Obstacles to Clinical Advances Pose Major Challenges

NUCLEAR MEDICINE FACES BRIGHT FUTURE WHEN NEW DIAGNOSTIC AGENTS REACH MARKET

"If there is any way to bring about some *action* in the efforts to improve the regulatory process, I believe that we will see a huge resurgence in nuclear medicine. We all have products in R&D, and we all need assistance to bring them out to the medical community."

Nuclear medicine faces a bright future, according to several industry representatives interviewed by *Newsline* in November 1985, although some major obstacles stand in the way. These manufacturers believe that a concerted effort from the medical and industrial communities is needed to clear these obstacles and move into a new era for nuclear medicine.

H. William Strauss, MD, director of the Division of Nuclear Medicine at Massachussetts General Hospital, said last year that "nuclear medicine is poised to take another major step forward that would lift our specialty to the 'next plateau' " (see *Newsline*, July 1985, p. 683).

Members of the nuclear medicine industrial community agreed with Dr. Strauss, and the next plateau that they described includes an expanded use of single-photon emission computed tomography (SPECT) with new agents for brain and heart imaging as well as with monoclonal antibody products, the introduction of very short half-life radionuclide generators, and more acceptance of positron emission computed tomography (PET) for patient care. In addition, more referring physicians will recognize the value of nuclear medicine in providing physiologic data, they said.

Clay Larsen, product manager for nuclear medicine systems at Picker International, an instrumentation manufacturer in Northford, CT, said that he senses much more interest in the marketplace today in nuclear medicine than he did two years ago. Although other modalities such as X-ray computed tomography (CT) and nuclear magnetic resonance imaging (NMRI) generated a lot of excitement within the medical community, and steered certain procedures away from nuclear medicine, "there's going to be a backlash against these other modalities once people realize that nuclear medicine—especially with new radionuclides—is going to give them unique information," said Mr. Larsen.

"We're very 'bullish' on nuclear medicine," said Peter Bergeron, director of sales and marketing at Squibb Diagnostics, a radiopharmaceutical company in New Brunswick, NJ. Mr. Bergeron said that his research group recruited academic scientist Michael D. Loberg, PhD, six years ago to head its research and development (R&D) program, and "the fruits of this R&D effort are about to be realized.

"This year we hope to introduce new hepatobiliary and liver imaging agents, as well as rubidium-82 for PET scanning. At The Society of Nuclear Medicine's (SNM) annual meeting this year, we hope to unveil a new class of technetium-99m-labeled heart agents. These new products will help lift nuclear medicine to that next plateau," he added.

Judy Walker, business segment manager at Du Pont NEN Medical Products in North Billerica, MA, said, "If we didn't feel very positive about the future of nuclear medicine, you wouldn't see the significant amount of research dollars being invested in developing new radiopharmaceuticals to move the whole industry up again."

Medi-Physics, Inc., a radiopharmaceutical manufacturer in Arlington Heights, IL, recently installed a 70-MeV cyclotron to produce iodine-123. The company has a new drug application (NDA) on file with the US Food and Drug Administration (FDA) for iodine-123 iodoamphetamine (IMP), an agent used for brain perfusion imaging.

Charles Cruse, marketing manager at Medi-Physics, said that the cyclotron is the largest in the world

