**REPLY:** We would like to thank Drs. Hornof and Koblik for their comments, however, we do not agree with their conclusions. The question of the placement of the region of interest (ROI) is relevant. The authors did not provide more extensive images showing that the activity leaving the ROI, in fact, passed through the pyloric sphincter into the small intestine. A review of these images clearly shows that the activity in the gastrointestinal tract, well outside of the stomach, continually increases in relationship to the decrease in the stomach. Future work in this area should include more extensive regional images so that questions concerning redistribution are adequately resolved. Based upon review of this information, we conclude that redistribution is not evident.

Hornof and Koblik are correct in concluding that all four of the initial data points are superimposed at 100% at t = 0, and that t = 0 is the end of the 15-min ingestion period. Although Elashoff et al. (*1*) stated that t = 0 should be the time of beginning of ingestion, we were faced with the practical concern that we did not have completely compliant subjects. That is, the cats, at times, would delay ingesting any food until near the end of the feeding period, and then eat quite rapidly. At times, they would eat at a steady rate throughout the period. We therefore felt that the standardization of the time to the end of the feeding period more accurately reflected the total amount of ingested food. The method of Elashoff et al. sets the fraction remaining at t = 0 to 1.0, i.e., 100%, therefore, apart from standardizing the time to the end of the feeding period to accommodate the feeding characteristics of animals, we feel we have used previously accepted methods of curve normalization and that the error associated with this method is acceptable by published procedures.

Furthermore, their concerns over the statistical conclusions seem to be based upon a misinterpretation of Table 1, which is data for control animals only. These data were provided to show that variability does exist from animal to animal and between control experiments. Our article's Figure 3, comparing untreated to treated animals, is based upon raw data not provided as a table within the paper. The statistical conclusions were based on using each animal as its own control and provides a conservative analysis of effect. Even when all nonresponders at 3 mg/kg were included in the overall analysis, there was statistical significance. We conclude that as seen in a similar clinical trial (*2*) CCK antagonists and in particular, MK-329, accelerates gastric emptying.

## REFERENCES


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## The Nuclear Pharmacist's Role in Compounding Radioactive Drugs

**TO THE EDITOR:** The Nuclear Regulatory Commission (NRC) interim final rule entitled "Authorization to Prepar Radiopharmaceutical Reagent Kits and Elute Radiopharmaceutical Generators; Uses or Radiopharmaceuticals for Therapy" (*1*) continues to disenfranchise nuclear pharmacists from the NRC recognized pool of skilled health care providers.

Nuclear pharmacists are not permitted to compound radioactive drugs except by following the manufacturer's instructions or in cases in which an authorized user-physician directs a specific departure, a precise description of the departure, and a brief description of why the departure from the manufacturer's instructions would obtain medical results not otherwise attainable or would reduce medical risks to particular patients because of their medical condition.

The author(s) of the new regulation erroneously assumes that: (1) the package insert direction for compounding cannot be improved upon by the pharmacist; (2) the manufacturer will file an amended new drug application whenever improved compounding procedures are developed; and (3) the "authorized user-physician" rather than the nuclear pharmacist is the expert in the compounding of radioactive drugs.

The new regulations, as they define the pharmacist's role in the compounding of radioactive drugs, fail to recognize the professional contribution of the pharmacist in the compounding of drugs. The pharmacist is the professional responsible to serve society in the appropriate use of radioactive drugs and serves to achieve optimal therapeutic (diagnostic) outcome (*2*).

Consider the case in which a nuclear physician wishes to prescribe for his patient 10 mCi of technetium-99m-autologous leukocytes for a nuclear imaging study. There is no package insert that describes the compounding procedure for this drug. There are package inserts for some of the radioactive and nonradioactive drug components. How will the physician write the prescription? The regulatory requirement is that the instructions must be precise. The nuclear physician must be intimately familiar with the compounding procedure and must flawlessly transmit the compounding procedure to the nuclear pharmacist. The physician must also transmit a brief statement of why the departure from the manufacturer's instructions would obtain medical results not otherwise attainable or would reduce medical risks to particular patients because of their medical condition.

The regulations should permit physicians to prescribe the radioactive drugs they need for their patients and allow pharmacists to compound those drugs in accordance with the directions from the prescriber and state-of-the-art technology. For example, a nuclear physician should be able to present the following prescription to a nuclear pharmacist:

From: Dr. Sam Jones, Anyhospital, Anywhere, USA 00000.
For: Mr. John J. Patient, Room 402, Anyhospital, Anywhere, USA 000000.
Rx: 10 mCi technetium-labeled autologous leukocytes injection.
Mix and make according to the art.
Sig: Administer intravenously for scintigraphic evaluation of inflammatory process.
Physician signature: _____