drugs, as well? Is it the agency's intent to remodel the entire practice of pharmacy in this country?

Please reconsider your actions. Albert Lavender stated in a telephone conversation with me in December 1986 that pharmacists should not compound any drugs which use any components that are not NDA-approved. I do not think this statement accurately reflects existing law.

Radiopharmaceuticals for PET Imaging

Positron Emission Tomography (PET) imaging is not a new modality. In 1974 it was described in the plenary session of the SNM Annual Meeting. It is a technique of unique capability and proven value. It is being crippled by bureaucracy and unwillingness to act. At issue is a form of approval for PET radiopharmaceuticals, all of which are made on site and none of which have NDAs. Many never will have NDAs because they will never be supplied by a manufacturer; their half-lives are too short. Yet calling many of these drugs "investigational" [e.g., fluorine-18-fluorodeoxyglucose (FDG)] is a mistake. "Investigational" also means "non-reimbursable," and this sort of economics is not practical. The preparation of these drugs in-house is simply the practice of pharmacy and medicine, and an approval mechanism must be found to make these drugs easily available and legitimate. Last year I proposed such a mechanism. Quite simply, I suggested using the old drug monograph mechanism. No "perpetual" investigational new drug (IND) exemption or NDA would be needed if this were done. We do not really care if the FDA chooses to use this mechanism or not. We do wish that the FDA would find some mechanism, however, and establish an approval basis for these drugs. This technology was supported by taxes from the people of the United States (US), and they deserve to reap its benefits.

In addition to the above problem, there are related regulatory nightmares afoot involving cyclotrons, automated drug synthesis devices, and the purchasing of fluorine-18 as a radiochemical from a central supplier for in-house fluorine-18–FDG preparation. Again, we have the problem of regulating intermediates rather than the final product, and the purchase of a radiochemical from which to prepare a radiopharmaceutical. We urge you to stop this regulatory meddling now. The responsibility for the final drug product quality rests on the shoulders of the pharmacists and physicians who put their professional competence on the line when they prepare these compounds for human use. It doesn't matter whether they use a cyclotron, an automated synthesis machine, a centrifuge, or chromatography equipment. These are not drugs or devices. They are intermediates in drug preparation. The final drug must be adequately tested for quality, and the pharmacist, physician, and institution determine what is appropriate. The consequences of carelessness are lawsuits against the institution and malpractice charges against the pharmacist and physician. These are strong deterrents to sloppiness. They are all that

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FDA Explains Delay in Response

Dr. Robert Temple has delegated the response to Dr. Carol Marcus's letter to John F. Palmer, MD, director of the Food and Drug Administration (FDA) Division of Oncology and Radiopharmaceutical Drug Products. At the last meeting of the Radiopharmaceutical Drugs Advisory Committee (RDAC), held November 16, 1987, in Bethesda, Maryland, Dr. Palmer said that he hoped to deliver an official response "within days or weeks."

The answers to some of Dr. Marcus's questions, however, require that the FDA create policies, which takes time. "Although we realize that it's important to respond as soon as possible, we would prefer to answer correctly rather than hurriedly," Dr. Palmer told *Newsline*.

A well-thought-out answer is being developed among FDA staff in the Radiopharmaceutical Drug Products Group, the Center for Devices and Radiological Health, the Office of Compliance, and the General Counsel (legal department), he said.

The General Counsel is "quite interested in the issue of positron emission tomography (PET), and their opinions are not totally in tune with the thinking we had developed," said Dr. Palmer. This group's main concern is that FDA policies are made in accordance with United States (US) law, he pointed out.

Dr. Marcus's letter has been discussed at about 10 meetings within the FDA, said Dr. Palmer. Three of those meetings involved representatives from the four above-mentioned groups. Other issues, beyond those raised in Dr. Marcus's letter, have surfaced during these meetings, he explained—issues involving the relation between radiopharmaceuticals and medical devices, and the manufacture of drugs in a hospital setting.

"It's not often that the FDA is pressed to create unique ways of handling new technologies, and we have to be careful in trying to identify and articulate new regulatory policies," said Dr. Palmer.