



Date: January 18, 2024

The Honorable Morgan Griffith (R-VA)  
2202 Rayburn House Office Building  
Washington, DC 20515

The Honorable Don Davis (D-NC)  
1123 Longworth House Office Building  
Washington, DC 20515

The Honorable Ben Cline (R-VA)  
2443 Rayburn House Office Building  
Washington, DC 20515

Dear Representatives Griffith, Davis, and Cline:

On behalf of the Leapfrog Group, our Board of Directors, and members who collectively comprise hundreds of leading purchaser and employer organizations across the country, we commend your introduction of the Nuclear Medicine Clarification Act (H.R. 6815) and offer our endorsement for its enactment into law.

The Leapfrog Group is committed to improving the safety, quality, and affordability of health care with meaningful metrics that inform consumer choice, payment, and quality improvement. Above all Leapfrog is a strong advocate for transparency in health care. For several years, we have watched with interest and concern as the U.S. Nuclear Regulatory Commission (NRC) has considered an update to its 44-year-old policy that erroneously exempted the medical event reporting of extravasations and failed to take patient-positive action that improves care and promotes transparency.

By NRC's estimation, 28,000 large nuclear medicine extravasations occur annually in the United States. NRC itself also acknowledges that these diagnostic and therapeutic misadministration can exceed statutory reporting limits, that they can cause injury, and that the current policy can result in patients never being told about this issue with their care. We find this situation to be unacceptable; that is why we participated in public comment on NRC's draft proposed rule on July 17, 2023, urging the Commission to make large nuclear medicine extravasations subject to the same 'medical event' reporting procedures as every other type of unintentional irradiation.

The Nuclear Medicine Clarification Act (H.R. 6815) would eliminate the loophole that currently allows large nuclear medicine extravasations – including those that cause harm or misdiagnosis – to be hidden from patients and from NRC itself. By using the same objective dose threshold as is used for all other reporting, licensees will be required to take immediate steps to mitigate potential harm. We also support including a grace period for reporting to ease burden of implementation.

Thank you for introducing this important legislation focused on improving care and transparency for patients. Please let me know if there are questions or if there is more the Leapfrog Group can do to help.

Sincerely,

A handwritten signature in black ink, appearing to read "Leah Binder". The signature is written in a cursive, flowing style.

Leah Binder, M.A., M.G.A  
President & Chief Executive Officer  
The Leapfrog Group