

From: [Kevin Williams](#)
To: [Tori Roszkowski \(She\)](#)
Subject: FW: Raymond Furstenau, Letter July 1st, 2024
Date: Friday, July 26, 2024 12:33:41 PM

From: Kevin Williams <Kevin.Williams@nrc.gov>

Sent: Friday, July 26, 2024 10:47 AM

To: Raymond Furstenau <Raymond.Furstenau@nrc.gov>

Cc: Jody Martin (He/Him) <Jody.Martin@nrc.gov>; Scott Morris <Scott.Morris@nrc.gov>; Araceli Billoch Colon <araceli.billochcolon@nrc.gov>; John Lubinski (He/Him/His) <John.Lubinski@nrc.gov>; Robert Lewis (He/Him) <Robert.Lewis@nrc.gov>; Adelaide Giantelli <Adelaide.Giantelli@nrc.gov>; Christian Einberg <Christian.Einberg@nrc.gov>

Subject: RE: Raymond Furstenau, Letter July 1st, 2024

Good morning, Ray,

I spoke with Simon Davies from Teen Cancer on Wednesday, July 24. Simon appreciated the call and felt that it was a positive dialogue and that I gave him the opportunity to express the views of the Patient Coalition. He wanted to emphasize a couple of points, one that he was representing the views of the Patients for Safer Nuclear Medicine Coalition and not just the views of himself representing Teen Cancer America and Simon also wanted to make it clear that he is not a medical expert and the issue of the right level of extravasation that should be reported is a matter for experts to decide. I also shared our next steps of providing the proposed rulemaking to the Commission and the process that could follow and provided the publicly available response to the OIG regarding the appearance of a conflict of interest. Overall, I thought the conversation went well and it was a good exchange of perspectives. Below is a summary of the conversation with Simon (Simon reviewed and provided comments which I accepted). I intend to put this response and the incoming email from Simon in ADAMS as publicly available.

- Simon conveyed the expected performance outcome which is to focus on actions to ensure patient safety. The concern is that patients are at risk from extravasations.
- Simon also conveyed that physicians should report extravasations at a specified level; we discussed that 10 gray may not be the specific level and that NRC should discuss with a range of experts to provide scientific evidence for the specific level. The Coalition is simply looking for a standard number that will not allow for any subjectivity.
- It was also conveyed that clear guidance on prevention should be issued with a goal of patients not being extravasated.
- There is a need for engagement with groups such as Teen Cancer America to ensure that all groups were heard, positions are supported, and that the consensus that all perspectives were captured. Simon shared that he believed that ACMUI and Industries thoughts ruled the day and ACMUI's advice to the staff was/is wrong. And that the evidence presented by the coalition and experts that support them had been ignored.
- Simon also expressed concern that the patient representative that is on the ACMUI has never consulted the coalition nor responded to them, bringing into question their role as the patient's 'voice,'

- Kevin shared that we engage all stakeholders and utilize their insights and perspectives to inform our decision making. Simon expressed that it hadn't felt that way to the coalition.
- Kevin stated that the NRC staff does maintain its independence in decision making and there are examples (T&E, Regulatory Guide 8.39, and extravasations) where the staff has not agreed with ACMUI or Industry.
- There is a need to ensure the NRC has dialogue with groups outside of ACMUI and Industry.
- If the Commission decides to pursue the staff's proposed rulemaking, there will be opportunities for Teen Cancer America and members of the coalition to engage. We also could consider having an NGO only type of meeting where we provide the opportunity for more in-depth discussion/dialogue to receive comments on the proposed rule.
- Having the engagement will help to build trust.
- Simon and members of the coalition are open to future discussions and dialogue on extravasations.
- The OIG investigation of the appearance of conflict of interest is a publicly available document (Simon to attempt to access the document again).
- Ultimately, Simon believes there should be a standard and safety procedures that include training of staff and the use of available (and affordable) technology for safe procedures that will reduce error and therefore make extravasation reporting a rare occurrence.

Kevin

From: Simon Davies <simon@teencanceramerica.org>

Sent: Wednesday, July 17, 2024 1:39 PM

To: Raymond Furstenuau <Raymond.Furstenuau@nrc.gov>; Kevin Williams <Kevin.Williams@nrc.gov>

Cc: William Johnson <William.Johnson2@nrc.gov>; Terri Spicher <Terri.Spicher@nrc.gov>

Subject: [External_Sender] Raymond Furstenuau, Letter July 1st, 2024

Dear Mr. Raymond Furstenuau,

Thank you for your letter dated July 1, 2024.