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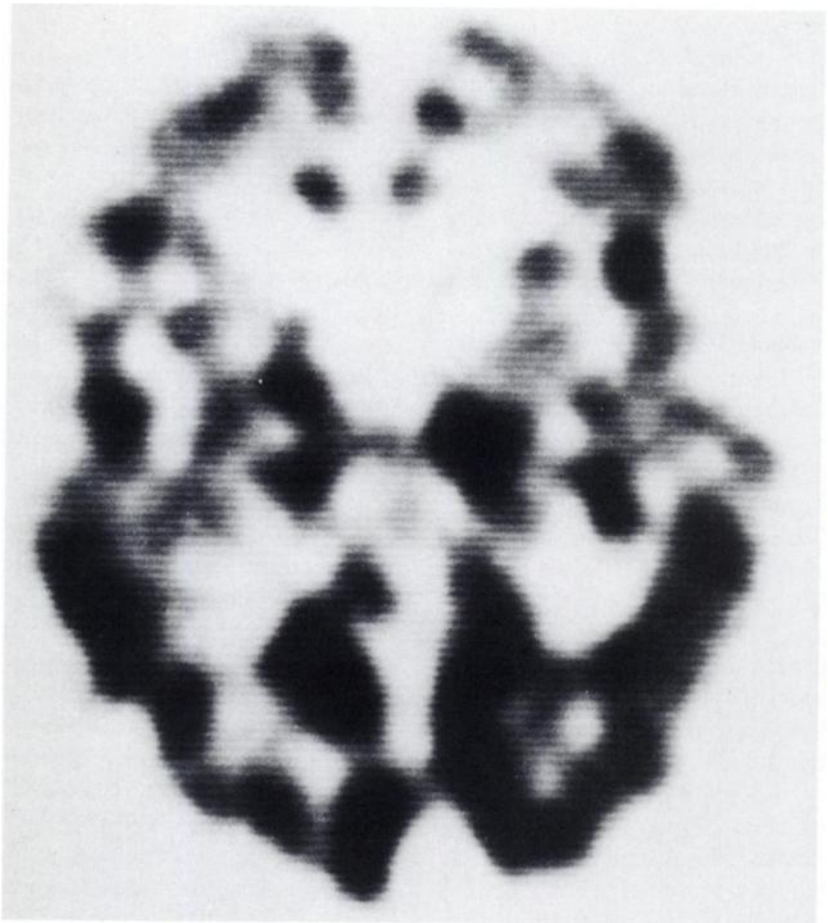
totally owned and operated by private industry, and represents a $10 million commitment to the future of nuclear medicine.

"Monoclonal antibodies will reinfuse the field with some of the momentum that has been lost," said Solange Israel-Mintz, director of marketing for Centocor, a biotechnology firm in Malvern, PA.

Mark Lamp, nuclear medicine product manager at ADAC laboratories, an instrumentation firm in San Jose, CA, said that his company has an agreement to develop imaging software for Hybritech's monoclonal antibody products, "which indicates where we believe nuclear medicine is heading in the future."

Wayne Webster, a marketing manager for Scanditronix, Inc. in Essex, MA, a PET manufacturer headquartered in Uppsala, Sweden, said that the next plateau will probably be reached within the next five to 10 years. "I think that the nuclear medicine department will become much stronger within the hospital because of its outpatient status and the new developments for examining physiologic processes."



Iodine-123 iodoamphetamine SPECT image of a normal control patient. "Cortical uptake appears related to gray-matter blood flow, with good demarcation of interlobar fissure. In this tomographic slice at 2 cm above orbito-meatal line, basal ganglia are clearly defined," explained B. Leonard Holman, MD, director of the Department of Clinical Nuclear Medicine at Brigham and Women's Hospital in Boston.
(Reprinted from Hill TC, Holman BL, Lovett R, et al: Initial experience with SPECT of the brain using N-isopropyl I-123 p-iodoamphetamine: Concise communication. *J Nucl Med* 23:191-195, 1982)

Transition State

In recent years, members of the nuclear medicine community have expressed concern over reduced funds for patient care and research, the declining number of referrals, a downturn in equipment sales, and the stagnating process of providing new radiopharmaceuticals to physicians.

In the United States, the Prospective Payment System (PPS), introduced in 1983 to trim Medicare reimbursements by using diagnosis-related groups (DRGs), essentially made diagnostic imaging a cost center rather than a revenue generator for the hospital. The nationalized health care systems in several European countries have also faced constraints in tighter economies.

Several companies pointed out that nuclear medicine is not in any more trouble than the rest of medicine because of funding pressures, although some manufacturers recommended ways for nuclear medicine to better adapt to the cost containment environment.

"I think nuclear medicine is in a state of transition now, and the problem seems to be that it has been difficult to keep pace with all the technologic advances," said Mr. Webster of Scanditronix. "The research community can continue move nuclear medicine ahead by concentrating on the clinical applications of all of this technology," he said, adding that there seems to be a problem bridging research and clinical application. "Researchers need to work with the end-user in mind, and could develop more software, for example, that would make diagnostics simpler," explained Mr. Webster.

