

RF
file Nuclear Pharmacy

1 December 1979

Mr. James Briesack
Director, Fuel Facility Material Safety Inspection Branch
Office of Inspection and Enforcement
United States Nuclear Regulatory Commission
Washington, DC 20545

EE: Nuclear Pharmacy, Inc.
Milwaukee facility fine
133-Xenon Not for Human Use

Dear Sir,

In late August 1979, USNRC announced a proposed fine against Nuclear Pharmacy, Incorporated (NPI) of Milwaukee, Wisconsin for the admitted and proven unauthorized acquisition, breakdown, re-packaging, dispensing and delivery, for human use, of 133-Xenon gas clearly labelled "Not for Human Use." Cited were examples of bulk container re-labeling and sale as well as re-packaging of aliquots of the "industrial grade" gas into smaller containers (vials) intended for use in human lung scanning procedures.

I understand that you may be considering mitigation of this fine (i.e., lowering the total dollar amount). I urge you NOT to do so and I hereby offer you additional information which may support my position and/or rebut NPI's defense of their actions. Hopefully some of this information is new to you. You should find it germane to the issue of the fine's severity.

I am told that NPI's license clearly specifies that they may ONLY possess "human-use" 133-Xenon. This is proper as they are licensed as medical distributors and, therefore, the strong assumption that the ultimate user is human should be justifiably made. Furthermore, and this is important: These materials were clearly not only RECEIVED by NPI in violation of that license, but were DISPENSED on prescription, as a drug, for HUMAN USE. The so-called "pharmacist's prerogative" under the Food, Drug, and Cosmetic Act permitting some to convert various chemicals, plant derivatives, and assorted compounds into drugs for human use is inapplicable here. Items labelled POISON or CHEMICAL GRADE or ANALYTICAL REAGENT or VETERINARY USE can, under the law, when circumstances dictate, become drugs for human consumption in the hands of a pharmacist. But there is no way under the law that ANY product, radioactive or otherwise, labelled NOT FOR HUMAN USE can become suitable for human use. Examine the record. NPI, by implied warranty, guaranteed this 133-Xenon suitable for human use, a use for which it was specifically EXCLUDED.

Because I have no access to NPI's reply to the proposed fine, I have no idea what possible excuse they gave to the USNRC that warrants mitigation. Thus, my wide-ranging comments. Please bear in mind, first and foremost, that the fine is for a possession and distribution violation, abundantly proven and multiple in scope. However, please also consider the following:

- 1) Hospitals and doctors accepted these vials and bulk containers in GOOD FAITH that they were suitable for human use. Any allegation that the recipient is in any way sharing responsibility with NPI is a total falsehood. I refer you to case law based on the Federal Food Drug and Cosmetic Act, both at

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the federal and state (ANY state) level to prove my point. I am not an attorney--I will not snow you with case quotations. This "warranty" is a well-known fact of which you should be aware.

- 2) Public health may have been adversely affected as there was insufficient testing for contaminants in the 133-Xenon. A 0.1% contamination of 131-Iodine would deliver 100 rads to a human thyroid (based on the partitioning and absorption of an effective 10 milliCurie dose of the 133-Xenon gas). This would be only 0.1 milliCurie of 131-Iodine--an amount no one can accurately measure in a nuclear medicine department dose calibrator.
- 3) NPI deliberately ordered and received and distributed material not for human use. They had (and have) a long-standing business relationship with suppliers of non-human-use 133-Xenon and indeed continued to distribute this very same material in the Milwaukee area into April, 1979 even though the citation was issued about ten weeks previously. Proof available to you on request. In my opinion, this is flagrant disregard for NRC's licensing authority.
- 4) NPI has lied to the hospitals concerned after the fine was announced publicly, claiming there was some misunderstanding and that the material was distributed to "industrial concerns" --this is, of course, contrary to fact.
- 5) NPI deliberately re-packaged the spurious 133-Xenon in "spent" New England Nuclear-labelled cartridge-vials and was sold as New England material. This is "adulteration" and "misbranding" and "counterfeiting" under the federal Food Drug and Cosmetic Act. This is most serious as the receiving department has ABSOLUTELY no way of knowing the material is not for human use--indeed, the labelling indicates human usage is APPROVED. Proof on request.
- 6) NPI's legal counsel has verbally intimidated medical users in the Milwaukee area, threatening lawsuits, etc. Proof on request. Their intent here is to suppress opposition to mitigation of the fine.
- 7) NPI has been cited for similar offenses at other locations--in Texas and in Chicago (Elmhurst), Illinois--to my knowledge. In fact, the Chicago facility, NRC License #12-18044-01MD, has yet to have its citations processed. The inspection was made 31 Jan 1979-2 Feb 1979 and shows SEVEN violations including another 133-Xenon violation similar to one under present discussion against the Milwaukee facility. The same regional manager, Mr. A.M. Zimmer, controls the purchasing policies of both locations. Proof on request.
- 8) A pharmacist-associate formerly employed by NPI has informed me that the 133-Xenon practice discussed here dates back many years at many NPI locations across the nation, and that my

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associate's responsibility during his tenure with MPI was to do the tasks described in 1,3,5, & 7 above. Proof on request.

CONCLUSION:

Many of the offenses mentioned above are violations of the artificial licensing regulations, the reality of the impact on health care in the Milwaukee area. The subsequent offenses can and should be pursued by the proper authorities (FDA, Wisconsin State Board of Pharmacy, New England Nuclear Corp., and others). Your decision will influence their decisions. Your decision will be used as evidence of the wrongdoing. Therefore, please, be firm, be severe. These practices, as discovered, must be punished appropriately or it will become more prevalent in nuclear pharmacy, resulting in adverse publicity and even further harassment of the WISNHC by the misinformed public. Strong action now will be a deterrent.

Thank you for your thoughtful consideration. A reply would be much appreciated.

Sincerely,

East Cleveland, OHIO

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from