

**PRO-PATIENT BIPARTISAN BILL TARGETS DECADES-OLD  
NUCLEAR REGULATORY COMMISSION LOOPHOLE**  
*Patients for Safer Nuclear Medicine coalition praises introduction of federal  
Nuclear Medicine Clarification Act to protect patients from the harm of extravasation.*

**WASHINGTON DC** - [Patients for Safer Nuclear Medicine](#), a coalition of 30 non-profit organizations advocating on behalf of patients nationwide, today praised the introduction of a federal bipartisan bill intended to protect patients undergoing nuclear medicine procedures.

The Nuclear Medicine Clarification Act (**H.R. 6815**) would close a regulatory loophole that has existed since 1980 for reporting mistakes during nuclear medicine procedures used to diagnose cancer and cardiovascular disease. The bill's authors include **Rep. Morgan Griffith (R-VA) and Rep. Don Davis (D-NC)**.

Every year in the U.S., medical professionals administer radioactive drugs nearly 30 million times as part of PET and SPECT procedures to diagnose cancer, heart and brain diseases, and more. These diagnostic images help clinicians determine the optimal course of treatment. Because these drugs are tagged with medical isotopes, the U.S. Nuclear Regulatory Commission (NRC) is responsible for their proper use and for ensuring that mistakes that accidentally expose patients to high radiation doses be reported to the NRC.

One such mistake is when radioactive drugs are accidentally injected or extravasated into the patient's tissue instead of a vein. Large extravasations can lead to high radiation doses that can cause pain and damage to underlying tissue, visible skin damage, and increased risk of cancer. Critically, extravasations can also negatively impact the images used to guide care.

"Shockingly, an NRC policy exempts clinicians from currently reporting an extravasation to the NRC. Even worse, there is no requirement to tell the patient in question that he or she has been extravasated," notes Mary Ajango, spokesperson for Patients for Safer Nuclear Medicine. "If radiation is inadvertently spilled *onto* a patient, that incident must be reported to NRC – yet if it is accidentally injected *into* a patient's tissue, no report is required. This policy makes zero sense and opens the door to lasting patient harm."

The Nuclear Medicine Clarification Act would close the loophole by requiring large extravasations are reported to the NRC as medical events, just like any other reportable event. It is estimated that 500,000 large extravasations merit reporting to the NRC each year. Evidence suggests that the transparency that comes with reporting could quickly reduce the number of large extravasations to fewer than 3,000 annually.

"To date, the NRC has failed to act in the best interests of patients. Legislation appears to be necessary to protect patients and inform them when mistakes happen." Ajango adds.

Patients for Safer Nuclear Medicine has led the effort to change NRC policy. While NRC accepted a petition to require reporting of some extravasations, the Commission's draft proposed rule merely creates new ways to avoid reporting. NRC's proposed solution will take years to enact and utterly fails to protect patients. Rather than encouraging clinicians to improve injection quality, NRC is proposing patients self-diagnose an extravasation and then convince the physician responsible for the extravasation to report it.

"This can be a costly, time-consuming process for patients, many of whom are already coping with a debilitating illness and don't need the additional stress and potential harm," Ajango says. "NRC has created an unacceptable non-solution, which is why we are grateful to members of Congress who recognize extravasations as a threat to the health and well-being of patients."