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REPLY: It is gratifying to learn that Lines From the President is read by the membership and even generates letters to the editor. Unfortunately, I think that Dr. Bianco did not understand the discussion in Lines From the President (*J Nucl Med* 1990;31:26A, 30A) concerning regulation of cyclotron-produced radionuclides. The issue was not "whether FDG has efficacy for detecting coronary artery disease for determining myocardial viability," as stated in Dr. Bianco's letter. My discussion dealt with politics, not science. The issue was *whether FDA has legitimate authority to regulate cyclotron radiopharmaceuticals produced in a clinical facility for patient use in that institution*, or whether the regulatory authority rests with the states under laws governing the practices of medicine and pharmacy. The Society of Nuclear Medicine and the American College of Nuclear physicians believe that *the regulatory authority for cyclotron radiopharmaceuticals produced in the same institution where they are to be used legitimately belongs with the states, not the FDA.* In fact, PET/cyclotron practice currently is governed under the rules of practices of pharmacy and medicine as there is no FDA NDA for [^{18}F]FDG, ^{13}N-ammonia, or any other cyclotron-produced nuclides used in patients. Only commercial firms, which wish in future to be involved in commercial distribution of these radiopharmaceuticals, legitimately fall under FDA regulation and must deal with NDA products.

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President, Society of Nuclear Medicine

Stability of 6-[^{18}F]Fluorodopa Preparations

TO THE EDITOR: We wish to comment upon the issue of the stability of 6-[^{18}F]fluoro-L-dopa, with special reference to the compound as produced at the National Institutes of Health (NIH).

In a paper presented in this *Journal*, Chen et al. (*1*) investigated the stability of the 6-[^{18}F]fluorodopa produced at the NIH. The authors prepared a diluted solution of the radiopharmaceutical formulation in saline (1:100) and analyzed this solution for chemical decomposition by high-performance liquid chromatography (HPLC) with electrochemical detection. They found that 6-[^{18}F]fluorodopa in this dilute saline solution, or diluted in 1% acetic acid, decreases in chemical purity by 20% after 1 hr and by 50% after 4 hr when stored in light at room temperature. These nonenzymatic oxidation mechanisms resulted in at least two new mass peaks as determined by electrochemical detection. The addition of EDTA (0.15%) to the formulation prevented these nonenzymatic oxidation mechanisms.

We wish to report that the quality control and stability studies conducted in the Cyclotron/Radiochemistry Section of NIH on several batches of 6-[^{18}F]fluorodopa indicate no decrease in chemical or radiochemical purity up to 4 hr from the end of synthesis. No color change or precipitate was noted in the vial containing the original pharmaceutical formulation when stored in an amber vial at room temperature for up to 4 hr. Thus, we are in concurrence with Pike et al. (*2*), who report that their preparations of 6-[^{18}F]fluorodopa maintain radiochemical purity for at least 1 hr without the need for added stabilizers. Our method was analysis of a 10-μl aliquot of the final radiopharmaceutical formulation by HPLC, without dilution, using a high speed C-18 analytical column with gradient elution, mass detection by UV (220 nm), and radioactivity detection (NaI) (*3*).

We think the discrepancy between the results reported by Chen et al. and ours is due to the method of handling the sample. Chen et al. reported in their experimental section that the evaluated samples were prepared by taking 10 μl of the end product and diluting 1:100 with 0.1 N $HClO_4$. One hundred microliters of this dilution were injected onto the HPLC system. Furthermore, the sample used for the long-term stability studies was a 1:100 dilution in saline, which was periodically injected onto the HPLC system. This long-term stability study was reported to show a 20% decrease in purity after 1 hr exposure to light at room temperature. Presumably, the increase in the percent impurities found in the Chen et al. analysis is a direct result of the dilution of the 6-[^{18}F]fluorodopa relative to the amount of dissolved oxygen. In our analyses, we do not dilute the formulation, but use it directly.

We conclude that our 6-[^{18}F]fluorodopa remains stable for up to 4 hr without the addition of Na_2EDTA or any other preservative when the formulation is stored in an amber vial at room temperature and the pH of the final formulation is between 6 and 7.

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REPLY: With the safety of patients and good production practices of radiopharmaceuticals in mind, both Chen et al. (*1*) and