COMMENTARY

ACNP Annual Meeting: Speakers' Visions

The following commentaries were presented as speeches at the 1995 Annual Meeting of the American College of Nuclear Physicians (ACNP) held this February in Cancun, Mexico. Due to space limitations, three speeches will be presented this month. Next month, Newsline will publish a fourth speech by Kenneth G. Kasses, PhD, president of the DuPont Merck Pharmaceutical Company's Radiopharmaceutical Division in North Billerica, MA.

R&D in Nuclear Medicine

By Peter C. Vermeeren

The Past

FIVE YEARS AGO, THE NUCLEAR medicine industry was in a crisis. It suffered from a serious lack of vision for the future. Prices and return on investments were too low. Few significant new products were introduced during the 1980s. Production equipment was old and not functioning properly. Radiopharmacies were not recuperating added value. There was a lack of communication between physicians and industry.

Many of the radiopharmaceutical producers considered exiting this unattractive market; however, exit barriers (price to leave) was too high. So, the decision was made in most industries to continue but to replace many in top management positions, particularly R&D, and to cut expenses. It became clear that the only way to survive was through rapid expansion beyond old generic product lines and by creating a new vision that most industries would accept.

For Mallinckrodt, this vision consisted of making new products the key to the future—specifically in the areas of oncology, cardiology, therapy and in focused areas like the brain. We also decided we had to make painful choices to redirect our focus from

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Health Care Reform: The Debate Ahead

By Jim Moody, PhD

ALTHOUGH COMPREHENSIVE universal health care reform will not pass Congress this year, the great national debate on this issue has been squarely joined and will intensify mid to late 1996. Clearly, this continuing debate is not about the scientific aspects of medicine, but about ethics and economics. Thus, the two major questions which remain before the country are: Do we receive good value for the great resources we expend? And are the benefits and costs of our health care system equitably distributed in our society? In other words, do we have an affordable and fair system?

Why Change a "Good Thing"?

U.S. *medicine* is probably the best in the world, but many criticize our health care system. The following illustrative contradictions may help explain why in virtually every poll—including exit polls at the recent election—well over 60 percent of the public believes that the U.S. health *system* needs fundamental change.

■ Most Americans don't like government intrusion, yet 72 per-

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The New Face of Health Care

By Henry N. Wagner, Jr., MD

ROBERT FROST WROTE THAT when he came to a crossroads, he "took the road less traveled, and that made all the difference." Physicians in nuclear medicine are at a crossroads, as they face many forces affecting the way they practice nuclear medicine. Each of us must ask ourselves: What is my vision of the future? What kind of nuclear medicine would I like to practice? How can I make my vision come true?

Physicians have always been the major decision makers with respect to patient care, but now we face decreasing control of the health care system. Where once we feared a government takeover of the health care system and "socialized" health care, now we find we've been "blind-sided" by capitalism. Businesses have begun to take control: Companies, such as Columbia-HCA, have stated that their goal is to deliver health care the way Wal-Mart delivers commodities.

If five or six huge companies eventually take over the health care system, it is conceivable that physicians will someday practice medicine in a manner analogous to the way that airline pilots fly airplanes—that is, high quality performance but no control of the airline.

What are we, as nuclear medicine physicians, to do in the face

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PET as a routine diagnostic tool and monoclonals. We increased our investments in R&D to about 7 to 9 percent of our total revenues. In other areas of the industry, enormous investments were made in new production equipment such as new cyclotrons, new technetium generator facilities and, in Mallinckrodt's case, in a new molybdenum plant. The result of these changes was promising: New products came on the market. Returns on investments increased. Pharmacy networks grew. Investors and managers had a renewed interest in nuclear medicine.

The Present

Recently, health care reform has thrown us for a loop. There has been an increasing demand on the health care community to simultaneously deliver broad access, high quality and low cost. At this point, discussion within the industry has shifted clearly away from medical efficacy towards a focus on economics. The nuclear medicine community, including industry, has been negatively affected by experiencing a decline in the number of procedures, a decrease in the price of products and an increase in competition with other imaging modalities .

The effect on the industry has been dramatic. Still fragile and in the recovery phase, it is clear that the economic impact of health reform is increasing competitive pressure. Therefore, the emphasis has shifted to consolidation and cost reductions. R&D will always be the first target for cost reductions because the effects are not felt immediately. However, in the long term, the effects of cutting R&D will be the most dramatic. The real future of nuclear medicine lies in market growth from innovative products that can show cost efficiency over other modalities.

