Understanding Patient Needs: Congressmen Aid Nuclear Medicine

Michael Phelps, PhD (left), and U.S. Senator Ted Stevens (R-AK).

When Susan Spenceley was undergoing treatment for Hodgkin's Disease, she failed 13 different regimens of chemotherapy and external beam radiation administered over several years. She had nearly given up hope for a cure when her doctors suggested treatments with experimental therapy involving the radionuclide Yttrium-90. "With no acute side effects, the radioimmunotherapy gave me a complete response and returned my good health when I had no other options," wrote Spenceley in a letter dated August 19, 1998, to Congressman Ron Packard (R-CA). "I'm alarmed to hear that the House has recommended lowering the funding allocated for the DOE's Medical Isotope Production and Distribution Program. Please work diligently to assure that the funding is expanded...."

Over the years, certain congressional representatives and senators have been eager to advance the field of nuclear medicine either by increasing funding for academic research and radioisotope production at Department of Energy (DOE) facilities or by encouraging the Health Care Financing Administration (HCFA) to reimburse for state-of-the-art nuclear imaging procedures. The past year has been particularly auspicious for nuclear medicine. Thanks to the efforts of congressional leaders, HCFA began to reimburse for positron emission tomography (PET) imaging in lung cancer patients. Moreover, Congress passed the Food and Drug Administration (FDA) reform bill last November, which contained distinct provisions for specifying that regulation for radiopharmaceuticals, including PET radiopharmaceuticals, should be simplified. This past May, several senators formally requested a 30% increase in funding in this year's budget for the DOE's Isotope Production and Distribution Program.

These recent efforts come at a time when radionuclide therapies are poised to become a new treatment option for cancer patients like Susan Spenceley. She and dozens of other cancer patients and their families have waged a letter-writing campaign in an effort to educate their own senators and representatives on the need for nuclear medicine research funding. Here are some key players in both the Senate and the House who have taken a special interest in nuclear medicine issues.

A PET Issue

For the past 15 years, Senator Ted Stevens (R-AK) has been a champion of PET and has long urged the government to make PET scans more accessible and affordable. "Senator Stevens is determined to see that benefits of PET become widely available to the public who have funded the research that led to the technology's development," said Elizabeth Connell, legislative assistant to Senator Stevens. The senator first became interested in PET as a result of his friendship with renowned PET researcher Michael Phelps, PhD, Norton Simon Professor and chairman of molecular and medical pharmacology at the UCLA Medical School. "Senator Stevens is a major force for nuclear medicine in Congress and has been one of the most consistent and strongest supporters of the field," said Phelps. "He appreciates that PET is part of nuclear medicine and made sure coincidence detection imaging was included as part of HCFA's reimbursement for PET."

In addition, Stevens convinced his colleagues that PET radiopharmaceuticals should be part of the FDA reform bill and wrote a separate section amending the FDA's plans to regulate PET imaging agents. The bill states that the FDA is required to take account of the special characteristics of PET radiopharmaceuticals and the special techniques and processes required to produce these drugs. The FDA was given two years to establish procedures for the approval of PET radiopharmaceuticals and two years to implement the regulations. Until new FDA regulations are implemented, the FDA will accept U.S. Pharmacopeia approval of PET radiopharmaceuticals. The FDA currently has been working with a committee composed of PET academic and industry leaders to draft the new regulations, and the committee has been reporting back to Stevens's office. "The PET community has told us that the process is proceeding along very well," said Connell. "If they were to report any problems, Senator Stevens's office would step in and discuss the matter with the FDA."

Stevens has also recognized that reimbursement for PET procedures and regulation by the FDA go hand in hand. Thus, when Congress was working on the FDA reform bill last year, Senator Stevens joined forces with Health and Human Services (HHS) Secretary Donna Shalala in an effort to obtain

reimbursements for PET radiopharmaceuticals. In November of last year, Shalala and Stevens reached an agreement to have HHS consider broadening Medicare coverage for PET. (The full text of Shalala's letter agreeing to this course of action appeared in *Newsline*: *Jour Nucl Med* 1998;39 (1): 22N, 25N). In January of this year, HCFA was supposed to officially begin reimbursing for PET scans for lung cancer diagnosis and staging and was to make a decision on coverage for brain cancer and myocardial viability within six months. The agency was also directed to conduct a fast-track review of other uses for PET to be completed by the summer of 1999.

