### *FDA Involvement in PET*

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at any PET facility throughout the country. The institute recently went to Health Source Provident—which insures 4 million patients through 14 health maintenance organizations—and asked them to uniformly cover PET scans in patients who have solitary pulmonary nodules of undetermined status. (All of these patients routinely undergo surgery even though half have benign nodules.) After reviewing data showing that PET has a high sensitivity for detecting malignant nodules, Health Source decided to provide reimbursements for all its patients. "We're cautiously optimistic that AETNA-US Healthcare, Kaiser Permanente and the United Auto Workers will also follow suit," said McGehee.

Whether PET will achieve true success as a clinical modality will depend on costs. In an article published in *Diagnostic Imaging* (December 1996), Wahl pointed out that various cost-benefit analyses of PET scans for diagnosing or staging various types of cancers all found that PET can lead to significant cost savings. One study from the University of California at Los Angeles found that PET could save $550 per patient over standard diagnostic procedures when used in solitary pulmonary nodule imaging. Another analysis from the Northern California PET Center found that PET changed the surgical management of 34% of colorectal cancer patients, with a savings of $5000 per patient. Although these results are impressive, the key is to convince insurance companies and hospitals that PET can indeed save them money. This will be the determining factor in whether the imaging modality will make the transition from the research lab to the clinical world.

*—Deborah Kotz*

## The Cost of FDA Regulations: An Innovative Solution

Over the past few years, PET facilities have been a financial drain on hospitals and universities that own and operate the cyclotrons with little hope of reimbursements for PET procedures. Recent efforts by the Food and Drug Administration (FDA) to regulate the production of PET tracers threaten to increase operating costs to a staggering amount. Many institutions have considered closing their PET centers rather than spend tens of thousands of dollars to upgrade their facilities to the FDA's standards.

Capitalizing on these monetary difficulties, a new pharmacy network, called PETNet Pharmaceutical Services, may offer some institutions an alternative. PETNet, a limited liability corporation formed six months ago as a joint venture between Syncor and CTI to distribute $^{18}$F-deoxyglucose (FDG), is offering to pay for and obtain FDA approval for PET facilities in exchange for using their cyclotrons to produce and sell FDG. "We try to make this a win-win situation," said Ruth Tesar, vice president of marketing for PETNet, which is based in Atlanta. "We do the necessary work to get FDA approval in the form of an aNDA [abbreviated new drug application], and they allow us to sell FDG outside of their institution."

As of presstime, PETNet had signed contracts with 10 sites throughout the country. They are currently negotiating contracts with 8 additional sites and plan to have 25 sites in operation within 3 years, according to Tesar. She stressed that PETNet has "no standardized agreement" with the institutions. For each site, the terms of the contract vary from PETNet owning the cyclotron outright to sharing the responsibilities of managing the cyclotron and lab with the institution. The main components of every contract is that PETNet—staffed with experts in FDA regulations—will obtain an aNDA for the production of FDG in exchange for selling FDG to its customer base. (Since FDG has only a two-hour half-life, PETNet needs access to cyclotrons throughout the country to meet its customers' demands.)

William Beaumont Hospital in Royal Oak, MI is currently negotiating a contract with PETNet to turn over the management of its PET facility in exchange for PETNet assuming all operating costs and upgrades to meet FDA guidelines. Before the prospect of PETNet, the hospital was considering closing its PET facility because of its escalating costs. Under the proposed contract, PETNet will not only sell FDG to its outside customers but to Beaumont Hospital as well (although at a slightly lower price), according to Jack E. Juni, MD, the director of Beaumont's PET Diagnostic Center.

"Our main incentive is to reduce our fixed operating costs," said Juni. He said the costs for the PET facility to come under compliance with the FDA would have been $100,000; this does not include the $50,000 annual costs for paperwork and quality control. PETNet will pick up those costs and will also pay the salary of a radiochemist currently employed by Beaumont who will operate the cyclotron. In addition, PETNet will produce the PET tracers $^{13}$N-ammonia, $^{15}$O-water, and $^{11}$C products free of charge to Beaumont for hospital research studies. "Our operating costs will go down a little, whereas they would have gone up drastically to meet FDA requirements," Juni said. Beaumont's PET facility will still be operating in the red, but it now has a fighting chance for survival.

## ERRATUM

In the December 1996 *Newsline* article entitled, "Chernobyl: 10 Years Later," (*J Nucl Med* 1996; 37:27N) David V. Becker's, MD, affiliation was printed incorrectly. Dr. Becker is the professor of radiology and medicine at the New York Hospital-Cornell Medical Center in New York, NY.