All the players in the field—physicians and scientists as well as manufacturers and suppliers—must work toward a common long-term vision of the role of nuclear medicine in health care. That vision should start with a mutual agreement on the areas of nuclear medicine that will yield the best potential for new products. Although antitrust laws prevent manufacturers from agreeing upon development areas, it is important that new development be more diversified. Nuclear medicine will not move forward if every producer is devoting a major chunk of their R&D money on developing their own Technetium heart agent.

We estimate the radiopharmaceutical market in the U.S. to be about $575 million. Of the products used today, 84 percent (about 30 products) were introduced before 1980. Therefore, new products, including Cardiolite (introduced after 1980), represent only 16 percent of the market or $94 million for a total of about 20 products. Since about half of this market is Cardiolite, 20 products introduced in the last 15 years generate less than $50 million for the industry. This means that on average, a new product generates $2.5 million in sales per year with an estimated profit of only $250,000. An average radiopharmaceutical R&D project costs about $30 million before the product is introduced. Thus, unless you introduce a blockbuster product, the industry cannot pay the interest for the required capital of any product.

We all know that not all projects in which money is invested come to market. If we consider monoclonal (biotech) companies, we estimate that one approved product generates about $7 million on a yearly basis. The approval process has been so slow that most of the enormous investments are lost. The investments were initially made based on a higher market expectation.

The Future

We need to make R&D more efficient but not by reducing costs. Instead, I suggest we follow these five steps:

1. Portfolio analysis: We need to achieve the best balance between risk and reward, stability and growth. This means investing in fewer more focused projects via a faster process. We should stay out of investing in "niche" market products, and we should account for cost effectiveness and patient management early in the process. We need to focus on new applications and indications—not on replacement. Several tools have been developed to help in assessing total project costs, risk analysis, market potential and time needed to get to the market. It is time to re-engineer the R&D process and make it "world class."

2. Project management: In the past, many CEO's and top managers found that R&D was the slot machine of the corporation for which money but not leadership was provided. R&D often lacked the rigor to bring projects to an end. Within Mallinckrodt, we are implementing the theories from "Third Generation R&D" by Roussel, Saad and Erickson. It breaks the traditional isolation of R&D by the creation of multifunctional teams, forming a matrix organization with input from all parties in the company, and even, from outside the company. R&D will be integrated as equal partners with the corporation and the businesses.

3. Better communication with physicians: There needs to be stronger involvement by the nuclear medicine professional and also the referring physician. Especially with the latter, we need to come to an integrated vision in defining the needs of the future. A much more important role will be played by primary care physicians within the clinical setting, and we should make an effort to get them to promote nuclear medicine and its benefits.

4. Assessment of the competition: We need to examine competing imaging modalities and their role in the future. It will be a clear indication which procedure will survive and which will not. We expect, for example, that in the long term, ejection fraction will go to Echo.

5. The trend towards therapies: We need to recognize the trend toward therapeutic nuclear medicine and its potential for higher profits.

In conclusion, the cycles for developing new products are becoming longer and more costly. Therefore, a clear vision of nuclear medicine is essential. This can only be achieved if every player in the profession works together. The industry needs to sustain long term growth and earnings in order to retain the interest of the investors. So, we need to focus R&D efforts on new products for new indications and to develop cost effectiveness data. Most importantly, we, as a nuclear medicine community, must involve referring physicians in the decision process.

—Peter C. Vermeeren

Mr. Vermeeren is the Chairperson of the Corporate Committee of the American College of Nuclear Physicians and is the Senior Vice President at Mallinckrodt Medical Incorporated in St. Louis, MO.

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cent think government should control doctor's fees.

■ The U.S. health system is by far the most costly in the industrialized world—15% of the GNP—yet leaves by far the largest percent of its population uninsured, 16%. (At least another 10% are underinsured).

■ The U.S. system is also the most high tech, yet there are huge gaps where low tech would do. Our MRI-to-person ratio is ten times that of Canada's, but we don't vaccinate all our children.

■ There is less government involvement in the U.S. system than any other country, yet ours is the most paperwork-intensive and has the highest percent of overhead and administrative cost. Many physicians typically spend over five hours a week on paperwork.

Clearly, the economics and the equity of our current health care system remain open to creditable and fundamental challenge.

Is Health Care a Right?

