Congress of the United States
Washington, DC 20515

June 18, 2020

The Honorable Kristine L. Svinicki
Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Chairman Svinicki,

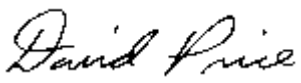
We are writing to respectfully urge the Nuclear Regulatory Commission (NRC) to expeditiously grant the petition for rulemaking Docket No. PRM-35-22 filed by Lucerno Dynamics, LLC. This petition would require licensees to report infiltrations – in which an injected radiopharmaceutical partially misses a vein and the dose is injected into a patient's soft tissue – that exceed existing medical event criteria to the NRC. There is concern amongst our constituents that existing NRC policy fails to protect the safety of patients who undergo diagnostic and therapeutic nuclear medicine procedures. We hope that through a public rulemaking, the NRC can establish clearer safety standards, increase transparency to patients, and protect the public from unintended irradiation.

In 1980, the NRC instituted a policy exempting infiltrations from medical event reporting requirements on the understanding that infiltrations occur frequently and are "virtually impossible to avoid," even if the infiltration irradiates patient tissue with doses that exceeds threshold reporting requirements. Since that time, we understand that new evidence provided to the NRC demonstrates that infiltrations can result in direct and indirect harm to patients and are avoidable through dedicated monitoring and quality improvement planning. This new evidence should be considered when updating these rules.

Since 1980, NRC's outside Advisory Committee on the Medical Uses of Isotopes has recommended maintaining the infiltration reporting exemption, citing concerns about administrative and reporting mechanisms while discounting evidence of patient safety implications. While we are sensitive to the administrative burdens facing providers who regularly infiltrate patients, such concerns are resolvable and cannot eclipse the need to protect patients and ensure the delivery of safe, high-quality health care services. We urge the NRC to prioritize patient safety.

We call on the NRC to grant the petition for rulemaking [docket number]. Infiltrations are avoidable and reporting of these events to the NRC will improve the safety and quality of diagnostic and therapeutic nuclear medicine procedures. Thank you for your attention to this matter.

Sincerely,



David Price
Member of Congress

George Holding
Member of Congress

G. K. Butterfield
Member of Congress

For Immediate Release
July 16, 2020
Contact: Matt Dennis 703-615-1007

2021 Appropriations Bills Enhance Nuclear Medicine Patient Safety, Transparency

Reports Accompanying Annual 'Must-Pass' Bills Direct NRC, CMS, VA to Prioritize Patient Safety

CARY, NC – Lucerno Dynamics, a North Carolina-based medical technology company, today announced that Fiscal Year 2021 bills advanced this week by the House Appropriations Committee to the House floor include critical language to protect the safety of nuclear medicine patients and enhance transparency within the American healthcare system.

Ron Lattanze, CEO of Lucerno Dynamics, said, "Patients undergoing nuclear medicine procedures want to know their procedures were performed safely and effectively. An infiltration or extravasation occurs when a radio-pharmaceutical is injected into the patient's tissue instead of their vein. Significant extravasations can negatively affect disease diagnosis and treatment in the short-term and can lead to adverse tissue reactions from the radiation in the long-term. We are pleased that Congress is asking federal agencies to prioritize patient safety by improving medical event reporting and encouraging communication with patients of these surprisingly frequent and preventable extravasations. These Congressional requests support the nuclear medicine community's goals of delivering high-quality and patient-centered procedures."

Lattanze continued, "It is essential that a patient (and their physician) be informed when a patient receives an unintentional dose of radiation to their tissue that exceeds the Nuclear Regulatory Commission (NRC) reporting limits. Our sincere thanks to Reps. David Price (D-NC) and George Holding (R-NC) for their focus on patient safety and transparency in their work to secure this important language."

Congressman David Price (D-NC), said, "Data helps paint a full picture when evaluating the safety of medical procedures. I'm pleased to see that the Appropriations Committee adopted report language to urge the federal government to keep patient safety at the forefront of nuclear medicine event reporting, and to request a briefing from the Nuclear Regulatory Commission on their progress and findings in investigating this issue."

