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

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SECRETARY OF THE COMMISSION
U.S. NUCLEAR REGULATORY COMMISSION
DOCKETING AND SERVICE BRANCH, DOCKET # PRM-35-9
WASHINGTON, D.C. 20555

DEAR MR. SECRETARY:

AS AN ACTIVE MEMBER OF THE NUCLEAR MEDICINE COMMUNITY I WOULD LIKE TO SUPPORT THE PETITION FOR RULEMAKING FILED BY THE AMERICAN COLLEGE OF NUCLEAR PHYSICIANS AND THE SOCIETY OF NUCLEAR MEDICINE. I HAVE BEEN WORKING AS A NUCLEAR MEDICINE TECHNOLOGIST FOR 20 YEARS. I AM CONCERNED OVER THE REVISED 10 CFR 35 REGULATIONS GOVERNING THE MEDICAL USE OF BYPRODUCT MATERIAL AS THEY SIGNIFICANTLY IMPACT MY ABILITY AS A TECHNOLOGIST TO ASSIST MY PHYSICIANS IN THE PRACTICE OF NUCLEAR MEDICINE. THIS ULTIMATELY PREVENTS AND/OR DELAYS THE PERFORMANCE OF OPTIMIZED CARE TO INDIVIDUAL PATIENTS.

FOR EXAMPLE, I MUST ADHERE TO THE LABELING INSTRUCTIONS FOR KITS EVEN THOUGH I READ IN THE LITERATURE ABOUT ALTERATION IN THE METHODS THAT LEAD TO MUCH BETTER SCANNING AND BETTER PATIENT MANAGEMENT. I HAVE ALWAYS THOUGHT PHYSICIANS COULD PRESCRIBE THE MEDICINE NEEDED AS LONG AS IT WAS IN THE FIELD OF THEIR TRAINING. THEY WOULD CERTAINLY BE ABLE TO TAILOR THE DIAGNOSTIC TEST TO THE CONDITION OF THE PATIENT MORE EFFECTIVELY THAN A LABEL ON A BOTTLE OR A PACKAGE INSERT. RADIOPHARMACEUTICALS ARE EXPENSIVE AND OR REGULATED TO DEATH AS IT IS. WHAT IS THE INTENT OF THE NRC IN REGULATING THE USE OF THESE DRUGS SO STRINGENTLY. FOR EXAMPLE THE ROUTE OF ADMINISTRATION, SPECIFIC INSTRUCTIONS AND SHORT EXPIRATION TIMES OFTEN DICTATE WHO AND HOW THESE PRODUCTS CAN BE USED. THIS IS NOT ALWAYS IN THE BEST INTEREST OF THE PATIENT WHEN RURAL AREAS OF THE NATION ARE AFFECTED.

THE NRC SHOULD RECOGNIZE THAT THE FDA DOES ALLOW, AND OFTEN ENCOURAGES, OTHER CLINICAL USES OF APPROVED DRUGS, AND ACTIVELY DISCOURAGES THE SUBMISSION OF PHYSICIAN-SPONSORED IND's THAT DESCRIBE NEW INDICATION FOR APPROVED DRUGS. THE PACKAGE INSERT WAS NEVER INTENDED TO PROHIBIT PHYSICIANS FROM DEVIATING FROM IT FOR OTHER INDICATIONS. ON THE CONTRARY, SUCH DEVIATION IS NECESSARY FOR GROWTH IN DEVELOPING NEW DIAGNOSTIC AND THERAPEUTIC PROCEDURES. IN MANY CASES, MANUFACTURERS WILL NEVER GO BACK TO THE FDA TO REVISE A PACKAGE INSERT TO INCLUDE A NEW INDICATION BECAUSE IT IS NOT REQUIRED BY THE FDA AND THERE IS SIMPLY NO ECONOMIC INCENTIVE TO DO SO.

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CURRENTLY, THE REGULATORY PROVISION IN PART 35 (35.100, 35.200, 35.300 AND 33.17(a)(4)) DO NOT ALLOW PRACTICES WHICH ARE LEGITIMATE AND LEGAL UNDER FDA REGULATIONS AND STATE MEDICINE AND PHARMACY LAWS. THESE REGULATIONS THEREFORE INAPPROPRIATELY INTERFERE WITH THE PRACTICE OF MEDICINE, WHICH DIRECTLY CONTRADICTS THE NRC's MEDICAL POLICY STATEMENT AGAINST SUCH INTERFERENCE.

RESTRICTING ACCESS TO APPROPRIATE NUCLEAR MEDICINE PROCEDURES, EXPOSING PATIENTS TO HIGHER RADIATION ABSORBED DOSES FROM ALTERNATIVE LEGAL, BUT NON-OPTIMAL, STUDIES, AND EXPOSING HOSPITAL PERSONNEL TO HIGHER RADIATION ABSORBED DOSES BECAUSE OF UNWARRANTED, REPETITIVE PROCEDURES JEOPARDIZES THE HEALTH AND SAFETY OF THE PUBLIC THAT IS SUPPOSED TO BE PROTECTED. THE NRC SHOULD NOT STRIVE TO CONSTRUCT PROSCRIPTIVE REGULATIONS TO COVER ALL ASPECTS OF MEDICINE NOR SHOULD IT ATTEMPT TO REGULATE RADIOPHARMACEUTICAL USE. INSTEAD, THE NRC SHOULD RELY ON THE EXPERTISE OF THE FDA, STATE BOARDS OF PHARMACY, STATE BOARDS OF MEDICAL QUALITY ASSURANCE, THE JOINT COMMISSION ON ACCREDITATION OF THE HEALTHCARE ORGANIZATIONS, RADIATION SAFETY COMMITTEES, INSTITUTIONAL Q/A REVIEW PROCEDURES, AND MOST IMPORTANTLY, THE PROFESSIONAL JUDGEMENT OF PHYSICIANS AND PHARMACISTS WHO HAVE BEEN WELL-TRAINED TO ADMINISTER AND PREPARE THESE MATERIALS.

SINCE THE NRC's PRIMARY REGULATORY FOCUS APPEARS TO BE BASED ON THE UNSUBSTANTIATED ASSUMPTION THAT MISADMINISTRATIONS, PARTICULARLY THOSE INVOLVING DIAGNOSTIC RADIOPHARMACEUTICALS, POSE A SERIOUS THREAT TO THE PUBLIC HEALTH AND SAFETY, I STRONGLY URGE THE NRC TO PURSUE A COMPREHENSIVE STUDY BY A REPUTABLE SCIENTIFIC PANEL, SUCH AS THE NATIONAL ACADEMY OF SCIENCES OF THE NCRP, TO ASSESS THE RADIOBIOLOGICAL EFFECTS OF MISADMINISTRATIONS FROM NUCLEAR MEDICINE DIAGNOSTIC AND THERAPEUTIC STUDIES. I FIRMLY BELIEVE THAT THE RESULTS OF SUCH A STUDY WILL DEMONSTRATE THAT THE NRC's EFFORTS TO IMPOSE MORE STRINGENT REGULATION ARE UNNECESSARY AND NOT COST-EFFECTIVE IN RELATION TO THE EXTREMELY LOW HEALTH RISKS OF THESE STUDIES.

IN CLOSING, I STRONGLY URGE THE NRC TO ADOPT THE ACNP/SNM PETITION FOR RULEMAKING AS EXPEDITIOUSLY AS POSSIBLE.

SINCERELY,

Art Hall

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