Underlying the twin issues of fairness and economic affordability is a central ethical question, usually avoided in explicit terms or cloaked in policy jargon: Is health care a right of all citizens? In all other modern countries, of course it is. But as was obvious in the recent Congressional debate, the U.S. is still grappling with this bed rock ethical issue.

If the answer to this question remains "No," we must accept the status quo and admit that we have a two-tiered system for health rights: seniors, yes; all others, including children, no. If, on the other hand, the answer to the rights question becomes "Yes," there are two alternative implications: First, we need to drastically simplify the system to remove both existing administrative barriers and the multi-tiered pricing and "reimbursement" system. Second, we must then decide: How much health care is in fact a right? Primary care? Unlimited amounts of any kind of care? Probably no one really believes that every patient has a right to an unlimited amount of health care.

I believe that by the end of the public debate, we as a nation will determine that on both ethical and practical bases the answer to the "rights" question is "yes," and the focus will move on to how we best create a simplified administrative structure to access that right. Establishing a rational framework to decide the "how much" issue is going to be much harder and will take longer to resolve because it requires melding two disciplines that seldom ever combine: medical science and economics.

The Structure Question

Although there were ten major bills in '94, there are only two basic models with respect to market forces: single payer and "managed competition." The McDermott/Wellstone bill is the clearest case of single payer. The other seven bills—all the way from Ted Kennedy's to Bill Clinton's to Bob Dole's—fit somewhere along the "managed" spectrum, depending on the particular mix of market forces and government control. The market incentives built into most of these bills do two basic things: (1) They push providers towards a capitated system and therefore towards integrated delivery systems. The creation of networks, affiliations, health plans with wider and deeper panels accelerates. The 80 million persons now in HMOs or IPAs will greatly increase, and the role of all surviving capitated groups expands. (2) They encourage the establishment of consumer purchasing co-ops—called "alliances" in Clinton's plan—to countervail the market power of insurance companies and integrated provider groups.

The "How Much Medicine" Question

This question is much more daunting since we still lack the necessary policy and intellectual tools. The single payer proposal basically leaves it to the professional judgment of the physician or other providers, subject to some overall budget caps—which are intended to force both administrators and physicians to think in terms of comparative efficacy. Managed care, on the other hand, seeks to dampen total spending by putting it in the financial interest of the provider—and the insurer—to restrain costs. Diagnostically Related Group (DRG) payments are an example of a managed care type device to financially encourage shorter hospital stays. The faith of this financial incentive approach is that it leads to an appropriate balance between "too little" medicine and "too much".

What do these terms "too much" or "too little" mean in reality? We basically know what "too little" medicine is. But "too much?" For economists, for health planners, and eventually for members of Congress, "too much" medicine is where the resources used up to provide the extra unit of care would do more good deployed somewhere else or on someone else.

The Emerging Challenge

The challenge over the next several years will be to devise a discipline of "clinical economics" which combines rational medical decision making with economic reasoning—within, of course, consensus ethical standards. Statistical tools, comparative risk analysis, "minimax" strategies and the many other apparati of economic decision theory are ready-made for medicing in a world of finite resources. They go largely unused, however, in clinical settings. And where such tools have been used, e.g. in the recent debate about the appropriate age to begin routine x-rays to detect breast cancer, it has set off a firestorm. The movement towards practice guidelines may take us in the desired direction without causing excessive controversy. By explicitly focusing on comparative medical outcomes, practice guidelines are a sort of start towards clinical economics. Obviously, in this context, detection and prevention are likely to rise in importance.

The birth pains of the political debate of 1994 about health care will only grow more intense after a brief pause in 1995. As with any birth process, we cannot stop in the middle, but must continue—and be optimistic that the exercise will produce great good. We have an historic opportunity and obligation to correct the growing deficiencies and contradictions in the way health care is governed, financed and apportioned among our people.

—Jim Moody, PhD

Jim Moody, PhD served as a member of Congress on the Health Subcommittee (1983-1993). He is currently Vice-President of Chambers Associates, Incorporated in Washington, DC.

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of these driving forces? First, you must not lose control over how you practice nuclear medicine. Health care system managers can be convinced that they should not tell doctors how to deliver care to their patients. In turn, we will have to insure that our patients are getting good care, be able to prove this fact to the system managers and show that nuclear medicine helps deliver care in a cost-effective manner. We must show the system managers, referring physicians and their patients the value of nuclear medicine. We must demonstrate on a case-by-case basis how we help care for specific, individual patients.