Over the past year, Stevens has been monitoring HCFA efforts to begin the process of PET reimbursement. In May Stevens wrote a harsh letter to Shalala criticizing her agency's failure to implement the provisions of the plan. He complained that a payment system for PET scans was not in place as of January 1, 1998, and that PET centers had been told to hold their invoices. He also took issue with the fact that some regional carriers were proposing to pay only $200 for a PET scan, compared to the average rate of $2,000 to $3,000 from private third-party payers. Stevens arranged a meeting with Shalala after which HCFA adopted a universal reimbursement policy of $1,980 for the scan. The senator has also met with Shalala to discuss implementing a broad indications policy where PET scans would be reimbursed for the diagnosing of multiple cancers, neurological and cardiovascular diseases (such as colorectal and breast cancer or epilepsy and the dementias) not just on an indication-by-indication basis.

Stevens has a personal interest in PET imaging that motivates his legislative initiatives. He tours the UCLA facility three or four times a year, according to Phelps, to stay up to date on the latest advances. "He believes in PET, has seen the important role PET played in improving the care of people close to him, and he himself has had PET scans when he was diagnosed with prostate cancer five years ago," said Phelps. As chairman of the Senate Appropriations Committee, Stevens has the clout to sound his concerns—as both a politician and a patient—over the need for better access to PET technologies.

Playing important supporting roles in PET legislation are Senators Bill Frist (R-TN) and Ted Kennedy (D-MA), who helped write the PET legislation included in FDA reform. Senator Kennedy also served as a liaison with the FDA to gain their acceptance of the new legislation.

Fighting for Research Funds

Senator Slade Gorton (R-WA) and Representative Doc Hastings (R-WA) have embarked on a crusade to garner more funding for the production of radioisotopes used in research and for the treatment of cancer and heart disease. In May, Gorton wrote a formal letter to Pete Domenici (R-NM), chairman of the Senate Appropriations Subcommittee on Energy and Water Development, asking for a $10 million increase in funds for the DOE's Isotope Production and Distribution program above the Senate's approved 1999 budget of $22.5 million. "Once treatments are finally approved, I am concerned about the availability of therapeutic isotopes," said Gorton. "Without adequate funding for production, we may find ourselves in a situation where we have the knowledge of a cure without the production capabilities." Hastings prepared a similar request for the House Appropriations Subcommittee on Energy and Water Development, which had approved a budget of only $14.5 million.

The funds would be earmarked for isotope production initiatives including the production of xenon-127 at TRIUMF, the production of research isotopes at Sandia, target development at Los Alamos, and the development of bismuth-213 generators and new medical isotope delivery systems at Pacific Northwest Lab. In the final budget negotiations between the Senate and the House, the additional $10 million in funds was not included. However, the final approved budget for 1999 was $21.5 million, an increase over the 1998 appropriation of $19.5 million. At press time, the DOE had not yet determined how the funds would be divided among the various national laboratories.

Both Gorton and Hastings have also been strong supporters of the Fast Flux Test Facility (FFTF) in Richland, WA, and have been working to restart the facility, which has been in "hot standby" since 1990. Hastings initially convinced the previous energy secretary, Hazel O'Leary, to stop the process of a full shut-down and to keep the reactor in hot standby. "He prevented the draining of the cooling mechanism which would have shut the reactor down forever," said Suzanne Heaston, the Tri-Cities regional coordinator for Senator Gorton's office. Last year, Gorton wrote a letter to the interim Secretary of Energy, Frederico Pena, urging him to proceed with an environmental impact statement assessing the viability of producing tritium and medical isotopes at FFTF. In the letter, Gorton said he fully supported "interim tritium production as a bridge to a long-term medical isotope mission." He also enclosed a petition signed by nuclear physicians and researchers, including two Nobel laureates, expressing the importance of establishing reliable medical isotope production in the U.S.

During the confirmation hearings for the new

Senator Slade Gorton (R-WA)

Representative Bart Stupak (D-MI)

The letter below from Senator Ted Stevens was received in June 1998 by then SNM President H.William Strauss, MD. It demonstrates Senator Stevens's commitment to improving medical care for Americans by increasing the availability of PET scans.
Conrad E. Nagle, MD
Editor, JNM Newsline

secretary of energy, William Richardson, Gorton made it clear that he wanted Richardson to support the restart of FFTF, according to Heaston. Recently, Hastings has met with Richardson to discuss the re-opening of FFTF and the importance of radioisotopes for medical research. The DOE is currently reviewing the possibility of conducting an environmental impact statement—the first step toward re-opening FFTF—and is expected to make a decision by the end of this year.

