



March 27, 2025

Dr. Marty Makary
Johns Hopkins University School of Medicine
733 N Broadway
Baltimore, MD 21205

Subject: Urgent Need for Your Voice on Radiopharmaceutical Extravasations and Medical Transparency

Dear Dr. Makary,

I'm reaching out on behalf of the Patients for Safer Nuclear Medicine Coalition, a collaboration of 30 patient advocacy organizations committed to advancing safer nuclear medicine practices. We are proud to have the Leapfrog Group, a watchdog organization advocating for safer, higher-quality care in U.S. hospitals, as a member of this vital coalition. Together, we are committed to ensuring that radiopharmaceutical administration errors receive the attention they deserve.

We appreciate your dedication to exposing medical errors and advocating for greater transparency in healthcare. Your research has shown that medical errors are a leading cause of death in the United States. In your new role at the FDA, you can help bring attention to these preventable errors in nuclear medicine, called extravasations, that expose patients to unnecessary radiation, can compromise diagnostic accuracy and therapeutic delivery, and ultimately drive up the cost of healthcare.

For over 45 years, radiopharmaceutical extravasations have remained hidden. As a result of the coalition's efforts, the Nuclear Regulatory Commission (NRC) has had to finally address this issue. Rather than truly address these medical errors, instead, the NRC are considering a rule that would allow nuclear medicine physicians—who are part of the industry the NRC regulates—to decide whether an extravasation should be reported, based on their **subjective judgment** of "potential radiation injury." This approach lacks scientific rigor, fails to align with existing NRC dose-based reporting thresholds, and ultimately **keeps patients in the dark** about medical mistakes that could impact their health.

Patients deserve transparency, accountability, and evidence-based safeguards against preventable medical harm. The NRC requires medical event reporting for all other accidental radiation exposures **except radiopharmaceutical extravasations**. Medical event reporting helps identify patient safety accidents that are the result of human error, lack of training, or lack of quality procedures and that result in a very large radiation dose to patients. The NRC is doing all

they can to keep radiopharmaceutical extravasations unreported. Instead, they want to maintain the status quo, where these events remain hidden from patients and regulators.

This is a serious matter for patients. Over 30 million radiopharmaceuticals are administered every year. The evidence shows that over 17% are extravasated and between 1-2% of all administrations are so large that the patient's procedure is affected.

The FDA should be concerned, as your agency approves radiopharmaceuticals, including high-dose radiotherapeutics. However, these treatments are not always being administered properly. How many adverse events have been reported to the FDA? Likely none because they are swept under the rug.

We believe your voice can help **push for real accountability and patient safety in nuclear medicine**. Your expertise in patient advocacy and exposing hidden medical errors makes you uniquely positioned to bring this issue into the national conversation. That is why we request that you consider taking the following steps:

- Engage directly with the NRC to make clear that the Commission's failure to require reporting of large extravasations results in the FDA not being informed of these incidents for required Adverse Event reporting. Large extravasations should be reported to the FDA, similar to how chemotherapy drug misadministrations are reported.
- Urge the NRC to learn the lesson the FDA learned about mammography standards – objective safety and quality standards are necessary to ensure that patients receive safe and effective care.
- Appoint an FDA representative to the NRC's Advisory Committee on Medical Use of Isotopes (ACMUI) who has demonstrated understanding of the impact of nuclear medicine extravasations on patient safety and quality of care.

We would greatly appreciate the opportunity to discuss this with you and explore ways to work together to **eliminate preventable harm** in nuclear medicine.

Thank you for your dedication to medical transparency and patient safety. We look forward to your thoughts and hope for your support in making nuclear medicine safer for all.

Sincerely,

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

www.safernuclearmedicine.org