Everyone who does clinical research is product-oriented by definition because they want something they can ultimately use in patients, said Rudi D. Neirinckx, PhD, man-

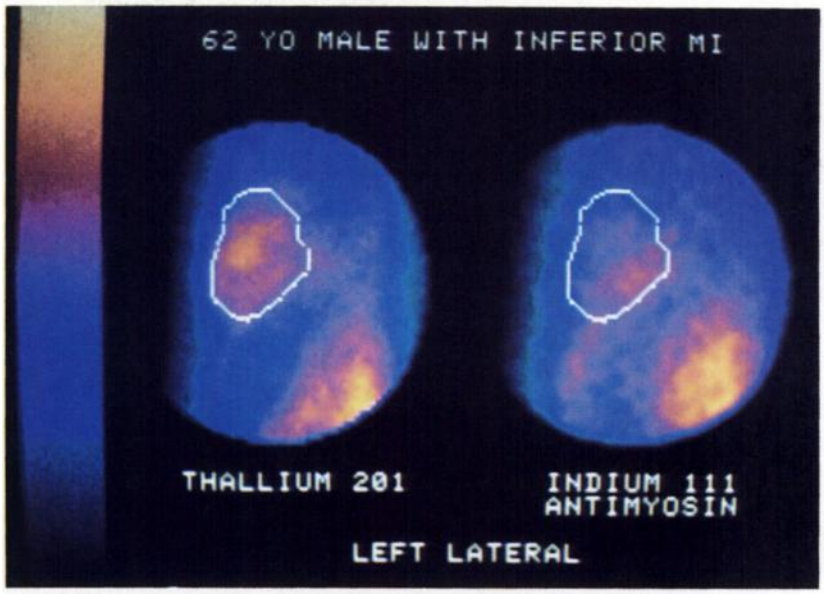
ager of pharmaceutical development at Amersham International in Buckinghamshire, England. When a manufacturer is funding clinical research, however, the investigators sometimes stray from the original intent, said Dr. Neirinckx, which does not lead to a viable product. If they are not redirected toward the original goal, the new radiopharmaceutical will take much longer to reach the marketplace, he explained.

Manufacturers could also redirect their efforts to help the field expand, said Dr. Neirinckx. "It's time that we put a lot of effort into developing the right kind of drugs and expand into fields which are not vulnerable to inroads from other imaging modalities. It's very important to develop a drug for a new application, rather than drugs that are slight improvements over existing agents," he explained.

Overinterpretation of Data

Iain Stark, president of Scintronix USA Inc., an instrumentation company headquartered in Livingston, Scotland, said that he observes a general tendency in nuclear medicine to overinterpret data and not study enough patients. "One area that concerns me as a manufacturer is that investigators acquire dynamic images of a 64 × 64 or a 32 × 32 matrix, and then proceed to draw regions of interest as if it were a 128 × 128 or 256 × 256 matrix, and they haven't realized that there is no accurate way of dividing up the pixels of information and knowing where the counts are coming from," he explained. In addition, "as you move away from the collimator, the pixel diverges because of the resolution of the camera-collimator system, and is not looking at the same location, resulting in cross-talk between pixels," he said.

This overinterpretation makes it difficult for other investigators to reproduce the results, said Mr. Stark. "They then may conclude that the technique doesn't work very well, and they may expand that conclusion and say that nuclear medicine doesn't work very well." added Mr. Stark.



Comparison of planar thallium-201 image with indium-III-labeled antimyosin (Myoscint™, Centocor) image shown in the left lateral position. A region of interest corresponding to the outer margin of the left ventricle on the thallium-201 study is superimposed over both images. "This study demonstrates the ability of the monoclonal antibody imaging agent to localize the area of acute myocardial necrosis. A large area of abnormal uptake is noted in the inferior wall on the antimyosin study," explained Harvey J. Berger, MD, of the Department of Radiology at the Emory University School of Medicine.

(Courtesy of Emory University School of Medicine)

It was inevitable for CT to take brain scans away from nuclear medicine because very little activity crossed the blood-brain barrier, resulting in poor images, said Mr. Stark. "Thallium-201 is also a poor radionuclide because it's the wrong energy and does not efficiently target the myocardium," he said. "It's less-than-ideal procedures like these which make people doubt nuclear medicine," said Mr. Stark.

Compromised Modality

"The general medical community sees nuclear medicine as a very compromised modality," said Gary Enos, nuclear product line manager for Raytheon, an instrumentation company in Melrose Park, IL. With the less-than-ideal radiopharmaceuticals available today for SPECT imaging, he explained, nuclear medicine cannot always provide accurate data.

"Although SPECT devices have improved significantly, and the computer technology has reached the point where it can acquire and reconstruct the data in a reasonable amount of time, we're still faced with an integral problem since we can't collect enough data because there really aren't the appropriate, photon-abundant, specially locating radiopharmaceuticals needed to make SPECT really take off," said Mr. Enos, adding that more communication is needed between the instrumentation and radiopharmaceutical manufacturers to work out these problems.

