloodstream as required by the procedure. This leakage can expose patients to unnecessary radiation, affecting diagnostic accuracy, and treatment effectiveness.

As Secretary of Health and Human Services overseeing the FDA, you have a direct stake in ensuring the safe administration of radiopharmaceuticals, including high-dose radiotherapeutics. Yet adverse events related to extravasations are never reported to the FDA.

This is because **radiopharmaceutical extravasations have never been shared with the FDA, patients, or the public for over 45 years.** The hidden nature of the issue directly results from an incorrect reporting exemption that prevents this particular type of accidental exposure from being reported to the Nuclear Regulatory Commission (NRC) and thus the FDA.

Due to the efforts of our coalition, the NRC has decided to remove the incorrect exemption. However, due to the lobbying of the industry and the officially documented unethical actions by members of the NRC's own advisory committee, the NRC is poised to replace the old reporting loophole with a new loophole. Instead of holding providers to the same objective standard for other accidental exposures, the NRC is proposing to allow nuclear medicine physicians—who represent the industry regulated by the NRC and who have misled the NRC to keep from having to report these accidental exposures—to subjectively determine if an extravasation should be reported based on their perceived "potential radiation injury."

This approach lacks scientific rigor, conflicts with existing NRC dose-based reporting standards, and ultimately denies patients essential transparency regarding medical errors that can significantly impact their health.

Ironically, if a radioactive drug is inadvertently spilled onto a patient and exceeds the risk-informed dose threshold, that incident must be reported to the NRC – yet if the same drug is injected **into a patient's tissue**, no report is required, even if the patient is exposed to extremely high radiation doses. This is irresponsible. Reporting is needed to identify preventable incidents caused by human error, inadequate training, or substandard procedures—events that often expose patients to substantial radiation doses.

This is a critical patient safety issue. Over **30 million** radiopharmaceutical administrations occur annually in the United States, with evidence indicating an extravasation rate exceeding 17%. Alarmingly, 1-2% of all administrations involve significant extravasations capable of impacting diagnostic accuracy or therapeutic efficacy, leading potentially to diagnostic errors, and improper treatment decisions. Younger patients have an increased risk of secondary cancer.

Given your commitment to wellness, prevention, patient advocacy, and medical transparency, we respectfully request that you:

1. Directly engage with the NRC to highlight how their current approach prevents the FDA from being informed about serious radiopharmaceutical extravasation incidents that constitute reportable adverse events.
2. Encourage the NRC to adopt objective safety and quality standards for radiopharmaceutical administration, similar to those implemented by the FDA for mammography, ensuring that patients receive the highest quality care.
3. Ensure an FDA representative with ionizing radiation expertise and a concern for patient safety is appointed to the NRC's Advisory Committee on Medical Use of Isotopes (ACMUI).

We would appreciate the opportunity to discuss this critical matter further and explore ways to collaborate in eliminating preventable harm within nuclear medicine.

Thank you for your ongoing leadership in patient safety and healthcare transparency. We look forward to your support in making nuclear medicine safer for all Americans.

Sincerely,

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

Cc: David Wright, Chairman, Nuclear Regulatory Commission
Marty Makary, MD, Commissioner of Food and Drugs
Representative Ben Cline
Representative Don Davis
Representative Morgan Griffith
Representative Brett Guthrie
Representative Frank Pallone