



April 3, 2024

Dear Chairman Hanson,

On behalf of the Patients for Safer Nuclear Medicine (PSNM) coalition, I am contacting you regarding the report issued March 26, 2024 by the Nuclear Regulatory Commission Office of the Inspector General (OIG) entitled “Special Inquiry into the Appearance of a Conflict of Interest Involving Members of the Advisory Committee on the Medical Uses of Isotopes.”

Unfortunately, the OIG findings are not a shock to us. PSNM has made no secret of its concern about the conflicts of interest that exist between NRC, its paid advisory committee members, and the Society of Nuclear Medicine and Molecular Imaging (SNMMI). Throughout the rulemaking process, PSNM has been concerned not only about the failure of NRC to close the 44-year-old extravasation loophole, but also the improper influence exercised over NRC by the community the NRC is supposed to regulate.

The OIG report makes crystal clear that NRC used biased information from conflicted advisors to develop the rule that you are now advancing, which essentially requires patients to diagnose and report their own radiopharmaceutical extravasations. Members of NRC’s Advisory Committee on the Medical Uses of Isotopes (ACMUI) violated federal ethics rules regarding rulemaking around extravasations. These members were on the subcommittee dealing with the extravasation topic and they were active leaders in SNMMI, an organization devoted to blocking the reporting of large extravasations. They never should have participated in discussions on the topic.

According to the OIG report, **“These members...carried out a campaign opposing PRM-35-22, at the same time they worked for the ACMUI on matters related to the petition.” (emphasis added)**

We were also struck by the systemic failures outlined in the OIG report, including the note that **“NRC does not currently have a policy requiring staff to perform conflict-of-interest reviews before assigning particular tasks to ACMUI members. The NRC, therefore, lacks internal controls in this context that could facilitate compliance with federal ethics requirements and help avoid both actual and apparent conflicts of interest.” (emphasis added)**

Although it was not mentioned in the report, the current patient advocate on ACMUI receives funding from SNMMI through his nonprofit organization, Northern California CarciNET. He has never met with our coalition to hear the patient perspective. Through an online SNMMI forum, he actively encouraged SNMMI members to voice their opinions on NRC’s most recent public comment process. This is a clear conflict of interest. NRC’s selection of this patient advocate for the ACMUI reinforces the systemic failures that OIG discussed in their report. The former patient advocate on ACMUI assigned to the subcommittee on extravasations did not receive funding from SNMMI and publicly opposed ACMUI’s position on the petition.



While the OIG report is troubling, we hope you will agree that there is a clear path forward to not only help protect patients but also show that NRC is committed to establishing its independence from special interests.

We ask you to please cancel the extravasation reporting exemption and require providers to take action to prevent large extravasations in the future. The premise for the exemption has been proven to be incorrect. Removing the exemption ensures extravasations are reportable.

Extravasations remain a daily occurrence in the U.S. How many more patients need to experience an extravasation?

You could take the action to close the loophole, which would help protect patients from harm while encouraging nuclear medicine providers to develop procedures that minimize extravasations in the future. This action would also go a long way toward establishing NRC's independence and credibility within the patient community.

The OIG report has exposed ethics violations within NRC that have thus far blocked real extravasation reform. Why continue to make patients pay the price? Show patients that your concern for their well-being trumps the arguments coming from those who think the status quo on extravasation is sufficient.

Please let me know if you have any questions. I look forward to your next steps with great interest.

Sincerely,

Simon Davies
Executive Director, Teen Cancer America
Spokesperson, Patients for Safer Nuclear Medicine Coalition