pared with knowledgeable, cost-effective proposals which are in the best interest of the Nuclear Medicine community.

I can report to you that the Society of Nuclear Medicine has already embarked on the first of these steps. On November 5, during the evening preceding the Executive Committee meeting, I convened a special ad hoc commission to begin addressing how the Health Security Act might affect nuclear medicine and how the Society might best respond. In analyzing the Act as well as documents supplied by other organizations in medicine, the commission identified a series of key questions—

- How will nuclear medicine ensure representation as health care reform reaches the planning stage?
- How can the profession influence research funding?
- What strategies can we use in approaching reformed specialty distribution?
- How can nuclear medicine collect and deliver manpower data?
- How can practice guidelines be used to promote the most effective use of nuclear medicine procedures?
- The commission discussed these and other questions, such as the positioning of the profession under managed care, and agreed to my proposed expansion of the SNM Health Care Policy Committee to address these issues more fully.

Because the process will only be initiated during the remainder of my term, I asked President-elect James J. Conway to analyze how the SNM Health Care Policy Committee could be restructured to assist the SNM membership to ensure that nuclear medicine practice will be accepted as a valuable part of the new health care system. The Executive Committee approved Dr. Conway’s proposal to restructure the Commission on Health Care Policy (CHCP). The CHCP will comprise three groups—a Scientific Committee, Standards Implementation Committee, and Health Care Reform Committee. The role of the Scientific Committee will be to continue ensuring the scientific validation of practice guidelines. That of the Standards Implementation Committee will be to guarantee a system of chapter or state representation as health care reform moves onto the regional level. Finally, the Health Care Reform Committee will initiate a broad-based analysis of issues likely to affect the Society of Nuclear Medicine.

As I noted, it is too early to determine the precise outlines of health care reform. Yet one thing seems clear: any reform will probably favor managed care. If that is the case, there will be substantive and far-reaching changes in the practice of nuclear medicine, as well as in education and research.

Whether or not primary care physicians become the “gatekeepers” much heralded in the media, physicians and allied health professionals in medical specialties may discover that their relations to referring physicians have greatly altered. At the same time, medical education quotas by specialty—if these are established—will change the human profile, and the numbers, in our field. The training of young nuclear medicine physicians will inevitably respond to this evolution.

I feel that another clear theme in health care reform will be that “research” will be come synonymous with “outcomes research.” This is an eventuality for which the Society needs to be prepared, and one for which the CHCP’s Scientific Committee must immediately address itself.

Of course, the nuclear medicine community spans many diverse areas, not the least of which are the industries whose health is joined to our own. For these companies, an uncertain future may mean a prudent reduction of some current expenditures. Advertising revenues in the Society’s journals, as well as exhibitor funding, may suffer in the short term. More crucially, industry funds for research could shrink.

The economic environment for nuclear medicine, then, shows signs of growing leaner. The Society will need to view budgets in terms of declining income and expanding responsibilities. New projects will be subject to meticulous and penetrating budgetary scrutiny.

The reality, in terms of the Society’s health in the near term, is clear. To maintain current activities—let alone expand into new areas—new sources of funding will be needed. Facing the threats and opportunities afforded by health care reform will mean sacrifices—in time, talents, and in money. An increase in Society dues—an anathema to all of us—may well be necessary to bolster shrinking revenues and to mount an effective response to nationwide reform.

In September’s column, I drew from Dr. William Strauss’s Plenary address in which he described the twofold connotation of the Chinese character for “crisis”—“danger” coupled with “opportunity.” The Health Security Act of 1993, whatever its final form, has shaken the dust from a host of long-held preconceptions.

Our opportunity is now to view health care reform with freshened vision, using our talents and our intelligence to analyze the many proposals vying for attention. Then we must discover the ways nuclear medicine will fit within the revived health care system of twenty-first-century America.

Our only real danger is to shrink from that challenge.

