



Elizabeth J. Connell

## U.S. Senator Champions PET

Positron Emission Tomography (PET) has a great champion in Senator Ted Stevens. He is a fearless and strong leader in the Senate, and when he goes after a goal he does not stop until after he has crossed over the goal line. Senator Stevens first became interested in PET during the early 1980s when he was in Los Angeles to give a

speech to a national veterans' convention. He contacted Mike Phelps, PhD, at the University of California at Los Angeles (UCLA) at the suggestion of a mutual friend, Norton Simon. He arranged to take a tour of Phelps' PET laboratory. The Senator was so enthralled by the PET technologies that he completely lost track of time and missed his speech to the veterans group.

Over the years since that first visit, Phelps and Stevens have forged a strong friendship and shared commitment to PET. They have worked together to make PET more accessible as a clinical tool in medical practice and to gain acceptance and insurance reimbursement for PET. In the past few years, I've been privileged to join in this crusade with them.

The struggle to get PET implemented in the clinical community has a long history. For years, PET faced two seemingly insurmountable problems: First of all, the Food and Drug Administration (FDA) refused to approve radiopharmaceuticals used for PET scans. Secondly, the Health Care Financing Administration (HCFA) used this lack of FDA approval to deny Medicare reimbursement for PET. Since Medicare reimbursement is considered to be the benchmark for whether private insurers will pay for new medical procedures, pharmaceuticals and treatments, HCFA's denial of coverage represents a serious obstacle to PET's widespread use in this country, even though PET is widely used in Western European countries.

Several years ago, Senator Stevens tried to overcome these obstacles by filing legislation to require Medicare to pay for PET scans for a broad list of indications. Unfortunately, under congressional rules dictated by the Gramm-Rudman-Hollings Budget Act, a legislative proposal that is considered to have a "cost" to the federal government (including its Medicare program) must have "offsets" or savings in other government programs, so that it is considered "budget neutral." This is necessary in order for the new legislation to be passed.

Those in the nuclear medicine community know that PET should represent a net savings to the Medicare program, because, for example, it can clearly identify and stage many cancers better than conventional diagnostic procedures. Thus, it can elim-

inate unnecessary surgeries, reduce the number of diagnostic procedures and otherwise demonstrate to clinicians the best, most effective mode of treatment for a patient. The Congressional Budget Office (CBO), however, has taken the unalterable position that any new item which Congress requires Medicare to cover is an added cost to the program. In the case of PET, CBO estimates for Medicare coverage, even for a limited list of indications, ranged upwards of \$1 billion.

I know that many of you may chuckle at this estimate, especially in light of your experience to date over the past year with actually getting paid—and getting paid a fair amount—for only diagnosis and staging of lung cancer, the only indication covered by Medicare. But this is the way CBO sees it and, I expect, will continue to see it. Faced with this perceived huge price tag, for a technology that many members of Congress were unfamiliar with, the Senator was not successful with his initial legislation.

Regarding FDA matters, we were not successful in our efforts to have the FDA develop a realistic regulatory scheme for approving PET radiopharmaceuticals. The agency simply would not listen to us. They would not listen, that is, until the 1997 Congress got serious about legislation to reform the FDA. We were suddenly presented with an opportunity to have a major impact on this legislation.

Working with allies including Senator Bill Frist on the Senate Labor and Human Resources Committee, Senator Stevens wrote an amendment to the legislation, which was accepted by the FDA Reform Committee, that completely exempted from FDA regulation those PET radiopharmaceuticals approved under the standards of the United States Pharmacopoeia (USP).

As you can imagine, this horrified FDA officials who were unwilling to lose jurisdiction over anything. It also brought Senator Ted Kennedy into the picture. Kennedy is a supporter of PET but is an even stronger supporter of the authority of the FDA. His staff asked us if we would work with FDA to see if a compromise solution could be worked out. It then occurred to Stevens and Frist that a compromise might be built on a larger platform and should include HCFA reimbursement for PET as a "trade-off" for allowing the FDA to continue to regulate PET radiopharmaceuticals on a separate and rational basis.

