COMMENTARY

THE FDA/SNM/ACNP RECRUITMENT VENTURE: A JOINT EFFORT FOR MUTUAL BENEFIT

arl C. Peck, MD, the director of the Food and Drug Administration (FDA)'s Center for Drug Evaluation and Research, has made us an offer we cannot refuse. He has asked the Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP) to augment the existing radiopharmaceutical staff by helping him recruit experts in radiopharmaceutical drug products who will join the FDA for at least two years in Rockville, Maryland. The additional staff needed consists of one or two physicians who have a substantial background in clinical research. One of these physicians should be knowledgeable about radiologic contrast agents. In addition, one or two radiopharmaceutical chemists and a pharmacologist are needed.

This unprecedented invitation to work with the FDA in choosing essential personnel is both an exciting prospect and a serious responsibility. For the first time, we have a unique opportunity to help determine events at the FDA which impact directly on the radiopharmaceutical drugs that we need and use. If this joint recruitment venture is a success, we can look forward to an ongoing relationship of this type with the FDA, which we hope will extend to the recruitment of more junior people in future positions.

Among the principal units in the Center for Drug Evaluation and Research are the eight drug review divisions where all new drugs are reviewed and evaluated before marketing. Biologicals are located in a companion center. All radio-pharmaceutical drugs are handled in the Divison of Oncology and Radiopharmaceutical Drug Products, headed by John Palmer, MD. Eric Jones, MD, is the Group Leader for Radiopharmaceuticals. Radiolabeled antibodies are handled in the Center for Biologics Evaluation and Research but in consultation with Dr. Jones' group concerning the radiolabeled portion. Dr. Peck believes that the recruitment of first-class experts to the Agency is a vital element that will lead to a significant enhancement of the FDA's evaluation of radiopharmaceuticals.

The need for outstanding physicians and scientists to evaluate INDs and NDAs has never been greater. Not only new radiopharmaceuticals, but new classes of radiopharmaceuticals are being conceived and developed in the United States. If we want to use them, we need to provide additional skilled staff to the FDA to evaluate these products. Also,

we require more experts at the FDA to participate actively in the design of appropriate clinical trials with radiopharmaceutical sponsors. This should streamline the review process, and be of benefit to all concerned. Now that farsighted radiopharmaceutical manufacturers are beginning to understand the immense value (and sheer necessity) of adding imaging physicians to their staffs, the FDA requires outstanding individuals to maintain effective communication with these physician representatives.

These FDA positions are difficult and challenging, but those individuals who join the radiopharmaceutical group will be performing an essential service to the nuclear medicine profession and its support industries. Government salaries at this time are adequate, although not as competitive as one would like, but by accepting you will earn the respect and gratitude of the nuclear medicine community. The type of experience to be gained cannot be matched elsewhere; knowledge would be gained of the entire spectrum of radiopharmaceutical drug development encompassing scientific, commercial and regulatory issues.

Dr. Peck is aware that outstanding people may have special professional needs, and is prepared to be flexible to attract appropriate candidates. These positions will permit a limited but flexible amount of time for clinical work, research, and teaching as professional development. The timing and extent of this flexibility, while limited, can accommodate a variety of proposals.

Please realize that we cannot expect enhanced FDA services unless additional excellent people are hired to provide them. A critical nucleus of first-class physicians and scientists would make the crucial difference. If we of the SNM and ACNP cannot provide this critical nucleus, who can?

For further discussion, please call Eric Jones at (301) 443-4260 or Carol Marcus at (213)533-2845.

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