PATIENTS PRAISE CONGRESS FOR ACTION ON NUCLEAR MEDICINE SAFETY

House-passed Appropriations Bills Include
Key Measures to Improve Nuclear Medicine Patient Safety

<u>Patients for Safer Nuclear Medicine</u>, a coalition of 29 patient advocacy organizations representing thousands of patients, along with more than 600 concerned US citizens today praised the House of Representatives for passing two appropriations bills that include important language calling on federal agencies to improve patient safety in nuclear medicine.

Radioactive drug misadministrations caused by human error, inadequate training, lack of quality procedures, and that exceed defined radiation dose thresholds are currently reportable to NRC. Extravasations occur when radioactive drugs used in nuclear medicine procedures are inadvertently injected into the patient's tissue instead of a vein. Despite potential consequence to patient safety, even the most severe extravasations are exempted from NRC reporting requirements due to a 42 year-old loophole in NRC policy.

Appropriations bills passed by the House of Representatives last week call on the U.S. Nuclear Regulatory Commission (NRC) to update its internal rules on reporting significant unintended irradiation, and call on the Veterans Health Administration to monitor injection quality and report significant extravasations.

"30 million administrations of radioactive drugs occur every year in the US, but NRC has excluded extravasations from reporting, even if they cause radiation doses hundreds of times higher than other reportable events," says Patients for Safer Nuclear Medicine spokesperson Mary Ajango. "Patients need to know if their care is affected. The worst approach is to do nothing and wait for patients to be injured."

The House-passed package of Appropriations bills included the following language regarding NRC: Re-Evaluation of Nuclear Medicine Event Reporting — The Committee is closely monitoring the Commission's reconsideration of its policy related to significant extravasations and medical event reporting. Evidence shows that nuclear medicine extravasations may be avoidable and that some extravasations may exceed medical event reporting provided in 10 C.F.R. Part 35 Subpart M. These events may harm patients through unintended radiation exposure, compromised imaging that negatively affects care, additional interventional procedures, and repeated imaging procedures. The Committee continues to encourage the Commission to consider the inclusion of significant extravasations in medical event reporting to improve safety, quality, and transparency for patients, treating physicians, and the Commission itself.

The package also included the following language regarding the VA:

Nuclear Medicine Quality Improvements —The Committee is aware of the consequence of extravasations in nuclear medicine procedures, and understands that the Nuclear Regulatory Commission and Centers for Medicare and Medicaid Services are considering regulatory actions to improve nuclear medicine injection

quality. The Committee continues to encourage VA to monitor injection quality, as well as image extravasations, perform dosimetry and notify patients when they occur, and urges the Department to adopt any new regulatory requirements.

Recent op-eds have also called for the NRC to corrects its outdated policy, including an article in <u>The Cancer Letter</u> and two opinion pieces published <u>by a radiation oncologist</u> and <u>the coinventor of the PET/CT scanner.</u>