COMMENTARY

LINES FROM THE PRESIDENT
NUCLEAR MEDICINE'S IMAGE—
FROM THE PERSPECTIVE OF PET AND TURF

In nuclear medicine we make images. But, have we looked in the mirror lately to see our own image? The nuclear medicine community did just that in September during a Summit meeting of the leadership of the various organizations concerned with nuclear medicine. Representatives of The Society of Nuclear Medicine (SNM), the American College of Nuclear Physicians (ACNP), the American College of Radiology (ACR), the American College of Nuclear Medicine (ACNM), the American Board of Nuclear Medicine (ABNM), the American Board of Radiology (ABR), the Residency Review Committee for Nuclear Medicine (RRC, NM), the Institute for Clinical PET (ICP), the SNM Technologist Section (SNM, TS), the SNM Education and Research Foundation (SNM, E&R), and industry convened for this two-day meeting. Topics included: recruitment of physicians, scientists, and technologists into nuclear medicine; reimbursement issues; regulatory agency issues; positron emission tomography (PET) vis-à-vis the Food and Drug Administration (FDA), state laws governing the practice of pharmacy and medicine, and the Health Care Financing Administration (HCFA); perceptions of nuclear medicine from medical students, radiologists, other physicians, industry, and the public; and turf battles over nuclear cardiology, radioimmunoimaging and radioimmunotherapy, and PET.

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For two days the group struggled and charged through the Summit's formidable agenda. Discussions were thorough, animated, spirited, and focused. The dominant tone of the interactions among the various representatives reflected cooperation and support. ABNM and ABR representatives ironed out some agreements on their differences to bring back to their respective boards. SNM, ACNP, and ACR resolved to cooperate more in addressing recruitment and regulatory issues and agreed to accept their differences on reimbursement strategy.

PET: Conflict over Reimbursement and Regulation

Since I cannot reasonably give adequate coverage to all the issues that contribute to nuclear medicine's "image," I have chosen to concentrate on the conflicts surrounding PET and turf. SNM and ACNP have argued that a physician's use of cyclotron products produced and used within an institution for PET imaging falls under the states' authority of governance under the laws of practice of pharmacy and medicine, not under the FDA's jurisdiction.

There is no FDA-issued Investigational New Drug (IND) or New Drug Application (NDA) status for fluorine-18 (^{18}F) fluorodeoxyglucose (FDG). Nonetheless, it is used for clinical and investigative human studies in PET centers throughout the United States, under each state's laws governing the practice of pharmacy and medicine. But, with the FDA's blessing, ICP is in the process of filing an NDA and has organized a prospective study to collect data to support the safety and efficacy of ^{18}FFDG for detecting coronary artery disease and determining myocardial viability. ICP is motivated by HCFA's requirement that there be an FDA-issued NDA for ^{18}FFDG before they consider reimbursement for the agent.

This approach is contrary to that of the SNM and the ACNP, which believe that no NDA should be necessary for government reimbursement or clinical PET practice. But, from the perspective of commercial radiopharmacies, which may wish to supply ^{18}FFDG across state lines, an FDA-issued NDA is necessary. Therefore, ICP can be viewed as pursuing the NDA process on behalf of commercial firms, which operate under the FDA's jurisdiction and not under the purview of the states. With this reasoning, the actions of ICP and the SNM and the ACNP can be reconciled, although the SNM and the ACNP certainly would have preferred that ICP not pursue an NDA for ^{18}FFDG, in part because of the complications that will follow for other cyclotron products, for example, carbon-11 (^{11}C) acetate. Will each institution have to operate under its own IND for this material? Who will undertake the filing of an NDA for ^{11}C acetate or

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Radioimmunoconjugates

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at the FDA have not been adequately dealt with." Placing the blame on Congress for not appropriating the necessary funds, he adds, "speeding up the review process could be accomplished without compromising safety and efficacy standards, and that would make products available for use more expeditiously."

On the other hand, Dr. Abrams says that since "these are the first products that [FDA] has seen as labeled antibodies or in vivo diagnostic imaging products, they need to satisfy their curiosities and concerns. That is quite appropriate."

Curtis L. Scribner, MD, chief of the hematologic products branch at the FDA, says the FDA's concerns center around the specificity and sensitivity of these agents. "There's no such thing as a truly tumor-specific antibody. The difficulties with radioantibodies as with all radioimaging agents are with the deposition of radioactivity over the normal structures. Radioimmunotherapy," he adds, "takes the cross-reactivity sort of to its extreme."

Despite the problems, he says, "The field of specific antibody targeting to tissues is still a very exciting area, and it holds a lot of promise."

But, as one who knows only too well how radioimmunoconjugates can be of benefit, Mr. Harrison expresses dismay at this untapped promise and the FDA's pace of approval. He says that after he went into remission, he asked Dr. Order, "how soon are you going to get this stuff out on the market? If it was Europe it would have been out yesterday."

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Lines from President

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nitrogen-13 ammonia? No individual PET practice can possibly undertake an NDA on its own.

Practitioners of nuclear medicine who make up their own kits for use within an institution for radiopharmaceutical compounding are able to do so under each state's rules of practice of pharmacy and medicine. In fact, that practice is no different from compounding ^{18}FFDG on site for use within an institution. These issues and SNM and ACNP's differences with ICP were discussed, understood, and, to some degree, reconciled. All concerned parties agreed to move forward and keep each other informed. These differences in approach are a source of confusion that blurs the image of nuclear medicine. The questioned jurisdiction of FDA to regulate what SNM and ACNP argue falls under state jurisdiction is the core of the issue.

Questions over turf are fierce. Everyone in the nuclear medicine community knows what they are and what their significance is to the future of nuclear medicine. Physicians have been taught and generally believe that the research of today becomes the clinical practice of tomorrow and that those who perform the research are most likely to be those who will inherit that clinical practice. It doesn't always happen that way. Particularly when the issue of income for physicians, hospitals, and joint venture groups is at stake, monetary incentives seem to overpower the logic that those who do the research to develop a clinical tool have the right and the best credentials to do that clinical work.

The ACR recently supported a landmark study that compared the costs of imaging performed by radiologists versus non-radiologists for a few specific clinical problems in a large population of patients. The costs to the same insurance company were shockingly higher when imaging was done by non-radiologists compared to radiologists. The reasons for the non-radiologists' increased costs were higher charges and higher utilization. Such data may provide a basis for anti-self referral legislation, which would undoubtedly alleviate some nuclear medicine turf conflicts.

Reflections on PET and turf touch only a small segment of the three-dimensional dynamic image of nuclear medicine as a specialty. The more comprehensive image of nuclear medicine that Summit participants saw indicated that the specialty looks good, but it could look better. The group speculated that if nuclear medicine practitioners can protect their turf, the future of the field probably will not be substantially different from the future of medicine in general. All indications are that the future of medicine in this country is not as bright as health professionals would like, but they are working hard to keep the flame glowing.

Summit participants were:
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