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April 13, 2022

The Honorable Chris Hanson
Chairman
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852-2738

Dear Chairman Hanson,

I read with interest the U.S. Nuclear Regulatory Commission (NRC) staff preliminary evaluation of radiopharmaceutical extravasation and medical event reporting dated April 1, 2021 but not made public until August in advance of a public meeting between NRC staff and the Advisory Committee for Medical Use of Isotopes (ACMUI). NRC's evaluation of this clinical and policy issue is of importance to patients across the county and to Congress, and it's troubling that NRC staff have acknowledged that under the Commission's current medical event reporting policy, "extravasations that cause patient harm, and even those that meet the public health and safety significance criteria for an abnormal occurrence (AO), are not required to be reported." As you are aware, 42 § U.S.C. 5848 requires NRC to report abnormal occurrences to Congress annually. It is concerning that an entire class of events, many of which result in unintended irradiation of patients beyond existing NRC limits, is not being reported to Congress.

In a letter dated June 25, 2021, 15 patient advocacy groups made clear that patients, physicians, and NRC should be made aware of radiopharmaceutical extravasations that result in significant unintentional irradiation. Patients have also voiced concern that adopting a harm-based criterion rather than a dose-based criterion for medical event reporting of extravasations, would put an undue burden on patients.

On August 17, 2021, NRC described the International Atomic Energy Agency (IAEA) as an "international authoritative scientific advisory body" and noted it "has been the longstanding practice of the NRC to generally place significant weight on the recommendations" of such a body. I wish to highlight for you that on August 3, 2021 IAEA published QUANUM 3.0: An Updated Tool for Nuclear Medicine Audits, which calls for the prevention, monitoring, and documentation of extravasations.

The slow pace of NRC's evaluation is concerning, and I urge the Commission to resolve this issue expeditiously. The clinical issue was presented to ACMUI and NRC in April 2019 and identified by Congress in the Fiscal Year 2020 Consolidated Appropriations Act enacted in December 2019; and a petition for rulemaking has been pending since May 2020. I hope that NRC will take this relevant information into account as the Commission continues considering whether radiopharmaceutical extravasations should be reported as medical events. Thank you for your thoughtful consideration.

Sincerely,

Thom Tillis

Thom Tillis
United States Senator

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