

MIKE SYNAR
2ND DISTRICT, OKLAHOMA

COMMITTEES:
JUDICIARY

GOVERNMENT OPERATIONS

Congress of the United States
House of Representatives
Washington, D.C. 20515

April 11, 1979

WASHINGTON OFFICE:
1338 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, D.C. 20515
(202) 225-2701

DISTRICT OFFICE:
2B27 FEDERAL BUILDING
125 SOUTH MAIN STREET
MUSKOGEE, OKLAHOMA 74401
(918) 687-2533

Mr. Carlton Kammerer
Director
Office of Congressional Affairs
Nuclear Regulatory Commission
1717 "H" Street, Northwest
Washington, D.C. 20505

Dear Mr. Kammerer:

The Dean of the University of Oklahoma College of Pharmacy, Dr. Rodney D. Ice, recently brought to my attention an apparent inconsistency which presently exists between FDA policy and NRC policy. This inconsistency concerns the regulation of nuclear pharmacy, and for your information I've attached a copy of Dr. Ice's description of the problem.

I hope that you will give this matter your most serious consideration, and I would appreciate hearing whatever comments you might have in regards to this matter.

Thank you very much for your cooperation, and I look forward to hearing from you soon.


Sincerely,



Mike Synar
Member of Congress

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The
University of Oklahoma
Health Sciences Center

P.O. Box 26001--644 N.E. 14th Street Oklahoma City, Oklahoma 73190

College of Pharmacy

March 30, 1979

Congressman Mike Synar
Room 1407
Longworth Building
Washington, D.C. 20515

Dear Congressman Synar:

I write to inform you and to seek your assistance in three matters, i.e., 1) a request for a waiver of enrollment assurance for the October 1979-1980 capitation grant, 2) the intrusion of the Nuclear Regulatory Commission into the practice of pharmacy, and 3) the federal government increase in prices of stable isotopes, e.g. tellurium 122, of 400%!

Capitation support of the College of Pharmacy program at the University of Oklahoma has been appreciated. This federal support has strengthened programmatic quality of the College of Pharmacy as well as increased pharmacy health manpower. At the University of Oklahoma College of Pharmacy, we lack a College of Pharmacy building. Our request for financial assistance for building a College of Pharmacy building, from both federal and state governments, has not been forthcoming. At present, we are housed in seven old houses around the University of Oklahoma Health Sciences Center. We have been assigned small temporary laboratories within the Health Sciences Center to teach the laboratory sections of our courses. As such we are limited to fifteen students per section. We are unable to house more than six sections of students limiting our enrollment to 90. The Bureau of Health Manpower has indicated that, for capitation grant funding we must have 110 students. A request for a waiver from the enrollment assurance of 110 students to 90 students has

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been submitted to the Bureau of Health Manpower. I would appreciate your office contacting the Bureau of Health Manpower in support of limiting our enrollment to 90 students which is the limit of our physical facilities. In support of our request, I attach a letter from the accrediting agency for pharmacy indicating a lack of suitable facilities.

Secondly, the Federal Register of February 9, 1979, indicates a new policy statement by the Nuclear Regulatory Commission. The policy statement, per se, when proposed in the March 17, 1978, Federal Register is satisfactory. However, as the policy has been published in the February 9, 1979, issue of the Federal Register, the interpretation goes far beyond the extent of the policy itself. It is apparent that the Nuclear Regulatory Commission is going to regulate the practice of nuclear pharmacy, an area which in the past has always been under state control. The FDA has always recognized the state's jurisdiction over the health professions and has exempted professional practice e.g., medicine and pharmacy. The NRC interpretation appears to be that since the FDA does not control this area, NRC will regulate via licensure.

This has led to a problem within the College of Pharmacy in that the College of Pharmacy is prohibited by the NRC from compounding prescriptions for radioactive drugs. This is not in the best interest of patient health. Most recently we sent an extemporaneous prescription to a physician in Muskogee for a new radiopharmaceutical that reduces the radiation dose to the patient by a factor of 4. Because the radiopharmaceutical had not been approved by the FDA, Ms. Pat Vacca of the Nuclear Regulatory Commission called the physician and said that he could not write a prescription and obtain this drug from our College operated pharmacy. This is really an intrusion into the practice of medicine and pharmacy.

Please note in the attached letter from NRC that we cannot compound radioactive drugs. Pharmacists by training are a profession taught to compound medications. If compounded prescriptions cannot be dispensed, who will ever know how to

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make radioactive medications? Radiopharmaceuticals are not magic conjured up by manufacturers! Pharmaceutical education requires the compounding and dispensing of drugs with patient interaction explaining the risk versus benefit. This area is fully controlled and adequately regulated by state boards of pharmacy. I request that you call Pat Vacca of the Nuclear Regulatory Commission and secure a clarification on the interpretation of these new federal regulations.

Finally, I call to your attention another problem facing the College of Pharmacy. We have recently been informed by Oak Ridge Laboratories, the suppliers of stable isotopes that an isotope we use - tellurium-122m has had a price increase of 400%! As much as we try to live within the guidelines established by President Carter, it is impossible when the federal government itself increases prices by such magnitude. I think your office should know what is happening within the federal government that is impacting so drastically on the educational programs in the state of Oklahoma.

Sincerely,



Rodney D. Ice, Ph.D.

Dean

RDI:ps

Enclosure

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