Mr. Stark of Scintronix also said that he would like to see more discussions between instrumentation and radiopharmaceutical manufacturers. "It's quite possible that these discus-

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sions don't take place because we engineers and physicists don't understand chemistry well enough," he said, but he would like to see more small, informal scientific meetings where people from various disciplines could exchange information and educate each other.

Mr. Cruse of Medi-Physics said that one problem, however, is the lengthy FDA approval process. "The instrumentation manufacturers are beating down the doors to develop new hardware and software at the first sign of a promising investigational new drug (IND). It's been estimated, though, to take seven to 10 years at a cost of approximately $90 million from product research through FDA review and approval. By that time, the instrumentation companies are into their third and fourth generation of equipment, and by that time there's another technique right behind it that will replace the procedure," he explained.

"There are many opportunities out there," said Ronald Kinder, director of marketing for Mallinckrodt, a radiopharmaceutical producer and nuclear pharmacy company in St. Louis, MO. "But when you weigh the time and expense involved in getting a new drug approved, and you look at your return on investment, it becomes a very risky venture," he said.

Everyone involved in radiopharmaceutical development noted that these products are used first in Europe because the approval process is not as formidable as the FDA's, and clinical research is more readily approved. There also seems to be more cooperation in Europe between the regulatory agencies, industry, and the academic community.

The regulatory process in Japan is more stringent than that in the United States, and usually requires clinical studies on the Japanese population. Despite these factors, however, drug companies still reported that it is easier to get a new drug approved in Japan than in the United States because the Japanese regulations are clearer and "more logical."

Pinpointing the FDA Problem

Even in the United States, the FDA is not perceived as such an obstacle to the growth of nuclear medicine by all members of the community.

Karen A. Klause, vice president of the planning division at Hybritech, a biotechnology firm in San Diego, CA, said that her company "has had no delays and no complaints about the FDA's response time. We work very closely with them," she said. Hybritech has INDs for its monoclonal antibody products on file with the FDA's Office of Biologic Research and Review, but the company has not yet submitted an NDA.

Although Ms. Israel-Mintz of Centocor, which has an IND for indium-111-labeled antimyosin (Myoscint™) on file with the FDA, said that "trying to get a product in monoclonal antibodies approved is like finding your way through a maze that's being built while you're going through it," she also stated that she does not blame the FDA because biotechnology is so new and the agency is still developing guidelines.

Mr. Webster of Scanditronix, which deals with the FDA's Center for Devices and Radiological Health, said that the FDA has helped his company by setting up an office for small businesses which do not have a staff of regulatory experts.

The problem area seems to be with the FDA's Division of Oncology, under the Office of Drug Research and Review, which reviews INDs and NDAs for drugs designed to treat cancer, acquired immunodeficiency syndrome (AIDS), and for diagnostic imaging agents.

"I'll be quite candid about it. There's one huge roadblock that is governing the growth of nuclear medicine, and that's the lack of resources within the FDA's Division of Oncology to handle radiopharmaceuticals," said Mallinckrodt's Mr. Kinder.

Mr. Cruse of Medi-Physics said that this apparent lack of resources is visible in the long waiting period between the application date for a new drug and the FDA's response. "Considering the limited resources, AIDS, and therapeutic drugs, it appears that radiopharmaceuticals are not the highest priority in the Division of Oncology," he added.

The manufacturers also said that they hoped the SNM and other medical associations would try to improve this situation. "There appears to be a consensus that reducing the time and cost of the FDA review process is possible without compromising patient safety, and that this reduction would go a long way toward revitalizing radiopharmaceutical development," said Stanley J. Goldsmith, MD, president of the SNM.

