

# A TIME FOR RENEWAL



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**A**LTHOUGH THE U.S. MARKET for radiopharmaceuticals grew at a healthy rate in the early 1990s, a close examination of the relevant data in light of changing health care economics and regulatory pressures reveals some troubling trends. Trends in the overall number of procedures and shifts in the types of procedures suggest that the value of nuclear medicine in the management of patients is often being called into question in the new medicoeconomic paradigm. These trends strongly suggest that a new paradigm may now also be required for nuclear medicine.

## Market Trends

No other medical specialty, in fact no other medical technology, depends more on pharmaceuticals than nuclear medicine. There is no practice of nuclear medicine without radiopharmaceuticals. As a result, there is an important correlation between the number of nuclear medicine procedures performed and the radiopharmaceutical market. According to data from the Technology Marketing Group (TMG) in Des Plaines, IL, only cardiology is growing significantly, and virtually all other procedures are flat or declining.

The radiopharmaceuticals market (at the manufacturers' level) totaled about \$406 million in 1993. This is a relatively small market to support the continued research and development of new products, especially in view of the escalating cost of bringing new products to market. Perhaps an even greater concern is that, according to our data, products introduced since 1988 accounted for only about 8% of the total number of procedures in 1993. This low penetration of new products combined with the disturbing declines in almost all types of nuclear medicine procedures indicates a very troubling lack of renewal in the field. Contrary to the belief of many, it is not the unavailability of new products hampering the growth of nuclear medicine, it is more the inability of the field to adequately demonstrate how it uniquely meets important needs in the management of patients.

Another indicator of this disturbing trend is the rate of growth of the market. To insure viability and to attract investment for the future, markets must show sustained and attractive growth rates. According to TMG, in 1991, 1992 and 1993, the radiopharmaceuticals market had annual growth rates of 9.2, 11.1 and 10 percent. However, a significant rate-limiting factor that could affect the market longer-term is the growth of U.S. nuclear medicine procedure volume, which increased very slowly over the last four to five years with an annualized growth rate of five percent or less. It is also significant that according to TMG, hospitals closed 26 on-site nuclear medicine laboratories in 1993.

As I have noted, nuclear cardiology has been the "jewel" in

terms of growth for nuclear medicine. It accounts for almost 40 percent of the over 10.9 million nuclear medicine procedures performed in 1993. The U.S. nuclear perfusion market sustained fairly healthy growth from 1989 to 1994. Growth in the early 1990s, with the advent of new cardiovascular radiopharmaceuticals and IV Persantine (dipyridamole USP), was especially significant. The nuclear perfusion imaging market grew over 26 percent in 1991 and by over 24 percent in 1992, but that rate has slowed to about 6 to 8 percent in 1993 and 1994.

In recent years, the way procedures are performed has also changed nuclear cardiology. SPECT imaging has grown relative to planar imaging. In fact, there has been a direct tradeoff between the two. In 1988, 60 percent of nuclear cardiology procedures were performed using planar imaging, but by 1994, 80 percent of all nuclear perfusion studies were performed with SPECT imaging.

While nuclear cardiology did experience steady growth, echocardiology, which is frequently viewed as a competitive modality to perfusion imaging, has grown even faster. According to Medicare claims data, the volume of echocardiography procedures is seven times greater than that of nuclear perfusion studies. The number of echocardiography claims submitted between 1992 and 1993 grew by over 25 percent compared with only a 12 percent increase for nuclear cardiology.

## The Changing Economic Paradigm

Although it is difficult to predict changes in the radiopharmaceuticals marketplace, there are some initiatives in the private and federal sectors that have the potential to affect not only nuclear medicine and nuclear cardiology but also the growth rate of other competitive modalities. In 1994, federal-sector initiatives in the area of health care reform failed, but public pressure stimulated the significant, private-sector, cost-containment initiatives that began in 1993. The resultant growth of managed care is now a significant factor in purchase decisions involving nuclear medicine and radiopharmaceuticals. One outcome of these initiatives is the trend towards hospital consolidations that will undoubtedly lead to a decrease in nuclear medicine procedures, at least in the near-term.

The national shift to managed care continues. According to the Employee Benefit Research Institute, in 1993, 85.1 million Americans were enrolled in some type of managed care, up from 44 million in 1989. The gains in managed care enrollment are coming directly from the traditional indemnity plans.

An uncertain factor in managed care growth is the number of Medicare recipients who will enroll in HMO plans. Data from 1987 to 1995 show that Medicare enrollment in HMOs, although small, is growing. In 1994, approximately six percent of all Medicare enrollees opted to enroll in managed care plans (although this number varies significantly by area of the country). As the managed care organizations mature and become more organi-

zationally and financially solvent, many of them will look for an untapped population base to increase their enrollment, and Medicare presents a tremendous opportunity.

