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ADD: Harriet Karagiannis, Bridget Curran,
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Comment (64)
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October 16, 2023

U.S. Nuclear Regulatory Commission
Mail Stop O-16 B33
Washington, DC 20555-0001

RE: Docket ID NRC–2023– 0086; Draft regulatory guide (DG), DG–8061, “Release of Patients Administered Radioactive Material,” Federal Register Vol. 88, No. 77, April 21, 2023

Esteemed Commissioners of the U.S. NRC:

This letter is intended to provide comments regarding Draft Regulatory Guide (DG), DG–8061, “Release of Patients Administered Radioactive Material.” The Prostate Cancer Foundation (PCF) is the world’s leading philanthropic organization dedicated to funding life-saving prostate cancer research. Many of the most important discoveries in the fight against prostate cancer since our founding in 1993 have resulted from PCF funding or coordination. This includes the novel imaging and radionuclide therapeutic strategies for prostate cancer that target prostate specific membrane antigen (PSMA). Specifically, lutetium Lu 177 vipivotide tetraxetan (PLUVICTO®), FDA-approved in 2022, offers life-extending therapy for patients with advanced prostate cancer who have exhausted many other treatment options. Additional compounds are in late-stage clinical trials.

In addition to funding research, through our education and outreach activities, PCF connects patients and their caregivers to information about developments that can extend survival and improve quality of life. We believe that patients should have access to the diagnostics and treatments that are appropriate for them, without undue burdens or barriers. Certainly, with respect to radioactive materials, this must be balanced with concern and regard for the safety of family members, health care providers, and the general public.

In our understanding, the change in the guidelines would require complicated patient radiation measurements in order for patients to be released after outpatient therapy using radioactive materials. Under the recommended guidelines, patients that currently can be released immediately may now have to spend up to one week as an inpatient in a hospital. This would significantly restrict patient access to care with life-extending radionuclide therapies, as the published thresholds for release are four times more restrictive than current standard practice.

There are differing views about the benefits of this radiation safety requirement to patients, their families, and the general public, given the tradeoffs that would result, such as limitations on access for any patient who requires this treatment to survive their metastatic prostate cancer. What may be more evident is that hospitals have little surplus capacity to admit patients simply

for observation following administration of radioactive therapies. This additional burden on hospital staff could compromise the safety of acutely ill hospitalized patients.

It is unclear who would bear the additional costs of hospitalization and of time and resources for caregivers. The increased costs would worsen existing disparities in prostate cancer care, disproportionately impacting patients of color and of lower socioeconomic status, who are less likely to have comprehensive health insurance benefits. Such patients are also less likely to have caregivers who can afford to miss additional days of work while their loved one is hospitalized.

PCF, as a supporter of prostate cancer research from the lab bench to clinical trials, has concerns about the effect on research. The requirement for hospitalization will extinguish efforts to investigate and develop such compounds. The burden on patients to enroll in trials requiring hospitalization will be too great. Researchers will not pursue treatments in these areas, and this promising field will be greatly diminished.

PCF joins esteemed organizations in the radiation safety arena in recommending that the NRC maintain the 0.25 occupancy factor as noted in the existing guidance in Regulatory Guide 8.39. This will allow patients continued access to life-prolonging and life-saving therapies, while maintaining safety for those same patients' caregivers, families, as well as the general public.

Respectfully submitted,

Gina B. Carithers

Gina B. Carithers
President
Prostate Cancer Foundation

NRCExecSec Resource

From: Becky Campbell (bcampbell@pcf.org) <bcampbell@pcf.org>
Sent: Monday, October 16, 2023 12:12 PM
To: NRCExecSec Resource
Cc: Gina Carithers (gcarithers@pcf.org)
Subject: [External_Sender] Letter to Commissioners re: Draft Regulatory Guide DG-806
Attachments: Prostate Cancer Foundation Docket ID NRC-2023- 0086 Commissioners.pdf

Dear Ms. Clark,

Would you be able to distribute the attached letter to the four NRC Commissioners?
It details the Prostate Cancer Foundation's comments regarding DG-8061, "Release of Patients Administered Radioactive Material."

Many thanks for your assistance.

Kind regards,

Becky Campbell
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The Global Public Square of Prostate Cancer:
Research, Educate, Communicate, Support