



Current Patient Rights Issues Before the ACMUI

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Three categories to discuss

- **Reportable events**
- **Public health implications of regulatory decisions**
- **Licensing considerations**

Common thread: potential for creation of limitations in access to health care

Reportable Events

- **Microspheres and permanent implant brachytherapy**
 - **Disproportionately large numbers of reportable events**
 - **Purpose of reporting is to monitor and improve patient safety**
 - **Events/occurrences need to be defined to capture preventable harms – not patient-sided issues**
 - **Event reporting requirements should not create unnecessary barriers to care**

Public Health Implications of Regulatory Decisions

- **Iodine 131: 1997 Patient Release**
 - **Health insurers now refuse to cover hospitalizations**
 - **Inadequate post-treatment instructions may have public health repercussions**
 - **Waste contamination**
 - **Radiation exposure to family members, hotel staff, the public**

Licensing decisions impact access

- **Radium 223 Dichloride**
 - **First in class alpha emitter**
 - **License under 10 CFR 35.1000 or 35.300?**
- **Gallium 68**
 - **Superior PET imaging for earlier diagnosis and treatment of neuroendocrine tumors**
 - **Onerous DFP requirement will most likely limit patients' access**

Summary

- **All ACMUI deliberations have patient advocacy components.**
- **Our recommendations strive to balance regulatory imperatives and patient safety with the need to prevent unreasonable barriers to treatment.**

Acronyms

**ACMUI – The Advisory Committee on
Medical Uses of Isotopes**

PET – positron emission tomography

DFP – Decommissioning Funding Plan