After months of negotiating a compromise, a provision was added to the FDA Reform Act which laid out the principles for developing a new regulatory system for PET radiopharmaceuticals. The provision takes into account the unique nature of these radiopharmaceuticals and requires the participation of the PET community in the drafting of new FDA rules for approval.

At the same time, we negotiated with the Department of Health and Human Services (HHS), which oversees HCFA, on Medicare reimbursement for PET. Stevens personally talked with HHS Secretary Donna Shalala to gain her cooperation. The upshot of these negotiations was the Shalala letter of

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November 3, 1997, to Stevens setting out the terms of their agreement for Medicare reimbursement of PET for lung cancer, with review and reimbursement of other indications to follow over an 18-month period.

Stevens announced the agreement two days later at a dinner in New York where he was honored by the Dana Foundation and its chairman, David Mahoney, another strong supporter of PET. We were all optimistic and were celebrating the fact that we had finally gotten Medicare to pay for PET!

What happened since that happy week in early November 1997 represents an object lesson in the disconnect between good faith agreements made between principals and the implementation of those agreements by the bureaucracy of HCFA. It also tells us how much remains to be done before our task is finished.

The catalogue of what went wrong with putting the Stevens-Shalala agreement into effect by January 1, 1998, is endless: The 45 days to "checks being cut" turned into a series of acrimonious negotiations between me and the HCFA staff, culminating in a "coverage policy" document that was faxed to me late in the evening of New Year's Eve 1997 at my home. Although the document provided reimbursement for PET, it contained some negative and restrictive language. Months passed before HCFA issued a payment code and policy. Those first attempts at reimbursement resulted in PET payments as low as \$200 in Florida!

Concerned that his agreement with Shalala had not been honored, Stevens spoke again with Shalala in early May and wrote her a letter dated May 8, 1998. That letter spelled out what had gone wrong with their agreement and requested that the Secretary agree to a modification of the November 3 letter so that the true spirit of their agreement could be fulfilled.

Shalala agreed verbally to Stevens that she would "do whatever was required to fulfill their agreement" and asked HCFA Administrator Nancy Ann Min DeParle to work with me and to oversee the PET issue directly. Nancy Ann and I had several conversations—and to HCFA's credit—we established a new payment policy of \$1,980 per PET scan.

Unfortunately, problems continued to grow and multiply. Even though a reasonable payment level had been set, only a few providers were actually receiving any checks. This problem is finally starting to reverse itself.

HCFA hired Jeff Kang, MD, to oversee the Medicare coverage policy for PET. Kang visited the PET Program at Duke headed by Ed Coleman, MD, and has been in contact with Coleman, Ruth Tesar, CNMT, president of the Institute for Clinical PET (ICP), and Ken McKusick, MD, head of the Society of Nuclear Medicine's Committee on Coding and Reimbursements. Unfortunately, the bureaucracy that surrounds Kang continues to create obstacles to the fulfillment of the Stevens-Shalala agreement.

Meanwhile, both Donna Shalala and Nancy Ann continue to believe that the agreement has been implemented and that PET scans are being paid for by Medicare for a wide range of indications. Maureen Reagan recently visited Secretary Shalala and brought up her life-saving experience with PET and

the importance of PET as a clinical tool. Shalala told her that PET scans for all types of cancer were paid by Medicare. On a recent visit to her home state of Tennessee, Nancy Ann met with Martin Sandler, MD, editor of *The Journal of Nuclear Medicine*, and his colleagues at Vanderbilt University and told them that PET had broad coverage by Medicare.



Senator Ted Stevens (R-AK)

#### Where Are We Now?

We've come a long way so far, especially since this has been a largely ad hoc effort without the assistance of highly paid lobbyists and a large network of patient advocacy grassroots organizations. On the FDA side, we've succeeded in getting legislation that requires the FDA to develop a new and unique regulatory system for PET radiopharmaceuticals. Since the passage of the FDA Reform Act, the agency has been working cooperatively with a committee headed by Jorge Barrio, MD, involving members of the ICP, Society of Nuclear Medicine, American College of Nuclear Physicians and industry to develop an effective regulatory framework for regulation of PET drugs.

