For Immediate Release
April 7, 2025
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Lucerno Dynamics Commends Re-Introduction of Nuclear Medicine Clarification Act (H.R. 2541)

Bipartisan Legislation Will Improve Care, Increase Transparency, Protect Patients from Harm

CARY, NC – Lucerno Dynamics, a North Carolina medical technology company, today commended the introduction of the Nuclear Medicine Clarification Act (H.R. 2541), bipartisan legislation that will improve the safety, quality, and transparency of nuclear medicine services and simplify federal regulations.

Introduced by Rep. Don Davis (D-NC) and original cosponsors Reps. Morgan Griffith (R-VA) and Ben Cline (R-VA), H.R. 2541 would close a 45-year-old loophole in U.S. Nuclear Regulatory Commission (NRC) rules that allows accidental radiation exposures to patients undergoing nuclear medicine procedures to go unreported to patients and to the NRC.

"Patients expect and deserve to benefit from high quality care, and I am pleased that Reps. Davis, Griffith, and Cline are taking strong action on patients' behalf," said Ron Lattanze, CEO of Lucerno Dynamics. **"As NRC itself acknowledges, diagnostic and therapeutic nuclear medicine extravasations can result in high unintended radiation doses to patients and their existing reporting exemption is outdated. But the NRC's proposed new rule to report only extravasations that physicians subjectively decide may cause potential injury is inconsistent with all other NRC radiation protection rules and will not effectively address these accidental exposures. The NRC's proposed rule will still leave patients in the dark when they have been extravasated. The Nuclear Medicine Clarification Act is simple, commonsense legislation that supports transparency in healthcare. The Act provides nuclear medicine centers with a grace period to reduce extravasations before reporting will be required. And if a large extravasation does still happen, the Act ensures NRC uses the existing, objective, risk-informed regulation to guide reporting. Because large extravasations can also negatively affect the nuclear medicine procedure used to treat patients or guide their care, this Act is critical for patients. I am thankful to Reps. Davis, Griffith, and Cline for putting patients first."**

At issue is a medical event in which a radioactive drug is mistakenly injected into the patient's tissue instead of the vein (an extravasation) during a diagnostic or therapeutic nuclear medicine procedure. Without a requirement to report these exposures, extravasations almost always goes unnoticed by nuclear medicine providers. 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 existing 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 (0.5 Gy), but a loophole in NRC policy allows extravasations to go unreported, even when patients receive extremely high doses above the reporting threshold. The reporting exemption also ensures that NRC is not meeting its obligation to report Abnormal Occurrences (exposures to patients greater than 10.0 Gy) to Congress. NRC created the loophole in 1980 due to a mistaken belief that extravasations are virtually impossible to avoid – a belief that is now shown conclusively to be untrue.

Lucerno Dynamics began discussions with NRC in 2018 and submitted a petition for rulemaking in 2020 to close the loophole. The petition presented 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 August 2024, NRC published a draft proposed rule including a subjective threshold requiring actual or potential patient injury for extravasations to be reported. By eschewing the objective dose-based criterion NRC uses for reporting all other unintentional exposures, NRC has proposed an entire new regulation for reporting extravasations rather than using the existing rule. Additionally, NRC is proposing that the regulated community that has actively lobbied to NOT report any extravasations be allowed to make subjective decisions to report or not. The proposed rule resulted in strong opposition from patients, patient advocacy groups, and physicians. The National Institutes of Health (NIH) also opposed the subjective reporting and encouraged NRC to use their existing reporting process. H.R. 2541 will supersede the NRC draft rule, making sure that extravasations are reported using objective criteria just like all other reported exposures.

Lattanze continued, "I encourage Members of Congress to cosponsor and support the Nuclear Medicine Clarification Act to improve safety, transparency, and quality of care for patients, and urge the House to move quickly to pass this commonsense legislation."

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