For Immediate Release
March 14, 2024
Contact: Matt Dennis 202-484-1100

Congress Enacts Nuclear Medicine Safety Provisions

Appropriations 'Minibus' signed into law instructs NRC and VA to protect safety and improve quality of care for patients

CARY, NC – Lucerno Dynamics, a North Carolina medical technology company, today praised Congress for enacting the first 'minibus' appropriations, which includes critical provisions pushing the U.S. Nuclear Regulatory Commission (NRC) and Veterans Health Administration (VHA) to improve quality, safety, and transparency of nuclear medicine services.

"Patients expect and deserve to benefit from high quality care, and I am pleased that Congress has taken strong action on behalf of patients by instructing federal agencies to take steps that will increase safety and transparency," said Ron Lattanze, CEO of Lucerno Dynamics. "Patients who are extravasated during a nuclear medicine procedure have ionizing radiation dumped in their arm tissue, instead of their vein. Quality of care standards should demand that extravasations be identified, measured, documented, and disclosed to patients. 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 Congress for putting patients first."

The Energy & Water division of the Minibus includes the following provision originally passed by the House of Representatives on October 26th, 2023:

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 Military Construction-VA division of the Minibus includes the following provision originally passed by the House of Representatives on July 27th, 2023:

Nuclear Medicine Quality Improvements.—The Committee notes the Nuclear Regulatory Commission's (NRC) commencement of a rulemaking to require reporting of some nuclear

medicine extravasations and acknowledges that significant nuclear medicine extravasations can cause patient injury. The Committee requests a report, not later than 180 days after enactment of this Act, regarding VA implementation of new NRC regulatory requirements, including any requirements related to the monitoring of injection quality, image extravasations, dosimetry, and patient notification.

The Senate also passed a corresponding provision on this issue in the chamber's own FY24 Military Construction-VA Appropriations bill.

At issue is inadvertent injections of a radioactive drug into the patient's tissue instead of their vein, a medical error that 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 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 doses that vastly exceed the threshold triggering reporting of other radiation safety events.

Lucerno Dynamics submitted a petition for rulemaking in 2020 presenting conclusive scientific and clinical evidence demonstrating that the NRC extravasation reporting exemption was incorrect. The petition asked the NRC to treat extravasations no differently than any other unintentional exposure that exceeds existing NRC objective radiation dose-based thresholds. 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. The NRC draft rule created a new loophole by suggesting a subjective patient injury threshold 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).

Rep. Morgan Griffith (R-VA), Rep. Don Davis (D-NC), and Rep. Ben Cline (R-VA) have also introduced the Nuclear Medicine Clarification Act (H.R. 6815), which would carry the force of law and direct NRC to close the loophole exempting large extravasations from reporting. A bipartisan group of 10 cosponsors has signed on in support of this commonsense legislation to protect patients.

###

Matt Dennis
Partner
mdennis@dc-crd.com
202-484-1100
703-615-1007 (cell)