C. Douglas Maynard, MD, chairman of the Department of Radiology

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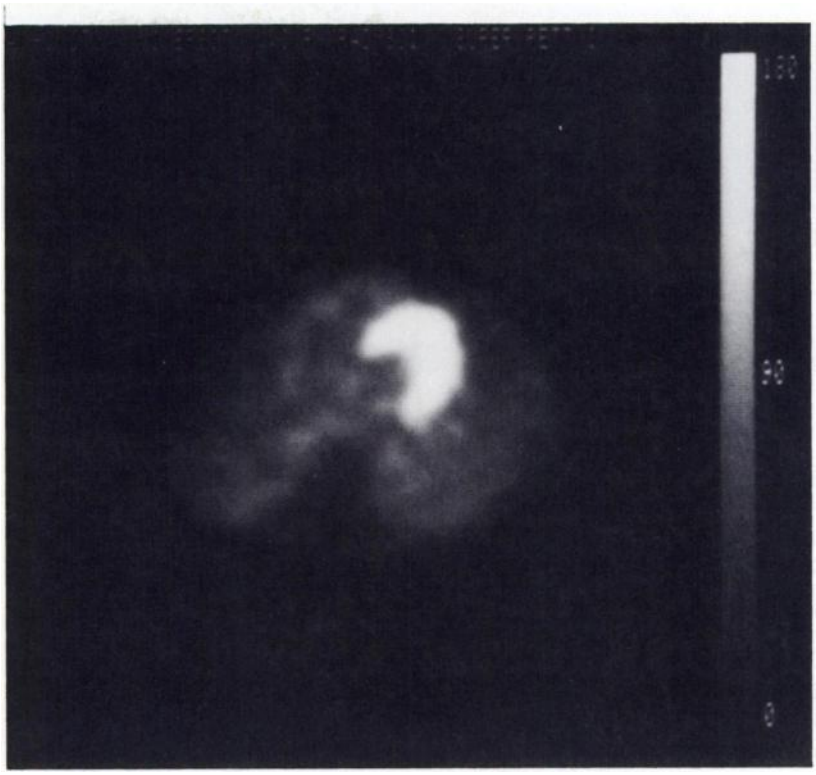
at the Bowman Gray School of Medicine of Wake Forest University, pointed out that physicians in all diagnostic specialties, not only nuclear medicine, recognize the need for the development of more pharmaceuticals for tracer methodology to target cell activity. "This area is a top priority in a recommendation from the Conjoint Committee on Diagnostic Radiology to the National Institutes of Health (NIH) this year," said Dr. Maynard, who is a member of the committee.

"People have been talking about this problem for years. If there is any way to bring about some *action* in the efforts to improve the regulatory process, I believe that we will see a huge resurgence in nuclear medicine. We all have products in R&D, and we all need assistance to bring them out to the medical community," said Mr. Kinder of Mallinckrodt.

Thomas P. Haynie, MD, director of the Department of Nuclear Medicine at M.D. Anderson Hospital and Tumor Institute, said that there may have been a logical reason historically for radiopharmaceuticals to be under the jurisdiction of the FDA's Division of Oncology. "Nuclear medicine in its early inception was targeted toward cancer, but today I think that radiopharmaceuticals are lost in the Division of Oncology, and we probably ought to push for the creation of a separate division under an individual who spends his or her time working on nuclear medicine applications," said Dr. Haynie.

The FDA has shown some signs of understanding the problems of the nuclear medicine community, noted John Witkowski, director of marketing for Syncor International, a nuclear pharmacy company in Sylmar, CA, that recently merged with Nuclear Pharmacy Incorporated of Albuquerque, NM. The agency allowed nuclear pharmacies to provide indium-111-labeled white blood cells to clinical investigators under an IND. If some investigators, however, have not kept up with their clinical reports, warned Mr. Witkowski, the FDA will react adversely.



A transaxial slice of a rubidium-82 PET image of the myocardium in a normal subject 80 seconds after injection, Mallinckrodt Institute of Radiology, Washington University. **(Courtesy of Squibb Diagnostics)**

Keith R. Collins, nuclear medicine product manager for Toshiba America, Inc., a division of Toshiba Medical Systems headquartered in Nasu, Japan, said that he is also concerned about the FDA's proposal to license medical software. "If that happens, it could be a major disaster, especially since the US government decided that software cannot be patented. The drug manufacturers at least are protected for a while with their patents. If the FDA gets involved in licensing software, though, everyone's software will be available to everyone, and there will be no incentive at all to develop something new," he said.

In the United States, FDA approval is only the first hurdle for a new technology. In order for new procedures to be clinically viable, they must be approved by the Health Care Financing Administration (HCFA) for Medicare reimbursement, and also by Blue Cross/Blue Shield and other third-party payers.

Reimbursement Approvals

Dual-photon absorptiometry is one procedure which is not yet reimbursed by Medicare. Richard B. Mazess, president of Lunar Radiation, a bone densitometer manufacturer in Madison, WI, said that "it is imperative that the existing structure at HCFA be changed. Technological assessment should have formal input from professional societies with less dependence on the governmental assessment."