It is good to know that the staff has conducted a thorough review of its policies to identify program enhancements to ensure continued avoidance of actual conflict of interests, as well as future apparent conflicts of interests. As of July 15, we have not been able to find the document (ML24180A124) that you say was sent to OIG on June 28, 2024. It would go a long way to improve public trust if we could see what steps have been taken. This is especially important since ACMUI members who held or currently hold leadership roles in, or who have received funding from professional societies provided misinformation to Commissioners during an April 8, 2024 discussion about radiopharmaceutical extravasations. This meeting was held after the OIG findings had been released to the Commission and we assume after the members of the ACMUI had met with OIG investigators.

Unfortunately, it will be a difficult task for the NRC medical staff to rebuild trust with the public. Your paragraph that begins with: "The NRC's rulemaking..." is a major reason why rebuilding trust will be difficult. Months after the OIG findings have been shared with you, and nearly 18 months after you received a detailed Information Correction Request

regarding SECY-22-043, you state that the staff's **independent** (emphasis added) evaluation considered input from...ACMUI...and the medical community. The recommendation set forth by the staff in its proposal to the Commission **was unanimously supported by the 13-member ACMUI, which underscores the validity of the staff's approach to this rulemaking.** (emphasis added) These comments reveals that the NRC has blinders on. Of course, the ACMUI provided unanimous support for the recommendation. This recommendation was the exact recommendation provided to the medical staff by the professional societies during a September 2021 public comment call. The same professional societies whose members populate all but 2 of the member positions on the ACMUI at that time.

Your comments reflect an alarming lack of knowledge about what has actually transpired on this issue. You do not seem to grasp the extent to which your staff has adopted ideas from the ACMUI and the regulated industry without applying any critical thinking. Had they done so, none of the advice would have been accepted, since there is no scientific or clinical support for the "opinions" of these organizations. Please note, these ACMUI members also unanimously (other than Laura Weil, the previous patient advocate who dissented in writing) supported a previous recommendation from the Subcommittee on Extravasations that suggested ALL EXTRAVASATIONS should remain exempt from reporting. The basis for their decision, according to the subcommittee members, was their fanciful creative suggestion that extravasations are impossible to avoid because they are caused by "passive patient intervention." Nothing could be further from the truth. Your claim that the ACMUI members do not determine, or direct actual decisions does not ring true with the public.

In addition, your comment that suggests the staff "continue to work to ensure and maintain transparency in our decision-making process" also does not ring true. Were this the case, the medical staff would have released SECY-22-043 to the public within a couple of weeks after submitting it to the Commission in May of 2022. They did not. The lack of transparency was also evident in this most recent ACMUI meeting. The meeting was scheduled for June 17, 2024, a Monday. The previous Monday, June 10, 2024, NRC requested that all public comments on the ACMUI subcommittee report regarding the proposed rule be submitted by COB June 11. However, the subcommittee report and the proposed rule were not made public until June 13, 2024, making it impossible for the public to comment. Congressional members and staff, who are also interested in this issue, did not receive an invitation to the meeting until a few hours before the meeting began. We mention all of these points to make sure you understand that your staff has very low credibility with the public regarding their independence and ability to know when they are being misled by the community they regulate.

We encourage you to seek independent expert opinion on the extravasation matter. The proposed rule remains entirely inadequate to protect patients. Instead, it will continue to protect those who extravasate patients with large doses of radiation and who do not want to report these mis-administrations to regulatory bodies or patients. Providing those responsible for these radiation exposures the subjective criteria to decide if they should self-report in NO WAY gives the public any confidence that NRC is looking out for patients.

While the patient coalition is patient-based, we don't need to be experts to know right from wrong. But we do need experts to support us. And we have them. We have experts from nuclear medicine or physics who are willing to meet. We suggest you do that. Listen to the

experts. Let them share with you the truth rather than the nonsense from ACMUI, ACR, HPS, etc., that has been shared with you and your staff. That would start the process of rebuilding trust. Using the right information will also help you and the staff realize that extravasations can be almost entirely avoided and can be improved quickly if providers know that the NRC will treat them like any other medical event.

I look forward to hearing your response.

Simon Davies

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Simon Davies

Executive Director

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