Richard C. Reba, MD

**COMMENTARY**

**GOVERNMENT RELATIONS UPDATE**

**REIMBURSEMENT**

* Relative Value Update Committee (RUC). HCFA evaluated 497 relative work values (physician work component) for new and revised 1994 CPT codes that the RUC recommended. HCFA says that 75% of these values were either accepted or increased in value, and the other 25% decreased from the orig-
nal recommendation. Pertinent to nuclear medicine, HCFA approved CPT 78807 (Radionuclide localization of abscess, SPECT) for the amount that SNM and ACNP originally recommended (1.1 RVU), but rejected the RVUs for codes 78608 and 78609 (PET brain imaging for metabolic and perfusion evaluation), as HCFA still considers PET imaging a non-covered technology. RVUs for dual energy x-ray absorptiometry (DEXA) and dual photon absorptiometry (DPA) were recommended to the RUC and approved; in June, HCFA will consider them for incorporation into the 1995 Medicare

**Fee Schedule.** To date, HCFA has yet to release the 1994 Medicare Fee Schedule; thus, though HCFA accepted RVUs, additional adjustments to maintain budget neutrality will be made to either the relative value scale, the conversion factor, or both. Congressional mandate to reinstate separate reimbursement for ECGs and equal payment for new physicians will result in an overall reduction to the RBRVS of 1.3%. At the most recent RUC meeting, a motion was passed to have the AMA Board of Trustees seek statutory relief by Congress from this continued erosion of the RVU base. HCFA also attempted to maintain budget neutrality within each family of codes.

The results of the five year review of the Medicare fee schedule will take effect in 1997. HCFA will decide within the next three months which methodology will be used to update the current RVUs and suggested four possible options: collect comments from everyone; contract with a research group to reevaluate all the codes; allow each specialty to make intraspecialty changes; or have the RUC recommend all new relative work values.

**CPT.** HCFA’s recent requirement that the RUC recommendations for CPT 1995 be submitted no later than May 27, 1993, has caused the AMA-CPT Panel to adjust its meeting dates. Previously, final submissions for any proposed deletions, additions, or revisions to the CPT handbook for the following year needed to be made at the April meeting. Now the last opportunity to submit changes that would appear in CPT 1995 will be the February meeting. ACNP and SNM will once again submit requests to establish codes for PET cardiac and tumor imaging for CPT 1995.

**Physician Payment Review Commission.** The Physician Payment Review Commission (PPRC) held a public hearing on November 29-30, 1993, allowing organizations the opportunity to comment on issues the PPRC will consider in its 1994 report to Congress. During the next several months, the PPRC’s workplan will include topics related to health care reform, like the structure and role of health alliances, quality assurance, and graduate medical education. Draft chapters of the PPRC’s 1994 report to Congress will be distributed in early 1994 to medical specialty secretaries for comment.

**Propective Payment Assessment Commission.** At an October 26, 1993 public meeting of the Prospective Payment Assessment Commission (ProPAC), staff presented the framework for analysing two prospective payment models for hospital outpatient services (radiology and surgery). The fee schedule models are based on HCPCS codes and Ambulatory Patient Groups (APGs). ProPAC described its analysis of the two payment models for radiology outpatient procedures as follows: aggregate payment-to-cost ratios are unchanged for urban and rural locations; and HCPCS model and APG model have similar payment to cost ratios. No ProPAC decision was requested at the October meeting regarding an approach to prospective outpatient payment; the issue will be further considered at the next Commission meeting in December, 1993.

**Practice Expense Component of the RBRVS.** The PPRC is analyzing the framework for developing resource-based practice expense values. To date, only one group has had a formal assessment of practice expenses (the vascular surgeons contracted with ABT Associates). PPRC is using this assessment as a reference model, although some of its evaluation of the methodology used by ABT is not positive. PPRC has stated that Ambulatory Patient Groups (APG) data compiled by the Center for Health Policy Studies (CHPS) will probably provide the cornerstone for the final formulation of practice expense data.

