good points about the dosimetry, and we agree with his evaluation of the differences between the estimates in his earlier paper (2) and ours (3). We have the following responses to his points:

- 1. Our dose estimates are given per unit of injected activity, as is traditional and as is implied by the use of the quantity resident time (4). But this was not explicitly stated in the text or in the heading of Table 4.
- 2. We agree that the estimates of Dr. Heggie are lower because of our use of the ICRP 30 dose conversion factors for bone and marrow, which are conservatively high, having been designed for use in radiation protection programs (which operate at or below the 50-mGy level). We chose to use this system, as previous S-values contained a systemic error for low energy photon absorption (5), and because it is questionable to interpolate between mean energies and spectral shapes. Recent efforts by researchers at ORNL (6) have updated the photon and electron dosimetry and represent a more accurate dosimetry system. In this system, absorbed fractions (and thus dose estimates) will be provided for marrow and bone surfaces in seven bone groups, with explicit treatment of the beta spectra. We are currently in the process of implementing these values in our standard methods. We agree with Dr. Heggie that a recalculation of these dose estimates will be in order when these better dose conversion factors are available.
- 3. We agree that the values given for absorbed dose in SI unites are misstated. They should all be " μ Gy/MGq" not "Gy/MGq." The SI units were added during the review process, at the suggestion of a reviewer, and without the oversight of the main authors responsible for the dosimetry (Stabin).

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Current Status of Clinical PET

TO THE EDITOR: The editorial (1) by Dr. Edward Deutsch is an insightful analysis of aspects of the current status of clinical PET relating to generator-produced radionuclides. There is no doubt that a good generator-produced radiopharmaceutical for PET use, whatever its application, has a useful niche in clinical PET due to ready commercial availability and lack of dependence on local radiopharmaceutical production.

Dr. Deutsch points out that the FDA seems uncomfortable with PET radiopharmaceuticals because their production does not fit into existing regulatory cubbyholes. The agency is reacting with indecision and long delay. Therefore, the medical and financial benefits of a unique and well-proven subset of clinical nuclear medicine remain largely untapped. However, the concept that FDA approval could be obtained only by concentrating on tracers which fit existing regulatory mechanisms is cause for alarm. Is the solution to our dilemma that we should abandon the organic radiopharmaceuticals which are the mainstay of PET? Should we give up ¹⁸F-2-fluoro-2-deoxyglucose now that FDG is almost a household word? Should we even replace cheap (when the cyclotron is already there), easy and effective ¹³N-ammonia with a generator method and its associated added costs and procedures? The inorganic chemistry of metabolic or functional radiopharmaceuticals is very difficult. There are some impressive instances which demonstrate that generator-produced nuclides are not limited to perfusion and blood pool markers, but at best we have many years of work to match the current array of PET metabolic and receptor agents.

I do not believe that we will benefit as practitioners of PET, or as health care *consumers*, by restricting medical tools to fit bureaucratic preconceptions. This is not the path of innovation along which nuclear medicine has grown, nor is it a path to cost-effective health care. Drugs were once things we isolated from plants. Somehow a mechanism arose that allowed them to be synthesized and distributed. Now we must hope that there is still some room for original thought in government and that we will someday have regulations for PET materials which protect without stifling. Let us not propose abandoning an entire class of valuable diagnostic tools and the decades of government-funded work which produced it. Instead, we can work with the FDA to create understanding and sensible regulations, and let them know in increasingly urgent terms that these materials will continue to be needed regardless of the number of generators which are produced.

REFERENCE

1. Deutsch E. Clinical PET: its time has come? [Editorial]. J Nucl Med 1993;34:1132-1133.

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