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emp

26 October 1981

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USNR

Mr. Robert D. Minogue, Director
Office of Nuclear Regulatory Research
United States Nuclear Regulatory Commission
Washington, D.C. 20555

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Dear Mr. Minogue:

Your notice of September 15, 1981 to all medical licensees concerning the intent of the Nuclear Regulatory Commission to amend its regulations in 10 CFR part 35 was received on October 22. All radioactive materials received by private physicians for use in patients are precalibrated by pharmaceutical companies and shipped directly to the physician. Your proposal is to require licensees to (1) measure the total activity of each radiopharmaceutical dosage, except those containing less than 10 microcuries or a pure beta-emitting radionuclide, before it is administered to a patient; (2) verify that smaller dosages contain less than 10 microcuries; and (3) keep a record of the measurements.

Regulations such as this and the previous regulations requiring such measurements are effectively preventing proper care of private patients by private physicians in the most effective manner. For the private physician to have the facilities and staff to make such measurements would be very expensive for the patient. For you to require that he obtain the materials through major institutions having such instrumentation also increases markedly the cost of the therapy.

Such regulations are the equivalent of requiring that we do chemical assays on each medication we prescribe to be certain that all medications are properly labeled by the pharmaceutical manufacturer. You should not license an incompetent pharmaceutical firm for isotopes so that your regulation is redundant and inefficient.

You also state that first this is a simplifying procedure. Secondly, you state that the purpose is to enhance radiation safety by minimizing potential misadministration caused by not measuring the patient dosage. This would be clear indication that pharmaceutical firms you have licensed are incompetent to produce and supply precalibrated medications.

DS10 S/O Add: Elizabeth Rodenbeck

11/9/81 emp

I would like to know the justification for such an assumption. If there is justification, then there is justification as stated above for a challenge of all drug dosages, particularly of the many toxic medications that are necessary in hematology and oncology patients which I must treat from day to day.

Yours very sincerely,

John W. DeVore, M.D.

JWD:tm

cc: Senator David Boren
Senator Don Nickels
Representative Mickey Edwards