

For Immediate Release
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**Omnibus Appropriations Package Contains
Critical Nuclear Medicine Patient Safety Provisions**

*Omnibus Directs NRC, CMS, VA to Investigate and Report to Congress on Nuclear Medicine Injection Quality*

*Senator Thom Tillis (R-NC), Rep. David Price (D-NC)
Helped Secure Key Provisions*

CARY, NC – The Omnibus Appropriations Act released this week contains three provisions intended to protect patients from unintended radiation exposure during diagnostic and therapeutic nuclear medicine procedures, directing key federal agencies to take steps toward monitoring injection quality and updating reporting requirements regarding medical events.

**Ron Lattanze, CEO of Lucerno Dynamics,** a North Carolina-based medical technology company that fought for these provisions, said, “This is an important step toward keeping patients safe from unintended radiation exposure, improving diagnostics, and ensuring medical events are not being ignored. Each of the provisions points out the clear scientific evidence about nuclear medicine injection infiltrations; directs the agency (NRC, CMS, or VA) to focus on the issue; and requires the agency to report back to Congress. This legislation puts the legislative branch on the record on the side of patient safety and healthcare quality transparency.”

“We would also like to thank our allies in Congress who have worked to include these critical patient safety provisions,” continued **Lattanze**, “particularly **Senator Thom Tillis, Congressman David Price**, and the leadership of the Appropriations Subcommittees in the House and Senate.”

**Senator Thom Tillis (R-NC)** said “With the increasing use of higher energy diagnostic radiopharmaceuticals and higher doses of radiotherapeutics over recent years, it is more critical than ever to protect patients from unintended radiation exposure. These provisions will ensure providers are more transparent in reporting medical events so that federal agencies can make well-informed, data-based decisions in monitoring injection quality and I am pleased to see their inclusion into the Omnibus Appropriations Act.”

**Congressman David Price (D-NC)**, said, "As new evidence emerges suggesting that PET/CT scan injections may infiltrate surrounding tissue during medical tests, I’m pleased that the appropriations bill includes language to encourage an investigation into whether this problem hinders medical test accuracy. These infiltrations could lead to misdiagnoses for patients and make it more difficult for doctors to determine the best treatment. I’ll continue advocating for research that improves patient safety."

**Background**

The Nuclear Regulatory Commission (NRC) requires nuclear medicine providers to report medical events that result in unintended radiation exposure of greater than 0.5 sieverts to the patient’s tissue. However, since 1980, a loophole in this rule has exempted “infiltrations” or “extravasations” from these reporting requirements. An infiltration occurs when a radiotracer is mistakenly injected– in whole or in part – into the soft tissue of the arm rather than into the vein as intended. In creating this loophole 39 years ago, NRC’s belief was that infiltrations are inconsequential, occur frequently, and are “virtually impossible to avoid.”

In April 2019 and for the following six months, Lucerno Dynamics presented scientific and clinical evidence to NRC’s Advisory Committee on Medical use of Isotopes (ACMUI). This evidence included recent cases of patients exposed to radiation levels far in excess of NRC reporting requirements. These cases were never reported to NRC, to the patient, or to the treating physician due to the existing loophole in NRC policy, raising the possibility of acute harm and long-term tissue damage. The evidence also included letters of support from nuclear medicine pioneers, including the co-inventor of the PET/CT scanner. Additionally, Lucerno provided the recently published results from a multi-center Quality Improvement study demonstrating that providers can drastically reduce the occurrence of infiltrations with dedicated monitoring and feedback to technologists.

Despite this evidence, in September 2019, the nuclear medicine industry representatives comprising ACMUI recommended NRC maintain the current loophole allowing providers to avoid reporting these radiological medical events. One dissenting opinion recommended eliminating the loophole. A decision is pending before NRC whether to accept or reject the recommendations of ACMUI.

**NRC**

The report accompanying the Energy & Water appropriations bill includes the following provision, a version of which was contained in both the House and Senate versions:

*Re-Evaluation of Nuclear Medicine Event Reporting. –* The Committee is aware of evidence demonstrating the prevalence of extravasations in nuclear medicine procedures within and across health care providers. 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. The Committee supports the work of the Commission and the Advisory Committee on medical Use of Isotopes to consider new evidence in evaluating whether all radiotracer extravasations should be reportable as medical events under 10 C.F.R. Part 35. Not later than 90 days after the enactment of this Act, the Commission shall provide to the Committees on Appropriations of both Houses of Congress a report on updates to injection quality monitoring, classification, and reporting requirements regarding extravasations.

**CMS**

The Centers for Medicare & Medicaid Services (CMS) maintains conditions of participation (CoPs), which providers must meet in order to begin and continue participating in the Medicare and Medicaid programs, including for nuclear medicine services. The report accompanying the Labor, Health & Human Services, Education Appropriations bill includes the following provision, a version of which was contained in both the House and Senate versions:

*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. 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. The Committee encourages CMS to consider adding required monitoring of injection quality and submission of reportable extravasations to the Nuclear Regulatory Commission to its conditions of participation for nuclear medicine services. The Committee requests an update on this issue in the fiscal year 2021 Congressional Budget Justification.

**VA**

The Veterans Health Administration is the largest integrated health care system in the United States, providing care at 170 VA Medical Centers. The report accompanying the Military Construction-VA Appropriations bill includes the following provision:

Nuclear Medicine Quality Improvements.—The Committee is aware of evidence demonstrating the prevalence of extravasations in nuclear medical 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. As America’s largest integrated healthcare system, the VAMC should lead by example in acting to reduce medical errors and medical waste. The Committee encourages VAMCs to monitor injection quality and develop a physician/patient reporting system to disclose when extravasations occur. No later than 90 days after the enactment of this Act, VHA shall provide to the Committees on Appropriations of both Houses of Congress a report on efforts to monitor injection quality and reduce the incidence of extravasations.

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