The CHPS says that by spring 1994 it will likely submit a grant proposal to collect practice expense data to either HCFA or PPRC. Funding would probably support the evaluation of high volume procedures only. CHPS would like all data—even that collected by smaller medical societies—incorporated into its final product. If all groups contribute funds and data unique to their particular specialty, then using only one methodology for everyone might retain greater relativity among medical specialty groups.

**SPECT Project.** The 1992-1993 project cycle concluded in June, with four projects were funded: assessment of Insurer SPECT Coverage and Reimbursement Practices and the Development of a SPECT Insurer Information Package; Establishing a Database on SPECT Use; Summary of the Scientific Literature for Myocardial Perfusion Imaging; and The Clinical Efficacy of Radionuclide Bone Imaging Using SPECT in Patients with Low Back Pain: A Structured Review of the Literature. All of the projects will be completed by February, 1994. The SPECT Project Steering Committee is evaluating the option of hiring a full time project director. Strategies will be needed for use of the data produced during the first cycle. Also, results from the initial projects may provide direction for the SPECT Project into the second cycle. The Steering Committee is considering a proposal from Charles River Associates to collect data on practice expenses. Funding for the development of practice standards and guidelines was discussed as a potential project for the second cycle of the SPECT Project.

**Radio pharmaceutical Price Resource.** The Radio pharmaceutical Price Resource is meant to be a survey tool for the Medicare carrier medical directors establishing local codes. Once a pricing structure is established for a specific region,
Pharmaceutical providers could bill electronically for radiopharmaceuticals; reimbursement amounts would be based on the invoice price. Florida and Texas had developed local codes based on list prices; Florida is resurveying its providers. Pennsylvania, Wisconsin and Arkansas have requested information on radiopharmaceutical pricing from the Joint Government Relations Office. The Price Resource is being distributed to the carriers upon request.

Agency for Health Care Policy and Research (AHCPR). Several groups, including The Blue Cross and Blue Shield Association and the AMA, are developing practice guidelines and technology assessments, but the AHCPR continues to lead the public and private sector in practice parameter development. Their purpose is to assist federally financed government insurance programs, i.e., CHAMPUS and Medicare, to form coverage decisions. AHCPR has completed two technology assessments for nuclear medicine—PET scanning and bone mineral density studies. Release of the PET evaluation is being withheld pending FDA approval of applicable radiopharmaceuticals, and the bone mineral density evaluation is in final draft form. The Blue Cross and Blue Shield Association recently joined with Kaiser Permanente to expand its technology assessment program. They have completed an evaluation for monoclonal antibody imaging for colon cancer and are evaluating PET cardiac imaging. The AMA is assessing myocardial perfusion imaging. All of the above groups welcome input from medical specialty groups.

On October 28, 1993, President Clinton approved the fiscal year 1994 budget for the AHCPR (Public Law 103-124), with a significant increase in funding—an FY 1994 budget of $154,399,000; the fiscal year 1993 budget was $128,041,000.

Carrier Medical Director Advisory Panels. The Joint Office is in the process of updating the list of Nuclear Medicine Physician Advisory Committee representatives who serve on the Carrier Medical Director Advisory Panels. Recently, the Joint Office contacted the Carrier Medical Directors who represent the forty-five Medicare regions. The results were: There is a nuclear medicine physician representative on twenty-eight advisory panels; in thirteen regions, nuclear medicine is represented by the Radiologist who sits on the panel (nominations to these committees have been denied on the basis that nuclear medicine is not a specialty requiring mandatory representation); and the remaining four regions without delegates have not received any nominations (it may still be possible to have Nuclear Medicine represented on these panels). Since much of health care reform is at the state level, it would be useful for the Joint Office to establish a carriers data bank of current reimbursement policies and guidelines established by Medicare.

