



July 17, 2024

Dave Adler: [dave.adler@astro.org](mailto:dave.adler@astro.org)

Anne Hubbard: [anne.hubbard@astro.org](mailto:anne.hubbard@astro.org)

Re: Clarification on Statements Regarding Radiopharmaceutical Injections and Patient Safety

Dear Mr. Adler and Ms. Hubbard,

I am writing to you on behalf of the Patients for Safer Nuclear Medicine Coalition (PSNM) to seek clarification regarding statements made by the American Society for Radiation Oncology (ASTRO) in two separate correspondences concerning radiopharmaceutical injections and their impact on patient safety. ASTRO statements have been shared with our coalition by members of your own organization.

In your letter to the Nuclear Regulatory Commission (NRC) dated August 31, 2023, ASTRO acknowledged that “serious patient harm can occur if an injection of a radiopharmaceutical goes awry.” This acknowledgment underscores the risks associated with radiopharmaceutical extravasations and aligns with our coalition’s belief that large extravasations should be reported as a medical event to the NRC like any other medical event and to the affected patient who has an inalienable right to know that this exposure has occurred.

However, in a subsequent letter to Congress dated May 31, 2024, ASTRO stated that increased oversight of radiopharmaceutical extravasations would have “no radiological or patient safety benefit.” This assertion is contradictory to your earlier acknowledgment of the potential for serious patient harm and raises concerns about the consistency and rationale behind ASTRO’s stance on this critical issue. In fact, the ASTRO supported website, [RT Answers](#), emphasizes delivering radiation safely and accurately, avoiding healthy tissue and organs. An extravasation can deposit large amounts of radiation in healthy tissue and result in absorbed doses that clearly are not in the patient’s best interest; doses that are known to result in deterministic effects weeks, months, or years later.

We find it essential to understand the basis for these seemingly contradictory statements. It is vital to ensure that patient safety is not compromised and that medical societies like ASTRO uphold their commitment to protecting patients above all else. Therefore, we respectfully request clarification on the following points:

1. **Risk Acknowledgment:** Given ASTRO’s acknowledgment of the potential for serious patient harm due to radiopharmaceutical extravasations, and given that most radiopharmaceutical extravasations can go unnoticed by patients, technologists, and reading physicians since the injection sites are rarely in the imaging field of view, what *specific evidence* led to the conclusion that additional oversight would provide no radiological or patient safety benefit?
2. **Evidence and Rationale:** We have identified numerous published studies and consulted with leading experts, all of whom concur that large extravasations can result in severe patient harm and compromise the resulting images that guide patient care. Could you please provide the clinical papers and the evidence from these papers that support your statements in your May 31 letter to members of Congress? Please note that our experts are leading members of your society and they have volunteered to evaluate your evidence.



- 3. Safety Measures:** We acknowledge that when radiopharmaceuticals are administered correctly, the benefits from nuclear medicine procedures far outweigh the risks associated with the radioactive materials injected into patients. However, we also know that when these radioactive drugs are misadministered, the risk/benefit ratio changes. What alternative measures, if any, does ASTRO propose to mitigate the risks associated with radiopharmaceutical extravasations and ensure patient safety? As patients who have received radiopharmaceutical injections, we are aware that most radiopharmaceuticals are not vesicants, that the injected volume is too small to cause visible swelling, and that it is extremely difficult to identify an extravasation at occurrence without using proper technology.

The ASTRO involvement in the May 31 letter to Congress suggests that ASTRO has lost focus on patient safety and ensuring the highest standards of care.

We hope your participation in the letter was an oversight and we are committed to working collaboratively with you to enhance safety protocols and reduce the risk of extravasations in nuclear medicine practices. We hope to engage in a constructive dialogue to address these important patient safety concerns. We are also lending our support to the six experts who provided a rebuttal of your letter on July 1, by copying the same members of Congress on this communication to you. Thank you for your attention to this matter and we look forward to your prompt response.

Sincerely,

Simon Davies, Executive Director  
Teen Cancer America, a partner in the Patients for Safer Nuclear Medicine Coalition

Mary Ajango, Director, Advocacy & Partnerships  
Young Survival Coalition, a partner in the Patients for Safer Nuclear Medicine Coalition

CC:  
Rep. Morgan Griffith  
Rep. Don Davis  
Rep. Ben Cline  
Rep. Jeff Duncan  
Rep. Diana DeGette  
Rep. Tom Carper  
Rep. Shelley Moore Capito  
Rep. Chuck Fleischmann  
Rep. Marcy Kaptur  
Sen. Patty Murray  
Sen. John Kennedy