At Hastings's and Gorton's behest, several nuclear medicine researchers have been working on a letter-writing campaign urging nuclear physicians and patients like Susan Spenceley to correspond with their senators and representatives "to sensitize legislators to the importance of supporting medical isotope research and development programs," said Robert Schenter, PhD, deputy Hanford site manager of the DOE Isotope Production and Distribution Program in Richland, WA. "The senator and congressman recognize that positive letters can help balance out letters from those who are afraid of anything involving nuclear radiation," said Schenter.

Supporting Players: Senators Larry Craig (R-ID), Patty Murray (D-WA) and Connie Mack (R-FL) co-signed a letter with Senator Gorton requesting $10 million in increased DOE budget funds for fiscal year 1999. Murray also supports the re-start of the FFTF if it is used solely for the purpose of medical isotope production and not for tritium production.

United States Senate
Committee on Appropriations
Washington, DC

June 3, 1998

Dr. William Strauss
President
Society of Nuclear Medicine
1850 Samuel Morse Dr.
Reston, VA 20190

Dear Dr. Strauss:

Congratulations to you and the Society of Nuclear Medicine on the occasion of your 45th Annual Meeting in Toronto from June 7th through June 11th. I know from personal experience as well as from my work in the Senate of the United States the great benefits that clinical applications of nuclear medicine in diagnosis and treatment of disease have brought to people around the world during the last half of the 20th century.

While other commitments prevent me from being at your meeting, I want to let you and your colleagues know of my strong and continuing support for Positron Emission Tomography (PET) technology. Over the past 20 years, millions of federal taxpayer dollars have helped support the development of PET, which my good friend Dr. Mike Phelps of UCLA pioneered. You, our experts in nuclear medicine, know what a powerful tool PET is in diagnosing and tracking cancer and heart disease and in studying the brain.

I have spent much time and effort during the past several years to increase the availability of PET to American citizens who financed its development. This past year, those efforts began to bear fruit when our Congress passed the FDA Reform Act of 1997, which set up a cooperative way for the PET community to work with FDA to develop a rational approval system for the radiopharmaceuticals used in PET scans.

I also am pleased that our Secretary of Health and Human Services, Donna Shalala, has agreed to begin Medicare payment for PET scans. While the initial response of the Health Care Financing Administration to implement our agreement has been slow, I have received recent assurances from Secretary Shalala that Medicare payment for PET scans will be assured in the near future. Just last week, HCFA issued a national payment policy for the technical component of PET scans of $1,980 per scan, a figure that is, I believe, satisfactory to the PET community.

PET scan technology must become widely available to the American people. I hope that the Society of Nuclear Medicine will join me in this effort.

My best wishes for a successful meeting.

Cordially,
TED STEVENS

Easing Regulations on Radiopharmaceuticals

Congressman Bart Stupak (D-MI) has been echoing what many in the nuclear medicine field have been saying for years: The Nuclear Regulatory Commission (NRC) does not have a medical mindset and should not be regulating nuclear medicine. During House Oversight Committee hearings in 1996, he questioned NRC Commissioner Shirley Jackson on whether the NRC was following the findings of the National Academy of Sciences report which recommended that the NRC ease its regulations on medical isotopes. "I'm open to getting the NRC out of its medical use program and handing the regulation of radioisotopes over to the FDA," said Stupak in an interview with *Newsline*. "A bill has been proposed in the House to do this, and we will be following it closely during the upcoming year."

Stupak also co-wrote the section of the FDA reform bill dealing with the regulation of radiopharmaceuticals. The main provision directs the FDA to issue new regulations for radiopharmaceuticals, taking into account that those used for diagnostic purposes are less toxic than other drugs. The bill also calls for the FDA to consider approval for broader disease indications for organ imaging. A third provi-

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vices because the new PPS will cover fewer services than HCFA estimated when it first addressed the bundling issue in a 1988 proposed rule. The rule cites a $10,000 penalty for unbundling outpatient services to increase Medicare reimbursement.

Correct Coding Initiative. HCFA will apply the Correct Coding Initiative (CCI) to hospital outpatient claims to ensure that the most comprehensive of a group of codes is billed instead of the component parts. The CCI also checks for mutually exclusive code pairs.

Extension of cost reductions. Hospital outpatient operating costs will be reduced by 5.8% and capital costs by 10%. These reductions were scheduled to end in fiscal year 1998, but the Balanced Budget Act has extended the reductions through December 31, 1999.

