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July 27, 2021

Michael J. Guastella
Executive Director
CORAR

Dear Mr. Guastella,

ICAN®, International Cancer Advocacy Network is a 501(c)(3) patient advocacy and research organization, focusing on our Personalized Medicine Cancer Case Navigation Programs, health information technology issues, legislative initiatives, and research projects.

We have aligned with 14 other patient organizations to form the **Patients for Safer Nuclear Medicine Coalition**. On June 25, 2021, we sent a letter asking the NRC to immediately approve a petition to eliminate an outdated policy that exempts clinicians from reporting when they significantly extravasate their patients during the administration of radiopharmaceuticals. We have also shared this request with many members of Congress.

As a group, we have informed our constituents about extravasations through social media, newsletters, and podcasts. Now, we are asking you and your peer companies to help patients by educating your customers on the need to report significant extravasations.

We understand that when radiopharmaceuticals are properly administered, nuclear medicine procedures are safe, and the benefits to patients far outweigh the risks. Extravasations of radiopharmaceuticals, however, are not an uncommon occurrence in nuclear medicine centers, and they have consequences.

The Society of Nuclear Medicine and Molecular Imaging has stated that extravasations compromise the quality and quantification of images and the delivery of therapy. Furthermore, it is now known that both diagnostic and therapeutic extravasations can lead to high absorbed radiation doses in patient tissue and overlying skin.

As part of the overarching *As Low As Reasonably Achievable* radiation protection principle that should be guiding patient-centric nuclear medicine, and with the increasing role of radiotherapeutics, the growing importance of quantification, and the expansion of precision medicine, radiopharmaceutical extravasations should not be ignored.

We understand that CORAR advocates for public policies that impact health care to expand access to safe and affordable health care treatments for patients. We also see that CORAR has advocated for a skin dose limit of 500 mSv averaged over 10 cm² of skin. In

your Position Paper on Skin Dose Limits, CORAR also recommends assessing the dose of affected skin to properly evaluate the skin dose with respect to the significances of dose to other tissues.

In our review of public comments submitted to the NRC on the topic of extravasations, we did not see a comment from an individual member of CORAR or from CORAR. We understand the reluctance of nuclear medicine providers to self-report radiopharmaceutical extravasations. We can also appreciate the difficult position a lone company may face with healthcare providers if they support a change to this long-standing NRC reporting exemption policy. However, we find it difficult to understand why CORAR, which advocates for safe healthcare, and which understands the patient effects of high doses to skin and tissue, has not supported removing the exemption from reporting significant extravasations (extravasations that exceed the exact dose limits you previously advocated).

As a coalition of organizations representing the voices of patients, we believe reporting significant extravasations is important for providing the highest quality patient care and for improving radiopharmaceutical administrations in the future. **We are encouraging your members and others in the industry to avoid inaction on this important patient issue and through the CORAR trade association, to further educate SNMMI members on the negative effects of radiopharmaceutical extravasations and the need to report significant occurrences.**

It is difficult to reconcile that in the year 2021 a patient could experience a significant extravasation that can compromise their image/treatment and irradiate their tissue with high absorbed doses and that this can go unnoticed. Even worse, when it is detected, there is no requirement that the patient or their treating physician be told, nor is there a requirement that this misadministration be reported to the state regulatory bodies and the NRC. For these reasons, we ask that CORAR take positive action to help protect patients and improve nuclear medicine.

Please do not hesitate to contact me at marcia@askican.org or at (602) 618-0183 if you need any additional information. Thank you for your consideration, and for your support.

Respectfully submitted,



Marcia K. Horn, JD
President and CEO
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Attachment: Patients for Safer Nuclear Medicine Coalition Letter to NRC, dated June 25, 2021

ICAN is a 501(c)(3) tax-exempt charitable organization (EIN 86-0818253) serving Stage IV metastatic cancer patients across the United States and in 54 countries since 1996. ICAN is one of the few national cancer organizations that is both Platinum-rated (the highest rating) on GuideStar, and five-star rated (also the highest) on Great Nonprofits.

ICAN, operating with the highest standards of board governance, has received the "Top-Rated Health Care Nonprofit" award from Great Nonprofits every year since 2010.