Mr. Webster of Scanditronix said that he believes there will be reimbursement for PET studies once the

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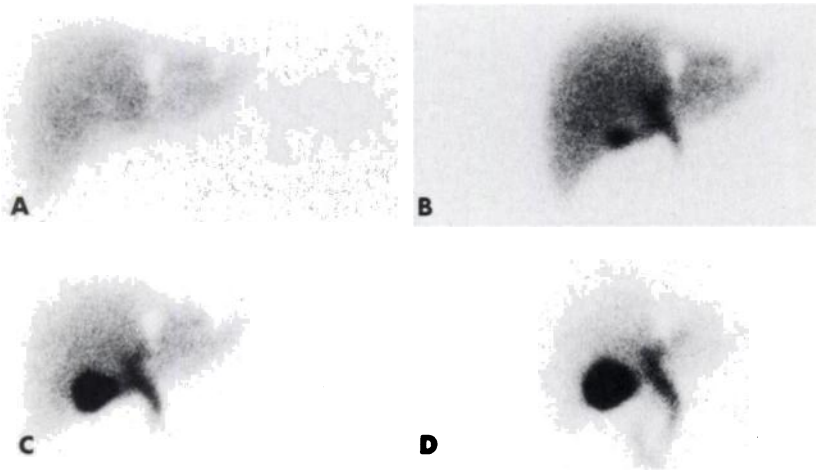

Anterior scan of a normal hepatobiliary system using technetium-99m mebrosenin at 5 min (A), 10 min (B), 15 min (C), and 30 min (D).

(Courtesy of Squibb Diagnostics)

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modality is available in more clinical situations, "and that'll be happening within the next two to five years."

Don Perrine, vice president of sales for Computer Technology & Imaging (CTI), a PET manufacturer in Knoxville, TN, said that one problem with HCFA is that it places the burden for the costs of proving efficacy principally on teaching institutions and industry. "If the government could sponsor programs that demonstrate both narrow-based efficacy and broader-based cost-effectiveness, it could help improve their medical technology assessment process," he said. "This type of program would fit in with the government's DRG concept, and the net effect would be a significant savings in health care delivery," he added.

Marketing Nuclear Medicine

Despite these issues, everyone agreed that the specialty has valuable services to offer referring physicians, and several manufacturers said that they are receiving requests from their customers for advice in marketing the nuclear medicine department within the hospital. Companies are providing educational materials on marketing and business management, newsletters, and technical reports to physicians.

Mr. Webster of Scanditronix stated that it is important for industry to have a cooperative effort with the SNM in providing these educational materials because "it's sometimes difficult for a company to put together an unbiased presentation."

Mr. Larsen of Picker said departments that market their services can realize dramatic results. "You can find a 150-bed hospital with three gamma cameras, two computers, and a full schedule in a department that markets, whereas you can find a 500-bed hospital with two cameras, an antiquated computer, and declining statistics in a department that does not promote its services," he noted.

Michael Bono, president of Amici, Inc., a nuclear respiratory products manufacturer in Royersford, PA, agreed. "Nuclear medicine is a business within a hospital, and for it to succeed, their customers have to be aware of what they offer—all the time. The size of the lab or institution doesn't matter. It's the dynamics of the individual running the department that increases the business. If they don't market their capabilities, they'll sit there waiting for the referrals to come and continue in the low-volume environment," he added.

Several manufacturers indicated that nuclear medicine physicians need to bridge the gap between themselves and other medical doctors.

"Nuclear medicine physicians need to become more familiar with their results so that they can converse with referring physicians and make a better case for their services instead of just putting out numbers and images," said Dr. Mazess of Lunar Radiation.

In addition to educating referring physicians about nuclear medicine, nuclear physicians need to educate themselves in the specialties that provide referrals. Dr. Neirinckx of Amersham said that he is learning more about neurology so he can better market his company's new agent for cerebral blood flow SPECT imaging, technetium-99m hexamethylpropyleneamineoxime (HMPAO). "You must understand their specialty better if you're going to convince them that your technology has an application they need," he added.

According to Mr. Perrine at CTI, "primary care groups are heavily involved in PET decision-making. We work closely with nuclear medicine, of course, but other groups such as oncology, neurology, neurosurgery, psychiatry, and cardiology are deeply involved in planning programs and determining how the equipment will be used."

Rather than taking a defensive stance, Mr. Perrine said that nuclear medicine could take an offensive stance and recognize new opportunities that require this type of teamwork. "To set up a protocol, primary physicians need to be involved. It's very difficult, however, for them to interpret PET information, which is where nuclear medicine fits into the team," he explained.

