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Hematology & Oncology Specialists, LLC
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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Secretary, U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, Maryland 20852

I support Dr. Stein's Petition for Rulemaking (PRM-35-19), requesting that the NRC amend its regulations to recognize that an 80-hour training and experience requirement is appropriate and sufficient for medical oncologists/hematologists to attain AU status for administration of Quadramet, Bexxar, and Zevalin. He has made very good arguments for his petition and it would be difficult to see how the NRC could uphold its prior decision on oral Na 131I by denying it.

I think that it is important to point out differences between medical oncologists/hematologists and radiation oncologists that speak for this petition, as there are those that would argue that the differences should speak against it. Medical oncologists/hematologists are the primary caregivers for patients with cancer and some members of Congress have suggested making them the principal orchestrators of cancer treatment. Radiation oncologists have a very important but much more restricted role, never assuming total patient care, partly reflecting their much more limited training in general medicine, and in keeping with their very limited hospital admitting privileges.

Somewhat ironically, even patients with complications from radiation exposure will be managed by medical oncologists/hematologists. These specialists are intimately familiar with the integrated management of cancer, including conditions pertinent to this petition, metastatic bone disease and lymphomas.

It is most unfortunate that the agents covered by this petition have been underused and in some cases poorly used, because of barriers to their administration by medical oncologists/hematologists, thereby limiting their great potential to palliate and even cure malignancies. This situation could be ameliorated by allowing medical oncologist/hematologists easy access to these agents, as easy as the access to chemotherapy drugs, growth factors, immune response modifiers, and the evolving armamentarium of cell pathway modulators, the fruits of the molecular biology revolution.

There is no "good enough" reason to block the renaissance effect that the approval of Dr. Stein's petition could bring about in the care of many cancer patients. I do not believe that there is a significant safety issue. The old way is failing patients. To act favorably on this petition could be one of the most significant actions that you as NRC members could take during your tenure.

Sincerely,

Thomas M. Cosgriff, MD, FACP

From: "Piazza, Sharon" <Sharon.Piazza@salco.net>
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Date: Fri, Aug 25, 2006 12:39 PM

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