COMMENTARY

LINES FROM THE PRESIDENT: STRATEGIC PLANNING

THE SOCIETY OF NUCLEAR MEDICINE (SNM) IS engaged in a strategic planning process which we hope will be completed within the next fiscal year. The strategic plan should chart a course into the future for the Society. Obviously, that course can be plotted only when there is active discussion regarding what we perceive to be the future direction of the actual practice and development of nuclear medicine.

Leon S. Malmud, MD

Nuclear medicine is a diverse discipline that includes full-time nuclear medicine practitioners, radiologists, cardiologists, physicists, radiopharmacists, radiochemists, technologists, academic practitioners and other specialists. Devising one strategic plan for an organization composed of such a variegated group presents a challenge.

The strategic plan for the Society will be a direct outgrowth of what we perceive trends of the discipline to be. Our perceptions of the future of the field will be the basis upon which we build the plans of the Society. We anticipate that we will then be better able to serve our membership, diverse as it is, and to foster the growth of the discipline for all of those who are involved with it. The process will of necessity first be internal to The Society of Nuclear Medicine. Eventually, we will collaborate with the American College of Nuclear Physicians (ACNP), the American College of Nuclear Medicine (ACNM), the SNM and ACNP Office for Government Relations in Washington, and perhaps even the ACNP Corporate Committee because of its distinctly separate character and interests. Just as the Society hopes to achieve a consensus within its membership, so do we hope to eventually conceive a consensus among these organizations as we present our strategies for implementing actions necessary to fulfill our unique and complementary missions.

The future holds enormous opportunities for continued growth of the discipline, if we can avoid the pitfalls. Our current challenges include those of timely introduction of new clinically useful techniques, enhancement of our use of unsealed radiopharmaceuticals in the treatment of malignancy, the ability to attract scientists and clinicians into our discipline, the problems of radiopharmaceutical production and the excessive costs of redundant regulation, and the issues of fair reimbursement for both the professional and technical costs of our technology. In the absence of adequate funding for research and development or adequate reimbursement for our clinical services, the discipline will wither and patient care will suffer for the lack of ability to attract clinicians and scientists.

The challenges mentioned above are intimately interrelated. In the future, as is now, priorities will be difficult to define and even more difficult to achieve. For example, there is no consensus regarding whether we should invest more aggressively in SPECT or PET. I ask, why not both? Another current question is should priority be given to the interest of radiopharmaceutical manufacturers or to the interest of radiopharmacies? Both have become essential to the practice of nuclear medicine. It may be that we must recognize the need for the distribution network as well as the obvious need for the source of the products. What is most important for us in the future is to remember that if we achieve a consensus we will survive and thrive, since what this discipline has to offer patients is clinically valuable and undoubtedly plays a positive role in patient outcome. If we focus on parochial interests or succumb to cannibalizing each other under the pressure of cost containment, then the future for all of us is bleak and most importantly the opportunities for our patients become limited if not totally unavailable. I firmly believe that we can resolve the problems we face if we establish a strategy born of consensus for the discipline of nuclear medicine to grow in the future.

The planning process may require the involvement of representatives from government and industry. This is appropriate since our specialty was brought forth with significant federal funding. The radioisotopes we use were first made available most often in national laboratories. Nuclear medicine is a direct outgrowth of federally-funded science. The economic problems that the discipline faces today are in many respects the result of the tightening of government purse strings and a perceived lack of interest by government in issues relating to nuclear medicine. The industrial infrastructure of nuclear medicine developed with federal assistance (as did many other industries in this country). As industry is increasingly encouraged to stand on its own feet, we would be remiss in not collaborating with industry to serve our patients best. To disregard the essential interaction with government or collaboration with industry on behalf of our discipline and our patients would be an error for which we should not be forgiven. As government investment slows, private industry would be expected to shoulder more of the burden.

Corporations must respond to investors. If analysis of nuclear medicine ventures finds them to be only marginally profitable due to the tangle of excessive regulation, then industry will in-

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Approvals

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ministered to most patients only once in a lifetime.

One suggested revision would move responsibility for radiopharmaceuticals from the drug division to the Center for Devices and Radiological Health. Dr. Alazraki says that "this certainly is an option which we hope will be thoroughly reviewed by the ombudsman's office."

At a meeting in May with FDA Deputy Commissioner James Benson and Ombudsman Amanda B. Pedersen, Esq., Dr. Alazraki and Capt. William H. Briner, then SNM chairman of government relations, asked the FDA representatives to make changes in the NDA process for radiopharmaceuticals. Among other things, they said that radiopharmaceuticals should be evaluated not by sensitivity and specificity data for assessing particular disease states, but by their documented performance in providing images of functions such as myocardial perfusion, or hepatobiliary excretion.

Other positions presented by the SNM and ACNP in May included the following:

- Review of radiopharmaceuticals would be more appropriate under the FDA's Center for Devices and Radiological Health.
- All radiolabeled materials, including monoclonal antibodies should be reviewed in the same category as diagnostic radiopharmaceuticals.
- FDA should not regulate cyclotron-produced tracers for positron emission tomography (PET) unless transported interstate.

Agency officials declined to comment on the FDA's position on any of these requests.

The FDA ombudsman's office embarked on a plan, initiated by the May meeting, to review these comments, but the process stalled three months ago due to a potential conflict of interest. The problem surfaced when routine examination of Ombudsman Pedersen's financial disclosure revealed ownership of stock in a company with a radiopharmaceutical product in the NDA phase.

Ms. Pedersen called the matter a "technical problem" that would be quickly resolved. She had no estimate of when the FDA would respond, but added that the regulators were interested in making the approval process for radiopharmaceuticals as efficient as possible. "The FDA wants to take a look—is there a better way to do things?" she said. "If I can't [oversee the process] then someone else at the FDA will."

"We really are unique—we are our own thing," says Dr. Alazraki. "In the drug division we've been treated more like drugs, not tracers—which have no pharmacological effects."

President

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vest elsewhere. Shareholders demand of industrial management a fair return on their investment.

If we recognize that the challenges of the present are multiple and interrelated, then we must also recognize that the issues must be addressed simultaneously, not sequentially. I anticipate that our strategic planning process will demonstrate that the problems facing us are multifaceted and they must be dealt with simultaneously and in an incremental fashion. As stated earlier, the currently perceived problems are those of attracting physicians and scientists into nuclear medicine, maintaining a stream of new radiopharmaceuticals and technical advances, seeking governmental support for research, assisting government in reducing redundant regulation, collaborating with industry in the development of new techniques for patients and in demanding fair reimbursement for both the professional and technical aspects of our work. The tasks can be divided into those of science, clinical practice, regulation, and reimbursement. The latter two issues are currently addressed by the ACNP and SNM government relations office in Washington. The scientific (research) and educational (clinical) challenges are based primarily in The Society of Nuclear Medicine and its mission statement identifies these issues. The roles of the SNM and ACNP are complementary and should be tightly integrated. Neither organization represents a threat to the other, nor should it be perceived to. Both organizations serve the nuclear medicine community as a whole, though from different vantage points.

As we plan for the future and attempt to resolve the issues of the present, as well as anticipate the issues of the future, we must be cognizant of our history of growth and support, and evolving trends in reimbursement for health care. Working together through the government relations office and in collaboration with other professional groups having a common interest, we shall advance our knowledge, maintain the critical mass necessary to grow, and thereby best serve our current and future patients' needs.

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