PATIENTS
FOR SAFER NUCLEAR MEDICINE

July 9, 2025

Chairman Wright,

Congratulations on becoming the new Chairman of the Nuclear Regulatory Commission (NRC). We are contacting you because the NRC continues to take a radiation protection position that has failed millions of patients for more than four decades by leaving them exposed to potential radiation harm.

We represent individual members and participating organizations of Patients for Safer Nuclear Medicine (PSNM), a coalition of 30 national and regional non-profit patient advocacy groups focused on revising the NRC's 45-year-old policy loophole regarding extravasation.

We respectfully urge you - as part of the Trump Administration's goal to Make America Healthy Again - to root out the incessant deferment to the regulated industry that infests NRC and fails to protect the health and welfare of patients nationwide.

Over the past 5 years, we made every good-faith effort to engage in a constructive dialogue with the NRC, including two meetings with former Chairman Hanson. PSNM submitted countless letters and papers, provided patient and provider testimony, issued news releases and social media posts, engaged in meetings, and so on. To date, the NRC has failed to take any action to monitor and require reporting of large extravasations, which occur when radioactive material is inadvertently injected into arm tissue instead of a vein.

Let us be clear: nuclear medicine is essential. We embrace its use in diagnosis and treatment decisions for patients. Nearly 30 million injections of radiopharmaceuticals are administered annually to American patients to scan for diseases including cancer, heart problems, and brain diseases.

Despite what you are hearing from the community you regulate, and the societies focused on protecting only their members and not the patients they serve, nuclear medicine administrations are not without hazards. In fact, the European Association of Nuclear Medicine in cooperation with EURADOS sponsored an entire seminar focused on extravasations and their hazards. This seminar highlighted the extravasation incidence rate, the harmful consequences from extravasated diagnostic and therapeutic radiopharmaceuticals, and the need to identify, characterize, and report large extravasations.

Unfortunately, because of the NRC's deferment to the nuclear medicine clinicians and their societies in the U.S., nearly five million patients are extravasated annually and approximately 500,000 patients experience large extravasations. Why is it that the European nuclear medicine community can recognize radiation protection and procedure issues with extravasations? Why is the U.S. lagging Europe on this issue? We should be leading the way.

If an extravasation occurs in the U.S., care teams are not even required to inform the patient, let alone alert the NRC. This situation can be traced back to the incorrect reporting exemption that the NRC established an astonishing 45 years ago. It is disappointing that this regulatory loophole still exists today, even after you, and your fellow commissioners, approved a petition for rulemaking three years ago that clearly showed the reporting exemption is incorrect.

Ironically, if nuclear medicine is inadvertently spilled onto a patient and exceeds your risk-informed dose threshold, that incident must be reported to the NRC – yet if it is injected into a patient's tissue accidentally, no report is required, even if the patient is exposed to radiation doses that hundreds times larger than your existing reporting threshold. This is irresponsible regulation.

Due in no small part to our years of effort, the NRC finally issued Draft Regulatory Guide DG-8062 for radiopharmaceutical extravasation reporting. However, it is a half-hearted effort to placate critics of NRC's **"patients-last"** policy.

The draft guide fails to require dosimetry to quantify the potential impact of extravasations to ensure appropriate follow-up care. The draft guide provides subjective reporting criteria and puts the responsibility to report in the hands of the community that doesn't want extravasations reported at all. The application of objective, dose-based and risk-informed standards is essential to determine whether an extravasation should be reported as a medical event.

Incredibly, the draft guide is based on the exact suggested wording from the regulated industry that violated federal ethics rules in the development of extravasation policy. We know because PSNM was also attending the September public comment meeting years ago when SNMMI suggested the harm-based criteria your staff adopted. In March 2024, the NRC Office of the Inspector General (OIG) concluded that two members of the NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI) were also key members of the Society of Nuclear Medicine and Molecular Imaging (SNMMI). This connection violated federal ethics rules pertaining to their response to the extravasation rulemaking petition. Read the full OIG report here: https://bit.ly/NRCOIG.

PSNM filed a separate complaint with the OIG in October 2023 with five evidence-backed examples of how NRC disregarded vital clinical data, cultivated factual errors in NRC documents, and more. We are told this remains under investigation but is yet another example of foot-dragging. We still await a formal response more than **20 months** after filing the complaint.

The NRC has known (at least since 2009) that their original extravasation reporting exemption was in error. Why are millions of patients still being unnecessarily exposed to potential harm 16 years later? Extravasations would virtually disappear almost overnight if the NRC made extravasations reportable, just like any other medical event. Reporting requirements will provide nuclear medicine centers with the justification they need to fund training to reduce extravasation.

PATIENTS
FOR SAFER NUCLEAR MEDICINE

Reporting drives improvement, as evidenced by its effectiveness in addressing other medical errors.

PSNM will continue to push to get the exemption immediately removed and large exposures reported to patients, their doctors, and to the NRC. We will continue to connect with the news media and spread the word on our social media channels. We will continue to push Congress to force the NRC to do what they should have done 45 years ago.

Chairman Wright, we believe closing the extravasation loophole is an easy fix. We are obviously frustrated by the degree to which the NRC has let down patients in favor of shielding the community it is charged with regulating. We hold out hope that you will drive much-needed change and welcome the opportunity to meet with you to discuss the policy further.

Sincerely,

Mary Ajango, Director, Advocacy & Partnerships
Young Survival Coalition (YSC)

CC:
Commissioners Caputo, Marzano, and Crowell
Representative Davis, Representative Griffith, and Representative Cline
Russell Vought
Vince Haley

Patients for Safer Nuclear Medicine Coalition Non-Profit Members Include:

2 for 2 Boobs
ACE Collaborative
Bay Area Cancer Connections
Cactus Cancer Society
Cancer in the Know
Cancer is an Asshole
Carrie's Touch
Cervivor
Chicago Hispanic Health Coalition
Dia de la Mujer Latina Inc
Dr. Susan Love Foundation
Elephants & Tea
Inflammatory Breast Cancer Research
International Cancer Advocacy Network
My Sister My Friend Breast Cancer Support
New Day Foundation for Families
Patients Rising Now
Peer Plus Advocates
Research Advocacy Network
Steven G Cancer Foundation
Stupid Cancer
Survivingbreastcancer.org
Teen Cancer America
The Leapfrog Group
The Pink Fund
Tigerlily Foundation
Touch, The Black Breast Cancer Alliance
Veterans Prostate Cancer Awareness
Young Adult Survivors United
Young Survival Coalition