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## House and Senate Act on Nuclear Medicine Safety

*Appropriations bills passed by each chamber include important provisions to protect safety and quality of care for patients*

CARY, NC – Lucerno Dynamics, a North Carolina medical technology company, today praised both the U.S. House of Representatives and the U.S. Senate for passing legislation that includes important provisions regarding a patient safety issue that affects thousands of patients every year and pushing the U.S. Nuclear Regulatory Commission (NRC) and Veterans Health Administration (VHA) to put patients first.

**“Patients expect and deserve to benefit from high quality care, and I am pleased that both the House and the Senate have taken strong action on behalf of patients by passing these provisions,”** said Ron Lattanze, CEO of Lucerno Dynamics. **“Patients who experience a radioactive drug extravasation have ionizing radiation stuck in their arm tissue, instead of their vein. Large extravasations need to be identified immediately so clinicians can start mitigation right away. These extravasations need to be measured and documented, and patients and their doctors need to be told since patient care may be affected. Congress is sending a clear message to the NRC and to the VHA: Don’t wait for patients to be injured; ensure your regulations and policies are focused on protecting patients. I am thankful to the members of Congress for putting patients first.”**

The FY24 Energy & Water bill was passed by the House on October 26<sup>th</sup> by a vote of 210-199, including the following provision.

*Nuclear Medicine Event Reporting.*—The Committee applauds the Commission’s acceptance of Petition for Rulemaking PRM–35– 22 and acknowledgments that large nuclear medicine extravasations can cause patient injury and that reporting such occurrences could improve patient care. The Committee strongly encourages the Commission to thoroughly consider all comments received during the proposed preliminary rulemaking comment period related to reporting criterion on patient harm. The Committee further encourages the Commission to utilize the risk-informed, dose-based reporting threshold the Commission uses in other aspects of radiation protection for reporting of large extravasations.

The FY24 Military Construction-VA bill was passed by the Senate on November 1<sup>st</sup> by a vote of 82-15, including the following provision:

*Nuclear Medicine Quality Improvements.*—The Committee notes the Nuclear Regulatory Commission recently began a rulemaking process to require reporting of some nuclear medicine extravasations. The Committee encourages all VA health facilities to monitor injection quality, as well as image extravasations and perform dosimetry and notify patients when such monitoring occurs, and urges the Department to adopt regulatory requirements to improve safety, quality, and transparency for patients.

At issue is a medical error that almost always goes unnoticed by nuclear medicine providers, who mistakenly inject a radiopharmaceutical, a radioactive drug, into the patient's tissue instead of their vein. An 'extravasation' can lead to adverse tissue effects weeks, months, or years later, but can have an immediate negative affect on a patient's diagnosis and treatment. An NRC rule requires nuclear medicine providers to report medical events that result in unintended irradiation of patient's tissue of a dose greater than 0.5 Sieverts (50 rem), but since 1980, a loophole has allowed extravasations to go unreported, even when patients receive extremely high doses, well above the reporting threshold.

**“The NRC has not been doing their job in protecting patients since 1980 when they erroneously exempted large radiation accidental exposures from being reported to them and patients,”** said Pam Kohl, a Metastatic Breast Cancer patient who has been extravasated during a routine bone scan and published a paper on her experience. Pam called on the NRC to take immediate action. **“The NRC had an opportunity to immediately fix the reporting loophole last year when they accepted a petition for rulemaking. Instead, they tried to slip in a new loophole so these preventable errors could continue to be hidden from patients and their families. Rather than treat these mistakes like NRC treats all other handling mistakes that cause accidental exposure, they suggested sick and untrained patients accept the responsibility of reporting radiation handling mistakes. I am excited that Congress has told NRC to use their existing objective dose-based reporting criterion so that providers measure and report these mistakes. NRC needs to scrap their proposed patient injury rule and immediately issue guidance to all the nuclear medicine centers—Report large extravasations like all other medical events. Doctors need to know that this preventable patient safety issue will no longer be tolerated.”**

Lucerno Dynamics submitted a petition for rulemaking in 2020 presenting conclusive scientific and clinical evidence demonstrating that providers can drastically reduce the occurrence of extravasations with dedicated monitoring and feedback to injection technologists. In December 2022, NRC accepted the petition and agreed with its statutory basis and clinical facts. However, in April 2023, NRC published a draft proposed rule based on incorrect and incomplete information, which relies on a subjective threshold requiring patient injury for extravasations to be reported. By eschewing the objective dose-based criterion used for all other unintentional exposures, NRC's draft proposed rule places burden squarely on patients and contravenes existing NRC policy; it has resulted in strong opposition from patients, patient advocacy groups, physicians, and even the National Institutes of Health (NIH).

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