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December 29, 2015

Advisory Committee on the Medical Use of Isotopes
Subcommittee on Training and Experience for Alpha and Beta Emitters
c/o Sophie Holiday
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Re: Alpha and Beta Emitters Training and Experience Requirements

Dear Subcommittee Members:

I write on behalf of the American Society of Hematology (ASH) to request that the Nuclear Regulatory Commission (NRC) set appropriate training and experience requirements for hematologists who wish to administer alpha- and beta-emitters to patients as part of an anti-cancer regimen. Our Society believes that your Agency has the opportunity to set a more appropriate requirement in its forthcoming rulemaking relating to the medical use of byproduct material.

ASH represents over 15,000 clinicians and scientists who are committed to the study of blood and blood-related diseases. These diseases encompass malignant hematologic disorders, such as leukemia, lymphoma, and myeloma; non-malignant conditions, including anemia and hemophilia; and congenital disorders, such as sickle cell anemia and thalassemia. In addition, hematologists have been pioneers in the fields of stem cell biology, regenerative medicine, bone marrow transplantation, transfusion medicine, gene therapy, and the development of many drugs for the prevention and treatment of heart attacks and strokes.

ASH's membership, which includes basic scientists, physician scientists, PhD researchers, as well as, physicians working in universities, hospitals, and community practices, is concerned that the current 700-hour training requirement as applied to alpha- and beta-emitters is inappropriate and limits physician use of clinically appropriate therapeutics. Our Society believes that this requirement is excessive and unduly restrictive of patient access to a valuable treatment option for non-Hodgkin lymphoma. ASH is pleased that the NRC formed a Subcommittee on Training and Experience for Alpha and Beta Emitters to further explore these issues. Our Society would like to take this opportunity to provide comments on this issue.

The Current 700-Hour Training and Experience Requirements are Not Appropriate

The current 700-hour requirement is aimed at training and certifying physicians in the use of an array of radioactive substances in the diagnosis and treatment of disease. While this may be appropriate for clinicians who seek to be certified for all uses of radioactive materials, it is not appropriate for a limited authorization for hematologists who seek to administer a limited set of products. We believe a reduced training and experience requirement is appropriate for alpha- and beta-emitters, such as Zevalin, which are prepared and packaged in a licensed radiopharmacy

and easily administered as a patient-ready dose in the hematologist/oncologist office setting. Such emitters present fewer risks than other radiopharmaceuticals, such as I-131, which requires more precautionary measures during administration, but is authorized after 80 hours of training and experience. Therefore, there is no reason why a similar pathway should not be provided here.

Furthermore, prior to a 2002 rulemaking, 80 hours of classroom and laboratory training was deemed sufficient for purposes of licensing Authorized Users to administer beta-emitting radiopharmaceuticals. And indeed, Authorized Users licensed under this training regimen have since been safely administering such products. To our knowledge, no hematologist has been so certified since the 700-hour licensing pathway was created in 2002.

The Current 700-Hour Training and Experience Requirements Restrict Patient Access to Effective Treatment Options

Since the implementation of the 700-hour requirement, it has become more difficult for patients in certain parts of the country to locate Authorized Users who are licensed to administer alpha- and beta-emitters outside of the academic medical center setting. We believe that the burdensome training and experience requirements are the primary impediment to providing greater patient access to these treatments. The additional 700 hours of training and experience is disproportionate and too onerous for the practicing community hematologist/oncologist to pursue. Without the ability to become an Authorized User or to locate an Authorized User within a reasonable distance, the rural hematology/oncology practitioner is unable to realistically offer this treatment as an option to their patients. This is a serious problem, given that alpha- and beta-emitters provide unique and effective treatment options for those suffering from non-Hodgkin lymphoma. Standard treatment options that offer excellent response rates should be available to all patients, whether those patients live near an academic medical center or in more rural areas of the country.

NRC Can Address the Training and Experience Requirements and Patient-Access Issue

With this current rulemaking, the NRC has the opportunity to improve access to these potentially life-saving anti-cancer treatments by addressing the shortage of Authorized Users able to administer them. Stakeholders have requested a change in the rules to permit a lesser training requirement of 80 hours of classroom and laboratory training, plus relevant work experience and case administrations for a limited authorization to administer alpha- and beta-emitters that are prepared at a licensed specialty pharmacy and delivered intravenously in a patient-ready dose. ASH supports this reasonable and limited proposed change in the regulations. Should the NRC decline to adopt this change via the ongoing rulemaking, ASH supports pursuing an exemption that would allow for more appropriate training and experience requirements with regard to alpha- and beta-emitters.

ASH urges the Advisory Committee on the Medical Use of Isotopes and its Subcommittee on Training and Experience for Alpha and Beta Emitters to consider a more proportionate training and experience requirement as applied to alpha- and beta-emitters and make appropriate recommendations to the NRC. This could significantly improve patient access to lifesaving treatments in the community hematology/oncology setting, while also addressing important safety considerations.

Thank you for considering our above comments, and please do not hesitate to contact Suzanne Leous, ASH Director of Government Relations and Practice at 202-292-0258, with any questions concerning this letter.

Sincerely,

Charles S. Abrams, MD
President