New method for calculating beneficiary copayment. Under the current system, beneficiary liability for outpatient services is based on 20% of charges, rather than on 20% of actual program payments, as is the case for other Medicare services. Because charges generally are substantially greater than payments, beneficiaries on average have been paying up to 50% of the costs of outpatient care. The year 2000 delay in implementation will cost beneficiaries $570 million.

To obtain a copy of the September 8th *Federal Register*, contact the Superintendent of Documents at (202) 512-1800. Readers may download the proposed rule by accessing the *Federal Register* (http://www.access.gpo.gov/su_docs/aces/aces140.html) and searching "Federal Register," date "09081998," keyword "Medicare."

SNM and the Nuclear Medicine APC Task Force

SNM is a member of the Nuclear Medicine APC Task Force, headed by Kenneth McKusick, MD (see "Commentary," following this article). As well as SNM and the SNM Technologist Section (the section is represented by Denise A. Merlino, MBA, CNMT), the task force includes the American College of Nuclear Physicians (represented by Robert E. Henkin, MD) the American Society of Nuclear Cardiology (William A. Van Decker, MD), and the Council on Radionuclides and Radiopharmaceuticals (CORAR, represented by Jack Slosky, PhD, MBA, and Gordon Schatz, Esq.). Working with HCFA officials over the last year, the group has been successful on two of the three most important issues: increasing the number of nuclear medicine APCs from four to nine and ensuring that all nuclear medicine procedures are considered significant ones not affected by the multiple-procedure reduction policy. The task force will ensure that HCFA corrects anomalies in nuclear medicine APCs and that the agency reimburses radiopharmaceutical costs fairly.

"Black Box" Commercial Coding Edits Now in Effect

Responding to congressional pressure to conserve Medicare funds, HCFA recently instituted 220 Commercial Correct Coding (CCC) edits. The agency compared its current National Correct Coding Initiative (NCCI) codes with 500 proposed codes in a side-by-side trial in Iowa before coming up with the reduced number. Although the aim appears to be to further improve Medicare's rebundling policy, the CCC coding combinations will remain unknown to physicians requesting Medicare reimbursement. Only when the physician receives a denial will he or she know that a certain combination isn't allowed under the new edits. According to Medicare officials, physicians calling to inquire about denials will be given explanations drawn from the carrier manual, which gives the rationale for prohibited code combinations. Carriers have been instructed to call a help desk set up by the contractor that created the edits for any questions they can't answer by referring to the manual. One reason given for "black-boxing" the new CCC edits is they are "proprietary" and will not be published by the National Technical Information Service.

HCFA says its goal is to chart additional cost-savings earned by the CCC edits. The money saved from the commercial edits will be tracked separately from the money saved by the NCCI edits

The American Medical Association and SNM are opposed to these new proprietary edits. Physician specialty organizations, like SNM, were not allowed to participate in the development of these edits, which will have a significant impact on specialty physician reimbursement.

For more information on APCs, contact Wendy Smith (703-708-9000 ext. 242, or by e-mail: wsmith@snm.org). Also contact Ms. Smith if you are affected by a "black box" coding edit and to report the code pairs involved. SNM will attempt to determine code edits that affect nuclear medicine and communicate these to its membership.

—Wendy Smith, MPH, is the SNM director of health care policy

Congress

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sion stipulates that radiopharmaceuticals and PET radiopharmaceuticals will be excluded from regulations concerning pharmacy compounding. "I thought that the FDA was not being realistic," said Stupak. "The FDA felt that radiopharmaceuticals injected into the body to diagnose tumors needed to be proven safe and effective in the same manner as drugs used to treat tumors. I felt there needed to be a distinction between diagnostic agents and therapeutic drugs."

In recent legislation, Stupak was also a co-sponsor of the patient's bill of rights, which would require managed care companies to reimburse for the costs patients incur when they enter a clinical trial using an experimental treatment. This could be useful for trials involving alpha emitters or radio-labeled monoclonal antibodies for the treatment of cancer. "Nuclear medicine is on the cutting edge of technology," said Stupak. "Why not allow patients to have coverage for these treatments and get some practical use out of the research?"

Supporting Players: With Stupak, Representative Tom Coburn (R-OK) co-authored the FDA reform bill's radiopharmaceutical provisions. Senator Ted Kennedy and Senate Minority Leader Tom Daschle (D-SD) plan to reintroduce the patient's rights bill in the Senate.

—Deborah Kotz