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PDR

April 30, 1987

Mr. William Parler
General Counsel, H-1035
U.S. Nuclear Regulatory Commission
1717 H Street, N.W.
Washington, D.C. 20555

Re: Nuclear Pharmacy Amendment to the Price-Anderson Act

Dear Mr. Parler:

Thank you for taking the time to speak with me yesterday regarding the legislative proposal I am working on behalf of the National Association of Nuclear Pharmacies. The Association promotes development and research in radiopharmaceuticals, life-saving drugs with short radioactive half lives used to treat millions of people in the U.S. annually. The amendment we propose would establish a $500,000 liability limitation for nuclear pharmacies and hospital nuclear medicine departments only for claims arising out of low level emissions of byproduct material from nuclear pharmacies. The amendment does not seek a limitation of liability in products liability or medical malpractice cases. The amendment would also exclude third party liability claims for damages allegedly resulting from emissions of radioactive material below levels permitted by federal regulation. In so doing, the proposed amendment merely seeks to provide nuclear pharmacies, hospitals and their insurers with some assurance that they will not incur liability if they operate within standards provided by law.

The amendment is necessary because of the severe insurance problems facing nuclear pharmacies. Claims due to low level emissions are not covered by the general liability insurance policies held by nuclear pharmacies. Specialized insurance coverage is also not available in the current insurance market. Furthermore, because nuclear pharmacies do not have sufficient profits to insure against third party claims, the concept of self-insurance for nuclear pharmacies is not feasible.

The amendment sought by the Association was proposed as a solution to this problem and taken to various members of the 99th Congress for their consideration. We also contacted Mr. Jerome Saltzman, Assistant Director of the Office of State Programs, at NRC. The Association sought a legislative amendment since the NRC discouraged a petition for rulemaking requesting coverage of Price-Anderson be extended to nuclear pharmacies. The 1980 NRC report of John G. Davis, Director of the Office of Nuclear Safety and Safeguards, indeed stated that NRC only has the authority to indemnify its own licensees. Where the licensee is an agreement state licensee, the report stated that new legislation would be needed in order to require that such a licensee be indemnified. More recently, in a meeting with Mr. Saltzman, he informed us that legislation proposing coverage for byproduct material licensees would have to take into account the NRC's concerns about the agreement state licensees.

Following the informational meeting with Mr. Saltzman and his staff last August, NRC staff prepared a response to Congressman Markey's questions dated September 12, 1986 in regard to Price-Anderson coverage of radiopharmacies, a copy of which is attached for your information. The staff relied upon a 1980 study performed by the Oak Ridge National Laboratories as well as the NRC staff analysis "that the accidents involving quantities and types of radioactive material handled by materials licensees would not result in public liability claims beyond the amount of liability insurance coverage than available to these licensees." Answer to Question No. 2. However, when asked about the level of insurance carried by radiopharmacies, the NRC staff responded that it did not have any information about the levels of insurance maintained by radiopharmaceutical companies. Answer to Question No. 5.

The 1980 study assumed that the same amount of commercial insurance available to nuclear utilities (then $140 million) was also available to other licensees. That is not now nor has it ever been the case for nuclear pharmacies. The staff's answers to Congressman Markey has suggested to us that perhaps we did not fully articulate our concerns and the purpose and practical effect of our amendment. If the proposed amendment is enacted, it is the present intention of nuclear pharmacies to seek insurance with limits of $500,000. Since the members of the NANP have no history of third-party claims in over 30 years of operation and an excellent safety record, it is our position that the proposed amendment does not expose the United States to any real danger from damage awards. Indeed, as you know, the half lives of the radioactivity in these life-saving

drugs is generally only six hours. Thus, the potential cost of such a program to the American taxpayer would be extremely minimal, particularly in comparison to the benefits to public health that would result from the increased availability, use and development of these valuable radiopharmaceuticals. Furthermore, since NRC comprehensively and tightly regulates nuclear pharmacies already, the governmental indemnification that would act as excess umbrella layer of insurance would not result in additional expenditures of governmental resources.

We understand that you may have further questions about the problems faced by nuclear pharmacies and the proposed amendment. My colleagues and I would be happy to meet with you at your convenience. Please let me know if you would like to arrange a meeting or if you require further information in your consideration of this matter. Thank you again for your time and consideration of this issue.

Very truly yours,

David Broome

David Broome

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

CHAIRMAN

September 12, 1986

The Honorable Edward J. Markey, Chairman
Subcommittee on Energy Conservation and Power
Committee on Energy and Commerce
United States House of Representatives
Washington, D. C. 20515

Dear Mr. Chairman:

Thank you for your letter of August 29, 1986. Enclosed are staff's responses to your questions in regard to Price-Anderson coverage of radiopharmacies.

