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October 1, 1998

Mr. Dennis K. Rathbarn
Nuclear Regulatory Commission
Office of Congressional Affairs
Washington, DC 20555

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Dear Mr. Rathbarn:

I am writing to request your assistance in helping a Wisconsin constituent. Enclosed please find a copy of their correspondence.

Any assistance you could provide in responding to these concerns would be greatly appreciated. Please respond directly to my constituent and send a copy to my office.

Thank you for your attention to this matter.

Sincerely,

Herb Kohl

Herb Kohl
U.S. Senator

HK:rg

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August 28, 1998

The Honorable Herb Kohl
SH-330
U.S. Senate
Washington DC 20510

Dear Senator Kohl:

I am writing to encourage you to contact the Nuclear Regulatory Commission and ask them to support the "risk-based" approach as they consider revising the training and experience necessary for the medical use of radioisotopes in a very specific type of interventional cardiology procedure. The procedure in question is termed intravascular brachytherapy. The NRC's Advisory Council for the Medical Use of Isotopes encouraged the NRC to classify intravascular brachytherapy as an emerging technology. This certainly reflects the status of this investigational procedure. The procedure is discussed in the attached news report from an August issue of the Milwaukee Journal Sentinel. As you can see, two centers in the state of Wisconsin are currently conducting clinical trials of intravascular brachytherapy in which radioactive seeds are implanted in the coronary artery in an attempt to reduce the likelihood of closure or recurrent blockage following percutaneous transluminal coronary angioplasty. The article makes it quite clear that this is indeed an experimental therapy. It is unrealistic, therefore, for the NRC to argue that fully-trained interventional cardiologists would have to go through extensive radiation oncology training in order to use a radioisotope in this very limited and specifically localized way. The experimental protocols incorporate a radiation oncologist fully in the design of the procedure.

In summary, this is very promising technology that has the potential for broad patient application. On the other hand, it is an extraordinarily limited use of very low dose radiation (far less than patients are exposed to when they have a routine fluoroscopic examination).

I sincerely hope that you will contact the NRC about this important issue.

Sincerely yours,

W. Bruce Fye, M.A., M.D., F.A.C.C.
Medical Director, Marshfield Heart Care

WBF:mkt
Enclosure

Radiation tested on patients after angioplasty

State doctors experiment with low levels aimed at reducing complication

By Neil D. Rosenberg
of the Journal Sentinel staff

Madison — Radiation, the same stuff that helped create Godzilla, is being used on an experimental basis in Madison and Marshfield by physicians to tame the monster inside coronary arteries following angioplasty.

Physicians are inserting a tiny pod filled with radioactive seeds into a heart artery to keep it from closing again after conventional angioplasty.

Since the advent of angioplasty in the 1970s, it has been dogged by a serious complication called restenosis in which the artery that is opened narrows again within several months after the procedure.

"It has been the Achilles heel of what we do," said William Miller, an interventional cardiologist and professor of medicine at the University of Wisconsin Medical School. Miller was speaking of restenosis,

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Heart/Radiation tested after angioplasty

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which occurs in roughly a third of all cases. That means that out of the 500,000 angioplasty cases each year in the United States, more than 165,000 end up being unsuccessful.

Restenosis is largely due to the body's own attempt to heal itself after angioplasty, a technique in which a sausage-shaped balloon is threaded into a narrowed or blocked heart artery and then is briefly inflated, flattening accumulations of fatty material and cellular debris against the artery wall.

In that process, the wall can become injured enough that it causes a proliferation of cells to develop to "scar" over the wound, and that narrows the artery again, Miller said.

Until now, the best treatment has been the insertion of a stent, which is a thin wire cage that mechanically holds back the walls like internal scaffolding. That has reduced the restenosis rate in those cases to about 15%, better but still worrisome.

Enter radiation. Novoste, a Norcross, Ga., firm, has developed a system that delivers a thin tube filled with seeds that give off beta radiation. Beta radiation penetrates only a fraction of an inch and is very localized in its effects.

The tube is placed in the artery at the exact site where it was just opened and left in place for less than five minutes. During that time the artery walls, or lumen, are bathed in radiation.

The radiation alters the nucleus of cells in such a way that when they receive a signal to reproduce following angioplasty, they die after the first replication, said Thomas Weldon, chairman and CEO of Novoste.

The radiation is at a dose that is just a fraction of what a patient is exposed to during normal angioplasty, where a type of X-ray called fluoroscopy is used to help physicians direct a catheter into the heart. Consequently, there is virtually no danger of radiation side effects, doctors say.

Preliminary studies, which had small numbers of people and were not controlled, show a 70% reduction in restenosis. Still, Miller says, the initial research findings are exciting.

The current trials at UW Marshfield and more than two dozen other sites around the country are the first controlled studies, and that means some patients are randomly selected to get the radiation, and others do not get it. Each patient is being followed for eight months.

If proved to be effective and approved by the Food and Drug Administration, the procedure would add about $1,300 to $1,500 to the cost of a single-vessel, uncomplicated angioplasty procedure. Such a procedure typically costs about $15,000, including hospital and physician fees.

In addition to Miller, Richard Stewart, assistant professor of medicine, Matt Wolf, associate professor of medicine, and Peter Mahler, assistant professor of radiation oncology, are involved in the study.

Both UW and Marshfield are seeking patients for the study. They must be older than 18 and need angioplasty for a single narrowing of one coronary artery. The problem area can be no longer than ⅝ of an inch, and the artery diameter must be at least ⅛ of an inch. Cost of the experimental procedure and all follow-up tests are free.

People who want to volunteer or to get more information should call (608) 263-1531 at UW or (800) 888-4755 at Marshfield.