In some institutions, noted Mr. Perrine, this type of cooperation between clincial departments may not be possible. "It becomes very clear early on that the chances of PET gain-

ing acceptance in those institutions are very small, simply because they're not drawing in all the groups that must participate in the program in order for it to succeed," he added.

Mr. Webster of Scanditronix agreed with the team approach. "We look at the entire institution and attempt to bring appropriate groups together to establish a PET program. There does seem to be some confusion on the part of end-users as to how to work together within their own institutions, which makes it seem as if industry sometimes takes a 'divide and conquer' attitude," he said.

Forefront of Technology

Several other manufacturers said that they do not limit their marketing efforts to nuclear medicine departments; they also seek business with, for example, cardiology, oncology, and neurology groups. Dr. Mazess at Lunar Radiation added that nuclear medicine will also work more closely with endocrinology, orthopedics, rheumatology, and gynecology with bone densitometry.

Jessica I. Bede, vice president at Capintec, Inc., emphasized that this dispersal of nuclear medicine technology enhances the field and allows it to grow. "If we redefine nuclear medicine as the 'extended arms' of nuclear medicine, such as nuclear cardiology, we can't help but feel optimistic about this field," she explained. Capintec, based in Ramsey, NJ, produces accessories, including an ambulatory ventricular evaluation system.

Nuclear medicine can provide the rest of the medical world with far-reaching advances, said Ms. Bede. "Pioneer them, and be the forefront of technology—but then disperse it. I don't think it's really a turf issue at that point. It's educating the rest of the medical community," she added.

Mr. Lamp of ADAC said that one factor which has helped the field significantly is that nuclear medicine physicians are presenting more papers at scientific meetings of primary care medical associations.

No Turf Battles in Europe

Most people in industry said that they observed turf battles between primary care and diagnostic specialists in the United States but not in Europe. Even within the diagnostic imaging community, Mr. Stark of Scintronix said that he found more communication in Europe between nuclear medicine physicians, radiologists, and physicists. Discussions between these groups are important, he said, because "you learn the value of their techniques and of your tests, and you perhaps learn ways to improve your own techniques."

Industry also described other differences among the various global markets. Of the world market for all nuclear medicine products, the United States represents 60%, Japan 20%, Europe 15%, and Australia 5%, according to Mr. Collins of Toshiba.

"Europe is extremely aggressive in monoclonal antibodies, more so than the United States," said Ms. Klause of Hybritech.

Mr. Stark of Scintronix said that, in general, the European market is inclined to spend more on the camera and less on accessories. "We now have an integrated multiformatter, for example, because the American market demanded it, whereas it is not considered as important in Britain," he said.

All of the equipment manufacturers interviewed stated that the industry is under more pressure in the United States than in Europe and Japan to give substantial discounts to its customers.

Relief Sought from Discounting

David Archibald, director of marketing for Siemens Gammasonics in Des Plaines, IL (of Siemens AG in Germany), said that when nuclear medicine started growing, manufacturers were eager to make special deals to get their equipment into the most prestigious institutions. "It's time to say that we can't afford it anymore. If we're going to continue to improve your product, we need relief from that pressure to discount."

Lewis H. Rosenblum, general

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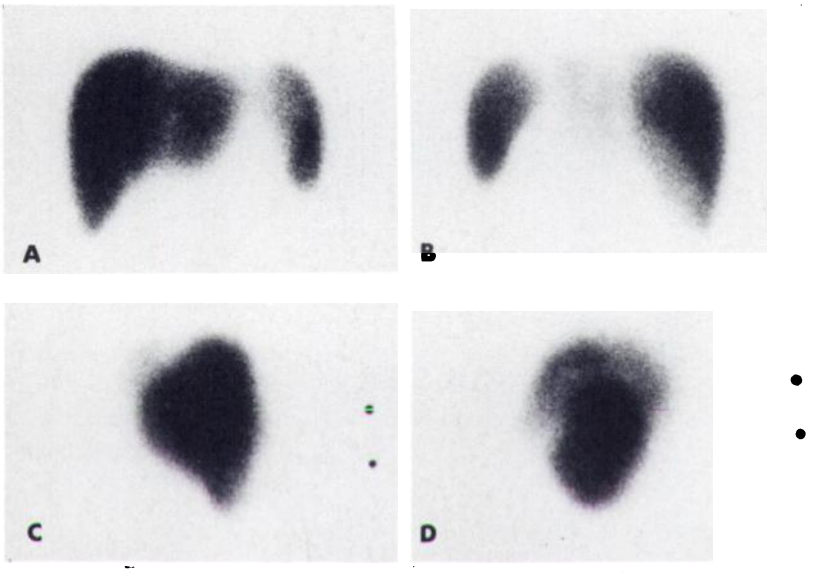

Four views of a liver/spleen scan in a normal volunteer using technetium-99m micro-aggregated albumin, anterior (A), posterior (B), right lateral (C), and left lateral (D). **(Courtesy of Squibb Diagnostics)**

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manager at Picker International, said that European investigators want to be at the leading edge of research, and are more willing to pay for equipment than investigators in the United States. "In this day and age, cost containment is as strong within the industry as it is within the medical community, and we can't afford to continue to give equipment away," he added.