Sincerely,

Thomas M. Roberts
Acting Chairman

Enclosure:
Responses to Questions

cc: Rep. Carlos Moorhead

8609300457 8pp.

Question 1. Does the Commission have authority under current law to extend Price-Anderson coverage to radiopharmacies? Has the Commission ever decided on whether coverage should be extended to these companies? When?

Answer.

Under subsection 170a. of the Atomic Energy Act of 1954, as amended, financial protection and government indemnity are mandatory for activities involving the construction and operation of production and utilization facilities, such as reactors, licensed under sections 103 and 104 of the Act. Subsection 170a. also allows NRC the discretion to require financial protection and to extend indemnity coverage to other NRC licensed activities not involving the operation of production or utilization facilities. Subsequent to the renewal of Price-Anderson in 1975, the Commission considered whether it should exercise its discretionary authority and require financial protection for materials licensees in general and specifically a certain class of materials licensees, i.e., those persons licensed to possess or use plutonium in plutonium processing and fuel fabrication facilities. After studying the issue, the Commission decided to exercise its discretionary authority by requiring financial protection of, and extending indemnity to, certain of these plutonium licensees. Based on subsequent work performed for NRC by the Oak Ridge National Laboratory (ORNL), NRC staff refinement of that work, and an in-house staff study of this question, the staff informed the Commission in 1980 that, in its view, no apparent need existed to extend Price-Anderson to other classes of materials licensees. This conclusion was based in part on the fact that the amount of radioactive material handled by these licensees would not result in accident scenarios that could involve third party liability claims greater than the amount of nuclear liability insurance available to fuel cycle licensees. While radiopharmacies and similar licensees that handle relatively small quantities of radioactive material were not specifically examined, this conclusion, based on licensees possessing much larger inventories of material, would appear to be equally valid for the licensees of smaller inventories.

Question 2. Has the Commission reviewed the potential public liability which could arise from the activity of a radiopharmacy? When? What is the risk of such liability? Please describe the Commission's findings on these questions for the Subcommittee.

Answer.

As described in the previous answer, it was the staff's conclusion in 1980, based on work performed by ORNL as well as in-house staff analysis, that the accidents involving quantities and types of radioactive material handled by materials licensees would not result in public liability claims beyond the amount of liability insurance coverage then available to these licensees.

Question 3. Has new information been discovered which would prompt the Commission to reexamine the question of extending Price-Anderson coverage to radiopharmacies? Is the Commission aware of any recent court decisions, either at the state or federal level, which might affect radiopharmacies? Please provide the Subcommittee with a legal memoranda examining recent court cases in this area and their potential impact on radiopharmacies and the Price-Anderson Act.

Answer.

There are two recent court cases in the State of Missouri, a non-Agreement State, which deal specifically with radiopharmacies. Maryland Heights Leasing, Inc. v. Mallinckrodt, Inc., 706 S.W.2d 218 (1985), and Bennett v. Mallinckrodt, Inc., 698 S.W.2d 854 (1985). In both of these cases plaintiff's complaint was dismissed by the trial court in response to defendant's motion to dismiss. As grounds for dismissal the trial court stated that it lacked subject matter jurisdiction and that the complaint failed to state a claim upon which relief could be granted. In both cases the Missouri Court of Appeals (Eastern District) reversed the trial court's judgment and remanded the case for a trial and judgment on the merits. Even though the Missouri Court of Appeals could have reversed both cases on narrow procedural grounds, in both instances the Court proceeded to discuss the merits of the case. Although both opinions are quite similar, the Court's opinion in Bennett v. Mallinckrodt, supra, is the more detailed of the two. In Bennett the defendant asserted that plaintiff's action was barred by the federal preemption doctrine. In response to this assertion, the Missouri court noted:

> In 1959, Congress amended the Atomic Energy Act and authorized the NRC to turn over some regulatory authority to those states [Agreement States] that adopted a suitable regulatory program, see 42 U.S.C. §2021, but states were still precluded from regulating the safety aspects of nuclear development, see 42 U.S.C. §2021(k). See also Pacific Gas & Electric Co v. State Energy Resources Conservation & Development Comm., 461 U.S. 190, 205 (1983); ...