Health Care Policy

National Health Care Reform. On November 18, 1993, Ira Magaziner, Senior Advisor to the President for Policy Development, briefed representatives of medical specialty and state societies on details of the Administration’s health system reform plan. Mr. Magaziner emphasized that the Administration is receptive to modifications as Congress considers the reform plan, and estimated a six to nine month health system reform debate prior to passage of health system reform. On November 20, 1993, Majority Leader Richard Gephardt (D-MO) introduced the Clinton plan as H. R. 3600, co-sponsored by 100 Representatives, and by Senate Majority Leader George Mitchell (D-ME) as S. 1757, co-sponsored by a total of 30 Senators. Annual Medicare savings in the reform bill are: $9.8 billion in fiscal year 1996; $14.3 billion in fiscal year 1997; $22.8 billion in fiscal year 1998; $33 billion in fiscal year 1999; and $41.7 billion in fiscal year 2000; total savings over five years: $124.4 billion.

On November 22, 1993, Senator John Chafee (R-RI) introduced the Senate Republicans’ health reform bill, S. 1770. The plan would mandate that all Americans have health insurance, create a Federal Benefits Commission, and establish state-based, voluntary managed competition.

State Health Care Reform: In 1993, many states outpaced the federal government in aggressively pursuing health system reform. Existing state reforms may be compatible with the President’s proposal. As of November, 1993, substantive state health system reform activity diminished as state legislatures were adjourned for the year. Despite financial and statutory limitations, a high level of activity by state legislatures on various health system reform issues is expected to continue in 1994. The Administration’s health reform legislation assigns much latitude as well as responsibility to the states. It will be important for ACNP and SNM members to monitor and become involved in state health system reform initiatives.

Medicare Budget Reconciliation. The 1993 Omnibus Budget Reconciliation Act (OBRA 1993) is the largest vehicle for health legislation since 1990. The final bill, which the President signed on August 10, 1993 (Public Law 103-66), includes $55.8 billion in reductions to the Medicare program over the next five years; the Medicaid program will be cut $7.1 billion over the next five years.

The following measures are included in OBRA 1993: the 2.6% inflation update for all physicians, except primary care providers, will end in fiscal years 1994 and 1995 (surgeons’ fees also will be reduced by one percent in fiscal year 1994 only) for a savings of $4.4 billion; the Medicare Volume Performance Standard (MVPS) target for surgeons and non-surgeons will be reduced, for a savings of $2.01 billion, with primary care physicians receiving their full 6.6% update in fiscal year 1994, and, after the reductions, non-surgeons’ fees rising 4% in fiscal year 1994 and surgical fees rising 8.6% (primary care doctors will get a separate MVPS target and anesthesiologists will be folded into the target already established for surgeons); an existing 5.8% reduction in payments for hospital outpatient services will be extended from fiscal year 1995 through fiscal year 1998, for a savings of $1.54 billion; and, effective January 1, 1994, for a savings of $350
million, physicians can no longer refer Medicare or Medicaid patients to a group of services in which the doctor has a financial or ownership interest stake, a provision that will extend to both public programs and to physical and occupational therapy services, radiation therapy, radiology and other diagnostic services, durable medical equipment, parenteral and enteral nutrition equipment and supplies, prosthetic devices and orthotics and prosthetics, and outpatient hospital services (exceptions apply to federally qualified health maintenance programs and health maintenance organizations with Medicare risk contracts, rural providers, and certain group practices).

DEPARTMENT OF ENERGY

Congressional Hearings. On October 14, 1993, Dr. Richard Holmes presented testimony before the House Science, Space, and Technology Committee; Energy Subcommittee, chaired by Representative Marilyn Lloyd (D-TN). The main focus of the hearing was to update committee members on the status of the domestic isotope production and the need for a domestic supply of reactor, accelerator, and stable isotopes. Several other Congressional Committees are also interested in domestic isotope production, including the Senate Energy and Natural Resources Committee and the House Government Operations Committee. Dr. Robert Atcher testified before the House Government Operations Committee; Environment, Energy, and Natural Resources Subcommittee chaired by Representative Mike Synar (D-OK) on December 6, 1993, focusing primarily on DOE’s progress in determining and establishing the need for a domestic supply of radioisotopes.