NRC

The report accompanying the Energy & Water Development Appropriations bill includes the following provision focused on the NRC:

> *Re-Evaluation of Nuclear Medicine Event Reporting*.—The Committee is pleased the Commission is independently evaluating extravasation medical event reporting and is engaging outside stakeholders and the Organization of Agreement States. Extravasations that exceed medical event reporting limits provided in 10 C.F.R. Part 35 Subpart M can harm patients through unintended radiation exposure, compromised imaging that negatively affects care, additional interventional procedures, and repeated imaging procedures. The Committee is concerned that the recommendations from the NRC Advisory Committee on Medical Use of Isotopes regarding the medical event reporting of extravasations are not focused on patient safety. The Committee encourages the Commission to keep patient safety at the forefront and to complete its evaluation of the inconsistent approach to medical event reporting expeditiously. Consistent application of medical event reporting criteria will reveal potential problems, both local or generic issues, with a facility's medical use of radioactive material and ensure that affected patients and their physicians will know about extravasations that exceed reporting limits. The Committee encourages the Commission to clarify when extravasations should not be excluded from the medical event reporting criteria and directs the Commission to provide a briefing on this topic not later than 30 days after enactment of this Act.

CMS

The report accompanying the Labor, Health & Human Services, Education Appropriations bill includes the following provision focused on Centers for Medicare & Medicaid Services (CMS):

> *Extravasations*.—The Committee is aware of evidence demonstrating the prevalence of extravasations in nuclear medicine procedures. Extravasations of diagnostic radiopharmaceuticals negatively affect the sensitivity and quantification of nuclear medicine scans and can affect disease staging and treatment assessment, result in unnecessary invasive procedures and additional radiation exposure, and lead to higher costs for patients and payers. The Committee is pleased CMS is engaging with outside stakeholders to consider using a variety of levers to encourage providers to engage in nuclear medicine injection quality control and assurance. The Committee requests an update on this issue in the fiscal year 2022 Congressional Budget Justification.

VA

The report accompanying the Military Construction & Veterans Affairs Appropriations bill includes the following provision focused on the Veterans Health Administration (VHA):

> *Nuclear Medicine Quality Improvements*.—The Committee is aware of evidence demonstrating the prevalence of extravasations in nuclear medicine procedures. Extravasations of diagnostic radiopharmaceuticals negatively affect the sensitivity and quantification of nuclear medicine scans. Extravasations can affect disease staging and treatment assessment, result in unnecessary invasive procedures and additional radiation exposure, and lead to higher costs for patients and payers. Additionally, extravasations of diagnostic and therapeutic radiopharmaceuticals can expose patient's tissue to radiation doses that far exceed dose thresholds that are known to lead to side effects. As America's largest integrated healthcare system, VHA should lead by example in acting to reduce medical errors and medical waste. The Committee encourages VHA to monitor injection quality, image extravasations when they occur, perform dosimetry, notify patients and their physicians when doses exceed reportable limits, and implement programs to reduce extravasations in the future. The Committee requests an update on this issue in the fiscal year 2022 Congressional Budget Justification.

Background
NRC requires nuclear medicine providers to report medical events that result in unintended irradiation of patient's tissue of a dose equivalent greater than 0.5 Sieverts. However, since 1980, a loophole in this rule has exempted extravasations from these reporting requirements, even when patients received extremely high doses. In creating this loophole 40 years ago, NRC's belief was that extravasations are inconsequential, occur frequently, and are "virtually impossible to avoid."

For more than a year, Lucerno Dynamics has presented scientific and clinical evidence to NRC and its Advisory Committee on Medical use of Isotopes (ACMUI), that providers can drastically reduce the occurrence of extravasations with dedicated monitoring and feedback to the injection technologists. This evidence included positive results from the largest quality improvement project ever conducted for nuclear medicine injections and letters of support from leaders in nuclear medicine, imaging technology, and patient advocacy. Lucerno also provided 23 recent extravasation cases where patient tissue was unintentionally irradiated with doses far in excess of NRC's 0.5 Sieverts limit.

Momentum Building
The appropriations report language is the most recent indication of the momentum building to protect patients, improve care, and increase transparency.
In January, the NRC stated it was conducting and "independent evaluation" of the extravasation issue.

In February, the Organization of Agreement States (OAS), whose member states regulate 89% of the nation's radioactive materials users, wrote a letter to NRC calling on the agency to change its outdated policy. The OAS letter says, "The Board is happy to hear the Commission has directed an independent review of extravasations." The letter continued, "[M]edical events] are possible by the injection of the radiopharmaceutical into an unintended tissue and should be reported upon occurrence."

In May, Dr. David Townsend, co-inventor of the PET-CT scanner, published an opinion column in STAT arguing that NRC's current "inconsistent reporting requirements make little sense." Dr. Townsend argued that updating this 40 year-old policy to require consistent medical event reporting requirement "would be a small step for hospitals to implement but a big step towards improving patient care."

A petition for rulemaking is currently pending before NRC on the issue. The rulemaking petition and public comment process provide an opportunity for subject matter experts, patient advocates, state-based regulators, and the general public to convey their support for prioritizing patient safety and transparency.

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