On the HCFA and Medicare reimbursement side, however, we continue to face problems. We need to make sure that all providers receive payment for PET scans for diagnosis and staging of lung cancer in an efficient manner. We must also move forward on the implementation of the broad coverage policy for PET that Shalala and DeParle support.

We all need to work together to educate HCFA on the great value that PET can provide to improving the healthcare of the American people and to move them forward with a positive attitude. Senator Stevens and I will watch over this process, and we will look to the nuclear medicine community at large for support.

We all need to keep in mind that our goal is to obtain Medicare coverage for PET scans for a broad range of indications as spelled out in the May 8, 1998 letter to Secretary Shalala. Only if this goal is achieved can we develop a sufficient database to permit a fair evaluation of PET as a clinical modality in the care of Medicare patients. After all, doctors are not going to invest in PET scanners and are not going to refer patients for PET scans unless the procedure is covered and widely available.

In terms of community outreach, I recently had the chance to review UCLA's newly-published booklet "Imaging for Hope," put together by Kim Pierce and Robert Stoddard of

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won't interfere with other equipment," is also a consideration. And lastly, "watch out for vaporware. There are lots of people selling software that doesn't yet exist."

The first step is to consider the need for FDG studies among the referral base, said O'Donnell. "The greatest need will be in oncology, so dual-head coincidence detection could be useful in hospitals with strong oncology programs. Right now, FDG plays a fairly minor role in cardiology." O'Donnell believes that most departments will plan to use the coincidence detection system for SPECT as well as FDG studies. "Those planning to use a dual-head coincidence system mainly for FDG studies might consider a dedicate PET system instead," he noted.

### Growing Demand for FDG Studies

Dual-head coincidence FDG imaging has entered the realm of clinical practice, but it's still early. "Some of our installed sites are just getting up to speed in generating referrals, learning about the technology, and gaining access to FDG," said one vendor. As this procedure continues to undergo evaluation, as reconstruction algorithms improve, and as clinical investigators collect more data in prospective trials, the use of dual-head coincidence imaging with FDG will be more clearly defined as it expands into various clinical applications. With a growing base of referring physicians who want FDG studies, nuclear medicine facilities are preparing to meet some of that demand with dual-head coincidence imaging.

—Linda E. Ketchum

### U.S. Senator Champions PET

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Mike Phelps's staff, which informs women about the benefits of PET in terms of diagnosis and staging of diseases like breast cancer. The booklet, and other efforts initiated by Mike and his staff, are resulting in new relationships with patient advocacy groups and their representatives, like Fran Visco and the National Breast Cancer Coalition, Mike Milken and CaP CURE, Nancy Brinker and the Susan G. Komen Foundation and Horace Deets and the American Association of Retired Persons. These alliances are critical next steps in future efforts we must undertake to develop a coordinated strategy to involve a broad range of interest groups and other members of Congress in advocating recognition and reimbursement for PET.

Senator Stevens needs your help. As effective as he is, he needs to have more of his colleagues informed about the benefits of PET and advocating its use. I urge all of you who operate PET centers, who are involved in medical societies, or who are leaders in industry to contact your House and Senate representatives and tell them about PET. Tell them how it can benefit them and their constituents, and tell them about the problems we are having in getting Medicare reimbursement.

The best thing you can do is to invite them to visit your PET centers and your companies to see this extraordinary technology for themselves, to see the magic of PET and the value it provides in improving the healthcare of the people they serve. The PET community also needs to educate patient advocacy groups about the benefits that PET can bring to those they represent. I'm glad to see that this process has begun, and I encourage you to expand it.

Now is the time when we need to have the PET industry—those who manufacture and sell PET equipment—commit financial and other resources to help realize broad-based reimbursement from Medicare for PET. As I noted before, we've come a long way on a shoestring, but now we need to have a real campaign to carry us the rest of the way. Finally, the broad PET community MUST WORK TOGETHER. Coordinated efforts are needed to make this effort successful. "Lone Ranger" tactics only serve to allow those who oppose PET to succeed.

I know that with your continued and coordinated efforts and enthusiasm, we will succeed in our goal of bringing the widespread use of PET to the American people. It is a great pleasure for me to be part of this effort.

—Elizabeth J. Connell