Director - Office of Energy Research. Martha Krebs, Ph.D. was confirmed by the Senate in October, 1993, as the new Director of the Office of Energy Research, a very influential position in the funding of nuclear medicine research. Dr. Richard Reba, Dr. Henry Wagner, and Dr. Wynn Volkert met with Dr. Krebs on September 22, 1993, to discuss the role that DOE would play in advancing nuclear medicine research and urge the DOE to develop a definitive mission statement for nuclear medicine research and to work closely with ACNP and SNM on this process.

NUCLEAR REGULATORY COMMISSION

Metzenbaum Amendment. At an October, 1993 markup of the Senate Environment and Public Works Committee, Senator Metzenbaum offered an amendment to a bill reauthorizing the Atomic Energy Act, that would establish a minimum amount for the civil penalty for violations of medical therapy licenses under the Atomic Energy Act of 1954. Currently, NRC has the authority to levy a fine on not more than $100,000 for a medical therapy misadministration. Senator Metzenbaum felt that this authority is not being exercised appropriately and that minuscule fines do little to deter misadministrations. His amendment would set a minimum of $20,000 for medical therapy misadministrations. ACNP and SNM have met with several congressional staffers, to express concern over the effects of the amendment on therapy practices. The bill will come before the full committee in March, 1994.

Radiopharmacy Petition. The NRC collected comments on the “Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use” proposed rule that would allow physicians and pharmacists to deviate from package inserts when using radiopharmaceuticals. SNM and ACNP filed a petition on this rule in 1989, generally supporting it but expressing concern about dual regulation and compatibility levels. SNM and ACNP also had concerns over setting the level of compatibility at two, despite a unanimous opinion from the Agreement States that this should not be a level one or two item of compatibility. Because many states already regulate the practice of pharmacy and medicine, an intrusion by the NRC would be unnecessary and duplicative. ACNP and SNM also pointed out that many states have permitted professional flexibility in radiopharmaceutical use without incident for many years. NRC should have a final rule on this topic by the end of 1993.

Below Regulatory Concern. In accordance with the Energy Policy Act of 1992, the NRC withdrew its Below Regulatory Concern policy statements. The NRC will now handle all exemption requests for specific radioactive waste streams on a case-by-case basis.

NRC Staff Briefing on the Proposed Management Plan for the Medical Program: On September 10, 1993, Carl Paperiello, PhD, proposed a staff management plan to Chairman Selin and the Commissioners that outlined 90 action points that needed alteration within the NRC’s medical program. The plan outlined nine major areas needing attention: policy issues; misadministrations and patient follow-up; rule-making; licensing guidance; inspection guidance; enforcement; management and radiation safety officer responsibilities; research; and information management systems. The resources to implement this management plan will require about 50 additional direct full time equivalents and $4.25 million over the next five fiscal years. This undertaking by Dr. Paperiello and NRC is an attempt to reorganize and create a more effective and efficient regulation of the medical community. The NRC plans on giving yearly briefings on the status of the items within this plan to keep the commissioners aware of the progress in these areas.

NRC-FDA Memorandum of Understanding: NRC Chairman Ivan Selin and FDA Commissioner David Kessler signed a Memorandum of Understanding (MOU) that coordinates the regulation of medical devices, drugs, and biological products which use radioactive materials under NRC’s jurisdiction, to foster cooperation between the two agencies and provide more effective exchanges of information. Under the MOU, the NRC and the FDA will: on request, assist each other in investigating incidents or complaints involving products of mutual regulatory concern; exchange information on investigations to provide expert technical assistance to either agency and to
reduce duplication of effort; share information on new technology or methods, including devices, drugs, or other biologics for which regulations have not yet been developed or that are related to the other agency’s mission; offer each other the opportunity to comment on notifications to manufacturers, operators, licensees, or patients and to comment on regulations, regulatory guides, or other communications that refer to activities, policies, or regulation of the other agency; and make the other agency aware of issues covered by the MOU.

