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August 12, 1998

Arlen Specter
United States Senate
Liberty & Grant Streets
Federal Bldg., Suite 2031
Pittsburgh, PA 15222

RE: Nuclear Regulatory Commission Revisions to Training and Experience Requirements for the Medical Use of Radioisotopes

Dear Senator Specter:

The Nuclear Regulatory Commission is currently in the process of revising its regulations governing the medical use of radioisotopes in an effort to make the training and experience requirements more reflective of the level of radiation risk they present. There are two areas that I am concerned about: namely diagnostic nuclear cardiology and experimental intravascular brachytherapy.

The NRC's Advisory Council for the Medical Use of Isotopes, (ACMUI) has endorsed streamlining the radiation safety training and experience requirements for diagnostic nuclear cardiology to 120 hours because of its minimal risk to patients and public safety. The current level of training is 1200 hours.

As a Fellow of the American College of Cardiology, I strongly agree with these changes as proposed by the Nuclear Regulatory Commission.

Radioisotopes have been used for several decades to create images of the heart, with minimal risk to patients and to public safety. These images help cardiovascular specialists evaluate heart function and blood flow. The cardiology community has developed effective training programs for cardiovascular specialists who perform these nuclear cardiology procedures. These physicians are also trained in the use of medical isotopes during their residency programs.

Reflecting on the safety of nuclear cardiology procedures and the training which cardiovascular specialists receive in this area, the NRC's Advisory Committees on the Medical Use of Isotopes supports streamlining the training and experience requirements for these procedures to 120 hours, and I strongly support these changes.

Intravascular brachytherapy is an experimental procedure that is currently only being performed in large academic medical centers under strict oversight. Because the procedure is experimental and because different modalities are being tested, as a cardiologist, I agree with the NRC that it is premature to set any definitive training and experience requirements in this area.

Intravascular brachytherapy is an experimental procedure that prevents arteries from reclosing after being opened by "balloon angioplasty". In this procedure, a cardiovascular specialist exposes the coronary artery walls to a low level radioactive source while clearing the arterial blockage. Because it is still experimental, this procedure is only being performed in large academic medical centers under the approval of institutional review boards (IRB's), using strict protocols. Cardiologists are teaming with medical physicists and radiation oncologists to determine the best method for this treatment modality.

At this point, it is too early for the NRC to set any definitive training and experience requirements for physicians using intravascular brachytherapy. As a Fellow of the American College of Cardiology, I believe that the NRC should reserve judgment in this area until the technology has developed to the point where regulatory standards can be developed with confidence based on the risks of the isotopes selected.

As a practicing cardiologist in Southwestern Pennsylvania, I urge you to support my position in an effort to streamline physician training and to maximize safe and cost effective patient care. Both of these areas are becoming increasingly important in the treatment of your constituents with coronary heart disease.

If you have any questions regarding this matter, please do not hesitate to contact me.

Sincerely,

Jeffrey A. Lins MD, FACC

JAL/plv