

DOCKET NUMBER
PETITION RULE PRM 35-9
(54FR 38239)

DOCKETED
USNR

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OFFICE OF
DOCKETING AND SERVICE
NOVEMBER 22, 1989
BRANCH

SECRETARY OF THE COMMISSION
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555

ATTENTION: DOCKETING AND SERVICE BRANCH, RE: DOCKET NO. PRM-35-9

LADIES AND GENTLEMEN:

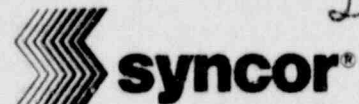
I HAVE BEEN A PRACTICING PHARMACIST FOR SIXTEEN YEARS. TWELVE YEARS IN A TRADITIONAL RETAIL AND HOSPITAL SETTING AND THE LAST FOUR YEARS AS A NUCLEAR PHARMACIST. I AM SENDING THIS LETTER IN SUPPORT OF THE AMERICAN COLLEGE OF NUCLEAR PHYSICIANS AND THE SOCIETY OF NUCLEAR MEDICINE; PETITION FOR RULEMAKING. THIS PETITION FOR RULEMAKING IS NECESSARY TO CLARIFY THE ABILITY OF PHARMACISTS TO PRACTICE PHARMACY.

AS NUCLEAR PHARMACISTS WE COMPOUND AND DISPENSE RADIOPHARMACEUTICALS UPON THE ORDER OF A LICENSED NUCLEAR PHYSICIAN. BOTH NUCLEAR PHARMACISTS AND PHYSICIANS ARE TRAINED PROFESSIONALS. THE NUCLEAR PHARMACIST HAS THE EXPERTISE TO COMPOUND THE RADIOPHARMACEUTICAL THE PHYSICIAN ORDERS. THE PRACTICE OF MEDICINE AND PHARMACY IS CLEARLY GOVERNED BY THE STATES REGARDLESS OF SPECIALTY. NRC REGULATION OF THE PRACTICE OF THESE PROFESSIONALS MUST BE AVOIDED SINCE IT WILL HAMPER THE PHYSICIANS AND PHARMACISTS ABILITY TO DELIVER QUALITY PATIENT CARE.

OF PARTICULAR INTEREST IS THE NRC'S RECENT FLINTERPRETATION OF LICENSE CONDITIONS FOR NUCLEAR PHARMACIES AND REGULATIONS FOR NUCLEAR MEDICINE LICENSEES. AT ISSUE IS A REQUIREMENT TO STRICTLY FOLLOW THE MANUFACTURER'S INSTRUCTIONS FOR PREPARATION OF RADIO-PHARMACEUTICALS AS PRINTED IN THE MANUFACTURER'S PACKAGE INSERT. THE PACKAGE INSERT INFORMATION SHOULD BE CONSIDERED AS A GUIDELINE IN THE PREPARATION AND USE OF ANY PRODUCT. IN THIS CASE AS IN TRADITIONAL PHARMACY AND MEDICAL PRACTICE, THERE ARE MANY CASES IN WHICH PROFESSIONAL JUDGEMENT AND EXPERIENCE MUST BE UTILIZED AND VARIANCES FROM THE PACKAGE INSERT BECOME MANDITORY IN MANY SITUATIONS. PHARMACISTS MUST HAVE THE ABILITY TO USE PROFESSIONAL JUDGEMENT IN COMPOUNDING TO ASSURE THE PRESCRIBING PHYSICIAN RECEIVES THE MOST EFFICACIOUS PRODUCT FOR HIS/HER PATIENT. PHYSICIANS MUST ALSO PRESCRIBE PRODUCTS WHICH ARE MOST APPROPRIATE FOR THEIR INDIVIDUAL PATIENTS. A STRICT FOLLOWING OF THE PACKAGE INSERT WOULD DELAY OR PREVENT DIAGNOSIS OF DISEASE IN SOME PATIENTS. THE QUALITY OF MEDICAL CARE FOR THESE PATIENTS COULD BE GREATLY INCREASED IF THEIR DIAGNOSES WERE SUPPLEMENTED WITH NUCLEAR MEDICINE STUDIES.

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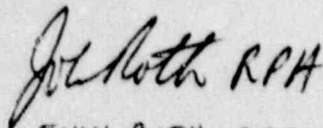


Syncor International Corporation
5347 West 86th Street
Indianapolis, IN 46268

THIS PETITION FOR RULEMAKING IS NECESSARY TO CLARIFY THAT PHYSICIANS AND PHARMACISTS HAVE THE FLEXIBILITY TO USE RADIO-PHARMACEUTICAL PRODUCTS AS NECESSARY AND APPROPRIATE IN THE DIAGNOSIS AND TREATMENT OF PATIENTS. DEATH, INJURY, OR INAPPROPRIATE TREATMENT OF PATIENTS MAY RESULT FROM ANY MANDATED, VERBATIM FOLLOWING OF THE PACKAGE INSERT INSTRUCTIONS.

I STRONGLY URGE YOU TO CONSIDER THE ACNP/SNM'S PETITION FOR RULEMAKING. ITS ADOPTION WOULD CLARIFY THE ABILITY OF NUCLEAR MEDICINE PHYSICIANS AND NUCLEAR PHARMACISTS TO GIVE THE BEST POSSIBLE PATIENT CARE.

SINCERELY,

A handwritten signature in cursive script that reads "John Roth RPH".

JOHN ROTH RPH
NUCLEAR PHARMACIST