NRC development of a NUREG dealing with Radiation Safety Programs: Having made several presentations before organizations interested in radiation safety—like the Health Physics Society—in an effort to create a regulatory guide that will clarify the role of the radiation safety officer and radiation safety programs in medical facilities, the NRC will make presentations at both the ACNP Annual Meeting and the SNM Mid-Winter meeting. Without intending to create any new regulations, the NRC primarily intends to develop a document that will allow the RSO to communicate and receive support from the hospital administration.

Advisory Committee on the Medical Uses of Isotopes (ACMUI): The ACMUI met on November 1-2, 1993, in Washington for one of their bi-annual meetings, and covered topics like user fees, the radiopharmacy petition, the development of a Nuclear Regulatory Guide on radiation safety programs, and an update on all current rulemakings. The ACMUI also expressed concern over the implementation of the new 10 CFR Part 20 requirements on January 1, 1994, citing problems with certain parts of the public and patient dose limits. The committee will be making a presentation before the Commission in February, 1994.

Sandy Bilko, Acting Director of Public Relations
David Nichols, Legislative Coordinator
Valerie Fedio, Assistant Director

NEWS BRIEFS

Uterine Response to Sincalide
SNM’s Pharmacopeia Committee wishes to communicate a previously unreported side effect of sincalide (KinevacR), the octapeptide moiety of cholecystokinin that is responsible for smooth muscle contraction in the gallbladder.

Within five minutes of sincalide injection, a patient who was six weeks pregnant noted vaginal bleeding and uterine contraction. Subsequent ultrasonographic examination showed the presence of a yolk sac, so the final diagnosis was “threatened abortion.”

While sincalide’s effects on the uterus have not been well documented, there is reason to believe that muscle contraction in this organ could be simulated, similar to its effect on the smooth muscle of the gallbladder and intestine. There is no chemical analogy between sincalide and the nonapeptide oxytocin.

The manufacturer and the Food and Drug Administration were contacted and, after an investigation, this potentially significant problem with sincalide now appears in the package insert, in the Precautions section.

This side effect of sincalide has not been published heretofore in the nuclear medicine literature or, in fact, in any other material which we were able to examine in the textbooks or in the medical literature, even employing MedLine. We hope that this letter will alert physicians involved in any imaging technique that employs sincalide to exercise appropriate caution.

Edward B. Silberstein, MD, Chair,
Pharmacopeia Committee
Cincinnati, OH
Carol S. Marcus, PhD, MD
Los Angeles, CA

New Publication
A new quarterly magazine, Radwaste, from the American Nuclear Society, is premiering this month to fill a niche in the growing radioactive waste management industry. Focusing on practical problems and solutions in all aspects of the industry, the articles will come primarily from managers and others in the field.

“This magazine was started because the people that run publications at ANS recognized that there’s a whole segment of the industry that’s not well represented in magazines,” said Radwaste editor David Schabes. “[Radwaste] is to represent people in low- and high-level radioactive waste areas—the DOD, weapons cleanup, etc. Also a good portion is addressing issues in nuclear medicine and environmental restoration.”

To keep the information in the magazine practical and applicable, a staff of editorial advisors from all different fields of nuclear science will solicit manuscripts and serve as technical referees. And there will be plenty of material—a hefty 70 pages of editorial per issue. Starting with a controlled circulation of 13,000, the publishers would like to increase the regularity to monthly within five years.

Correction
In the December 1993, Newsline, “New York Gets another Reprieve on LLRW Disposal,” Eugene Gleason, deputy commissioner of New York Energy Commission, was mistakenly named as “Gene Gleason, deputy commissioner of the New York State Environmental Office.” We regret the error.