"Price War" in Instrumentation

"I find that the medical community expects that their instrumentation will be discounted to an absolutely low level, or that there will be no cost," said Mr. Enos of Raytheon. "And if we don't do it, someone else will," he added.

Some people said that there is almost a price war going on among the major companies, and if the medical community did not apply so much pressure, everyone could hold the line.

"Physicians ask why we aren't developing anything new, but the way manufacturers are discounting, there is nothing to invest in future development," said Mr. Collins of Toshiba.

Adapting to DRGs

With the exception of the PET manufacturers, most of the instrumentation companies said that they have responded to DRG pressures by "value engineering," or producing better products at a lower cost to the consumer, and by decreasing R&D efforts.

The radiopharmaceutical companies, on the other hand, said that they have shifted money away from their marketing efforts and channeled more into R&D.

Companies also said that they have tried to reduce the cost of a procedure by, for example, making it more labor-saving. Some manufacturers noted that there is a certain amount of buying activity now because the DRGs have not yet taken effect for capital equipment, but when they do, the major impact will just be a delay in purchases because the need for equipment will not change.

Longer Life for Camera Systems

Mr. Archibald of Siemens said that instrumentation manufacturers have reached the limit on price reductions. His company is now concentrating on making products that will have a useful life of five to 10 years, as opposed to the industry average of five years, so that the medical community will still realize savings per year although the initial cost will be the same.

At Lunar Radiation, the marketing strategy adapted to DRGs by developing programs for physician partnerships in placement of outpatient instruments, said Dr. Mazess.

Robert Ranieri, director of sales for Atomic Products, an accessory manufacturer in Center Moriches, NY, said he is seeing an increased movement toward private laboratories and outpatient clinics. He also said that his company keeps track of feedback from the medical community, which helps significantly in tailoring products to meet its needs. The latest version of Atomic's thyroid uptake system, for example, includes more memory, automatic decay correction of the sample, increased count rates, and a built-in monitor—all suggestions from customers, said Mr. Ranieri.

Tsur Bernstein, PhD, product manager for nuclear medicine at Elscint, Inc., an instrumentation company based in Israel, said that his products were prepared for DRGs because of the cost-effectiveness of their integrated systems. "We set the trend for integrated systems, using the same computer capability for data acquisition and processing," said Dr. Bernstein. He noted that this integration results in unexpected benefits, as with the array processor, for example, which is an option in many systems. "We actually put it there to enhance the high-count-rate acquisition, but since we designed it to be programmable, it is now also used for SPECT reconstructions and other processing functions that require a 'number-crunching' type of analysis," he said.

Most of the PET people believe that DRGs will eventually work toward their benefit when the medical community realizes the financial savings from the predictive value of PET information, particularly in determining the prognosis of bypass surgery versus nonsurgical intervention in patients with coronary artery disease.

DRGs Forcing Shake-Out

Diagnostic medicine was already heading toward a shake-out between nuclear medicine, CT, NMRI, and ultrasound, said Dr. Neirinckx of Amersham, and the DRGs are just forcing that shake-out to occur sooner. "Overall, it will be healthy and eliminate some unnecessary testing and poor technology, and we hope that nuclear medicine can ride out the storm," he added.

In addition to the cost containment factors, Dr. Haynie pointed out another reason for declining statistics in nuclear medicine. "What we do for patients has become more lengthy and complex. We're getting more exact in the information we're supplying, but it doesn't show up on the books as patient through-put," he added.

"Our Fates Are Linked"

Nuclear medicine will grow again, according to most manufacturers, if the challenges of developing new procedures, streamlining the regulatory process, and adapting to cost containment can be met by both the clinical and industrial communities. "Everyone must recognize that our fates are very much linked together," said Dr. Neirinckx, "otherwise nuclear medicine could become a pure research science."

Linda E. Ketchum