The Missouri Court then proceeded to state that the United States "Supreme Court has declared, in essence, that states are precluded from regulating the safety aspects of nuclear development and of hazardous nuclear materials" citing Pacific Gas & Electric Co., 461 U.S. at 204, and Silkwood v.Kerr- McGee Corp., 104 S. Ct. 615, 622 (1984). It also stated, "This prohibition is premised on Congress' belief that the NRC is more qualified than the individual states to determine what type of safety standards should be enacted in this complex area." Silkwood, 104 S. Ct. at 622.

Question 3 (Continued)

The Missouri Court in Bennett used the existence of the Price-Anderson Act and the fact that one of its "cardinal attributes ...has been its minimal interference with State law" as partial justification for the following three propositions:

> (1) As other manufacturers, producers, and operators functioning in a regulated field, Mallinckrodt is not guaranteed absolute insulation from the consequences of its acts through compliance with federal regulation;
>
> (2) State law remedies, in whatever form they might take, are available to those injured by "nuclear incidents;" and
>
> (3) States may be preempted from setting their own emission standards, but they are not preempted from compensating injured citizens.

Finally, the Court in Bennett asserted that the ALARA principle set forth in 10 C.F.R. §20.1(c) "clearly implies that federal standards are, at best, guidelines to state tort law," and "...the use of nuclear material is not yet so common that strict liability should not be applied [in Missouri] at this time."

It should be noted, however, that the legal principles relied on by the Missouri Court of Appeals are those applicable to production and utilization facilities, e.g. nuclear reactors, licensed by the NRC. Radiopharmacies are licensed by the NRC under section 81 of the Atomic Energy Act of 1954, as amended, or are licensed by an Agreement State pursuant to authority passed to such a State in accordance with section 274 of that Act. In fact there are 28 Agreement States which issue licenses to persons to acquire, possess, use, etc., source mateiral, byproduct material, and special nuclear material in quantities less than sufficient to form a critical mass.

Radiopharmacies are facing the same problem that is being faced by other segments of the medical community and by other radioactive materials licensees - the high cost and low availability of third party liability insurance. The NRC finds no "new information" that would prompt it to indemnify these radiopharmacies, particularly since many of them are Agreement State licensees regulated by the States.

Question 4. Is there a process under current law which would require the Commission to extend coverage of the Price-Anderson Act to NRC licensees not now covered? If the answer is yes, has this process ever been initiated by any NRC licensee? By a radiopharmaceutical company? If the answer is no, then please describe how NRC licensees not now covered by the Price-Anderson Act can receive coverage.

Answer.

There is no such requirement under the Price-Anderson Act. As discussed in a previous answer, the Commission has the discretionary authority to extend Price-Anderson coverage to materials licensees. Only one materials licensee, Kerr-McGee Corporation, has ever requested (in testimony before the Joint Committee on Atomic Energy) indemnification of plutonium processing activities under the Commission's discretionary authority and, in fact, the Commission exercised its discretionary authority for five such licensees. A request for the Commission to exercise its discretionary authority to indemnify the activities of radiopharmacies could be made in the form of a petition for rulemaking addressed to the Secretary of the Commission providing full details as to why such authority should be exercised (see 10 CFR 2.802).

Question 5. What is the level of insurance carried by radiopharmaceutical companies? How has this changed over the past ten years? How does their insurance coverage compare with other NRC licensees?

Answer.

The NRC does not have any information about the levels of insurance maintained by radiopharmaceutical companies.

Question 6. Does the Commission believe that the Price-Anderson Act should be extended to cover radiopharmacies? Why or why not? If the answer is yes, please include recommendations as to how the Act should be amended to accomplish that goal. If the answer is no, please explain to the Subcommittee why the concerns raised by some radiopharmacy companies do not warrant action under the Price-Anderson Act.

Answer.

The staff does not have any information that would lead it to recommend to the Commission that radiopharmacies should be indemnified under the Commission's discretionary authority. Based both on previous risk/consequence studies alluded to in the previous answers and the fact that no new information has been developed that would render these studies obsolete, the staff believes that in the event of an accident the quantities and types of radioactive material utilized by radiopharmacies would not result in significant offsite public liability consequences for which adequate insurance could not be purchased. The 1957 legislative history of the Price-Anderson Act states the following about the discretionary authority provision:

> "In addition, the Commission is given the option of requiring financial protection for any license issued under section 53, 63, or 81... It is not expected that ordinarily the Commission will use the authority given it with respect to those latter three types of materials. However, there may be rare instances in which the licensee of a facility may have larger quantities of materials or such quantities of especially dangerous or hazardous materials as to warrant the imposition of the provisions of this bill. (Senate Report No. 296, 85th Congress, 1st Session, May 9, 1957, p. 19)."

No new information has been brought to our attention that would warrant further Commission consideration of this question at the present time.