It is very important to keep in mind that in general the aim of managed care plans is to provide quality patient care at reduced costs. As a result, many facilities entering into managed care arrangements are seeking ways to reduce costs including examining testing procedures such as nuclear medicine.

In fact, nuclear medicine has been viewed as a cost center by many hospitals. With this in mind, hospital administrators—especially those who have entered into managed care contracts and who already view nuclear medicine as a cost center—will examine “high cost” line items billed to the nuclear medicine department, including radiopharmaceuticals. A relatively small sample size survey that we conducted in the mid-1980s and again in 1994 showed, however, that the significant increases in average nuclear medicine charges (over 150 percent) were predominantly related to hospital technical charges, overhead charges and mark-ups. (Professional fees were assumed to be a fixed percentage of total charges and therefore increased proportionally.) Radiopharmaceutical charges actually accounted for only a very small percentage of average procedure charges (less than 10 percent) and actually declined as a percentage of the total charges over the period.

Still, radiopharmaceuticals continue to be a very visible line item, and administrators may opt to control these costs rather than make tougher financial management decisions. I should also note that radiopharmaceutical prices did not increase significantly over the period and are thus a smaller fraction of the total. In fact, data compiled by the Radiopharmaceutical Manufacturer's Group showed that radiopharmaceutical prices have grown at a rate below that of the CPI. It is likely that recent product introductions have not followed this pattern because the increased development costs and limited market opportunities require greater revenues per study to provide a return on the investment.

One of the ways managed care attempts to share financial risk is by taking an active role in patient-management decision making. Therefore, practice guidelines are becoming increasingly important within managed care organizations and hospitals and facilities that have ventured into a managed care arrangement. Guidelines attempt to find the correct balance between potentially competitive needs and across a variety of interests. Basically, the competitive needs are quality of care on the one hand and value on the other. The various interests include the patients, the providers and the payers. It is likely that practice guidelines will play an important role in determining the future of nuclear medicine and the radiopharmaceuticals market. The AMA has issued a directory of practice parameters that already lists 1500 such guidelines, and in 1989 the federal Agency for Health Care Price Research (AHCPR) was created with the objective of developing clinical practice guidelines.

In the U.S., regulatory actions by the Food and Drug Administration (FDA) will continue to affect the radiopharmaceuticals marketplace. The FDA's evolving standards for the demonstration of efficacy of radiopharmaceutical products require either

more or more extensive pre-approval studies or significantly limit the proposed uses of such agents. These factors tend to increase the radiopharmaceutical industry's investment and decrease the potential return. As a result, either health care costs go up or the benefits of new technology are lost.

### Renewal or Termination?

The challenges facing nuclear medicine and the radiopharmaceutical industry are clear. Insuring that both survive—and even thrive—in the new paradigm of health care economics depends on renewal, an essential part of growth and development. Nonetheless, of late the market has been slow to adopt new products and newer technologies such as gated imaging and combined function and perfusion analysis that could serve to help renew the cardiology market. Other approaches are also emerging such as in cancer management, CNS disorders and acute chest pain. It will be up to nuclear medicine, however, to assure that this technology finds its place in appropriate clinical applications. Will nuclear medicine seize these opportunities for renewal or not? Will the field adapt itself to external changes to see and exploit the opportunities that come from change?

In his book *Surviving Corporate Transition* (Doubleday, 1988), William Bridges, PhD, describes the life-cycle of business organizations in terms of “seven phases,” which are The Dream, The Venture, Getting Organized, Making It, Becoming an Institution, Closing In and Termination. The final phases are characterized by an increasingly inward focus rather than an outward, or customer-oriented focus and by internal process becoming more important than external results or products. In this context, it is important for us to constantly remember that the goal of nuclear medicine is to provide patient-management benefits and value to the referring physicians who make patient-management decisions and who choose the techniques to employ. The inclusion of a broader segment of medicine in the fold of nuclear medicine advocates is essential to the future of the technology. It should be the role of the specialty to insure that physicians outside the specialty are actively involved in and with nuclear medicine and to insure that the technology is vital and renewing itself. Without renewal, termination is the inevitable outcome.

The nuclear medicine community knows that nuclear medicine is a vital and necessary technology that provides real value to patients, providers and payers. But do the economic decision makers and the non-nuclear medicine providers know it? Renewal of nuclear medicine depends on changing the way nuclear medicine is perceived by providers and by payers. It is essential that industry and nuclear medicine physicians work collaboratively to educate the key players in the changing marketplace. The message we can and should bring is this: Nuclear medicine and managed care are ideal partners because nuclear medicine meets economic and clinical needs and expedites the decision-making process.

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