The nuclear medicine physician must be a physician as well as an expert in nuclear medicine technology. When practiced well, nuclear medicine really is "high-tech primary care"—a holistic specialty integrating all organ systems. For example, sudden ventricular fibrillation is a disease of the brain and heart.

The nuclear physician of the future will interact with every patient, examine patients when it is helpful in defining the problems, and then follow up to see what happens to the patient. The outcome of each procedure will be assessed by the individual physician in his or her care of the individual patient, as well as by organized nuclear medicine at the state and national level. As the delivery of health care changes, the nuclear medicine physician who does not have clinical contact with his or her patients is soon going to become as rare as a dodo or dinosaur. Only by being involved in clinical care can the nuclear physician create a demand for nuclear medicine services.

Of course, some nuclear medicine physicians will join the increasing number of physicians who are themselves becoming managers of health provider organizations. Others will remain in the full-time practice of nuclear medicine, recognizing the enormous value of molecular nuclear medicine in solving health care problems. Those who are professionally and financially able to follow this course of action are lucky and will benefit from the new "home run" products and procedures, such as FDG, octreotide, therapeutic radionuclides, as they continue to move from science into clinical service into practice. Reinstatement of the waiver of FDA requirements for diagnostic radiotracers that existed between 1946 and the early 1970s should become a goal of organized nuclear medicine.

Other nuclear physicians will combine the practice of nuclear medicine with that of another specialty, such as radiology, internal medicine, cardiology, neurology or oncology. This will facilitate their taking a problem-oriented approach based on physiological and biochemical measurements rather than being simply a technology-dominated specialist. Dual certification in a clinical specialty as well as board certification in nuclear medicine should be promoted by the American Board of Nuclear Medicine and other specialty boards and societies.

Organized nuclear medicine and individual nuclear medicine practitioners at the local level must participate in efforts to show how nuclear medicine reduces costs and improves the quality of medical practices. Jim Sylvester's TV programs on CNBC are an important step in the right direction. These programs are directed towards primary care physicians but have been designed to appeal to the intelligent patient as well.

Practicing preventive medicine via early diagnosis has become an increasingly important role of nuclear medicine. For instance, nuclear medicine often reduces the need for fruitless surgery and decreases the interval between obtaining diagnoses and administering effective treatment. Yet, nuclear medicine is still undervalued and underutilized in most medical settings. To be sure, we must eliminate unhelpful procedures and improve the quality of care. We need to expand quality improvement programs and be certain that we are involved in developing practice guidelines and new radioactive tracers. Guidelines that we develop should not be limited to the technical performance of the procedures, but also to the overall quality of patient care. We must document how nuclear medicine solves patient problems and improves their care. Such documentation of efficacy and relevance to patient problems can be carried out by individual nuclear medicine departments and multi-institutional studies.

Prospective clinical trials are also needed to measure efficacy and effectiveness and to determine whether a procedure can be helpful under controlled conditions of practice. Such studies could be made in every nuclear medicine department in the country. Once we obtain this information, we need to communicate it to other physicians, administrators and the public.

The assessment of cost effectiveness of a nuclear medicine procedure is often easier than determining the outcome of a therapy which may take months or years. Within the context of specific decision-making, one can examine how the information provided by the study affects decisions such as whether or not to select chemotherapy rather than imminent surgery in a patient with cancer. Nuclear medicine results are often incorporated immediately into medical decision making. An example that goes back over thirty years is lung scanning. If nuclear medicine says with certainty that the patient does not have pulmonary embolism, this is accurate enough to make the decision not to admit the patient to the hospital or to anticoagulate the patient, which is a tremendous benefit to the patient as well as the health care system.

In summary, the appropriate response to changes in the health care system, such as the increase in managed care, is to: (1) increase expertise; (2) increase productivity; (3) promote the need and value of one's expertise; and (4) work with others to pursue common goals. The Health Care Financing Administration has found that the best hospitals were the most successful financially. The most financially successful physicians and technologists will be those who practice cost-effective high quality health care, who provide accurate, valid, meaningful, and useful information that helps care for the patient. As Francis Peabody said many years ago, "the care of the patient depends on caring for the patient, combining a high level of technical expertise with a high level of clinical expertise."

—Henry N. Wagner, Jr., MD

Henry N. Wagner, Jr., MD, is a professor of medicine, radiology and environmental sciences at The Johns Hopkins Medical Institutions in Baltimore, MD.