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WASHINGTON, DC 20515

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AND COUNSEL

LEE McELVAIN
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RICHARD AGNEW
CHIEF MINORITY COUNSEL

April 12, 1988

The Honorable Lando Zech, Jr.
Chairman
Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Chairman:

A year ago, you answered a number of questions I raised concerning an amendment then pending before this Committee that would have provided federal indemnification to persons who produce or use radiopharmaceuticals. Your answers proved most helpful and the Committee disapproved the amendment.

As I am sure you are aware, last month, the Senate passed a different radiopharmaceuticals amendment. While the purpose of the amendment appears the same as the one considered by this Committee last year, the scope and effect of the new amendment may differ.

I would greatly appreciate the views of the Commission on the Senate amendment. In particular I would like to know if the differences between the Senate amendment and the one you commented on last year in any way diminish or heighten the concerns expressed in your May 5, 1988 letter.

In addition, I would appreciate the Commission's recommendations on how, assuming Congress decides to extend indemnification to producers and users of radiopharmaceuticals, legislation could be drafted to mitigate your concerns.

I am grateful for your assistance.

Sincerely,

M. Udall
MORRIS K. UDALL
Chairman

BB05100060 BB0422
PDR COMMS NRCC
CORRESPONDENCE PDR

4/15...To EDO to Prepare Response for Signature of Chairman

Date due Comm: April 28...Cpys to: RF, OCA to Ack, Cmrs, ..88-0315



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

April 22, 1988

OFFICE OF THE
SECRETARY

The Honorable Morris K. Udall, Chairman
Subcommittee on Energy and the Environment
Committee on Interior and Insular Affairs
United States House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This responds to your April 12, 1988 letter requesting the Commission's views on the provision in the Senate-passed Price-Anderson Act extension which would provide for Federal indemnification of persons producing or using radio-pharmaceuticals. The Commission believes that both the Senate-passed bill, and the bill amendment on the same subject that was pending before your Subcommittee about one year ago, present the same fundamental policy concerns.

Section 170a of the Atomic Energy Act, which expired on August 1, 1987, granted the NRC discretionary authority to require financial protection and to extend indemnity to persons possessing NRC materials licenses. The 1957 legislative history of the Price-Anderson Act states that:

It is not expected that ordinarily the Commission will use the [discretionary] authority given it with respect to these latter three types of materials [sections 53, 63, and 81]. 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 the bill.

The small amounts of radioactive materials possessed by nuclear pharmacies and hospitals, coupled with the short decay period for radiopharmaceuticals, has convinced the Commission that extending Price-Anderson coverage to nuclear pharmacies, hospital nuclear medicine departments, and radiopharmaceutical manufacturers would be inconsistent with the original concept of Price-Anderson as expressed in the language quoted above. The Price-Anderson Act should not become an available alternative for all those users of nuclear materials who have encountered some difficulty in obtaining liability insurance at favorable rates.

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We would also like to address criticisms raised by representatives of the National Association of Nuclear Pharmacies (NANP) on our previous response to your questions and on our responses to questions by Congressman Markey and Senator Johnston. The information we provided was, to the best of our knowledge, accurate. However, the questions we were asked to respond to were premised on differing versions of the basic indemnification amendment. We were correct in stating that the Commission has discretionary authority to extend Price-Anderson coverage to nuclear pharmacies licensed by NRC, but we have never maintained that we had such authority with regard to Agreement State licensees. In addition, the amendment originally offered before your Subcommittee provided for coverage of misadministration and malpractice claims. This is no longer true for the version of Price-Anderson recently passed by the Senate.

The NANP has also stated on a number of occasions that the Commission was incorrect in its estimates of approximately 7500 licensees that would be covered by the proposed amendment by counting radiopharmaceutical manufacturers in those estimates. The proposed Senate amendment does, however, include these manufacturers, as explained in the following statement by Senator Breaux on the Senate floor on March 16, 1988:

In this respect, the language of the amendment is quite clear. The amendment only covers persons conducting medical and related activities of operating nuclear pharmacies or hospital nuclear medicine departments. In our Committee report we indicated that the "related activities" addressed by the amendment only included the manufacture of the radiopharmaceuticals, since the intent of the provision is to remove barriers to the production and distribution of these items. 134 Cong. Rec. S2338, (Daily Ed., March 16, 1988).

With regard to NANP's comments on the availability of commercial insurance, we understand from insurance industry representatives that many nuclear pharmacies, radiopharmaceutical manufacturers, and hospitals do maintain comprehensive general liability insurance (CGL) policies. These CGL policies contain a provision entitled "Broad Form Nuclear Exclusion." This exclusion, however, does not exclude radioisotopes from its coverage. Therefore, any claim arising out of radioisotopic exposure for personal injury or bodily damage should be covered under the CGL policy. While some nuclear pharmacies or hospitals may not choose to purchase CGL policies, this is not a situation unique to this particular industry.

You asked for the Commission's recommendations on how, if the Congress should decide to extend indemnification along the lines of the Senate-passed bill, legislation could be drafted to mitigate our policy concerns. Our concern goes to the fundamental purpose of the Price-Anderson Act, and we do not believe it can be obviated by legislative drafting. However, if the Price-Anderson Act is to be used as a solution to liability insurance problems for a class of licensees, as provided in the Senate-passed bill, then we would likely need to request additional funds to implement the new program. We have not budgeted for the 6 to 8 additional FTE that would be needed. Consideration should also be given to whether the indemnity should be extended to individual practitioners to avoid a disparity in treatment between institutions and individuals (our figure of 7500 licensees includes individuals).

Finally, the Congress should recognize that the Commission cannot exercise any regulatory oversight over individual Agreement State licensees. While we expect Agreement States to perform their regulatory functions diligently, it is nevertheless still possible under the Senate-passed bill for the Commission to be required to indemnify a licensee for damages arising out of a regulatory violation where the Commission itself did not issue the license. Such a requirement would not be helpful to the Agreement State program. We can appreciate why Agreement State indemnity coverages may be thought to be desirable to avoid a de facto economic penalty on Agreement State licensees, and we do not recommend that Agreement State licensees be excluded from coverage. However, in view of the risks and uncertainties associated with this new kind of coverage, the Commission believes that section 170f. should be amended to authorize the Commission to charge other than a nominal fee for this Federal indemnity.

We hope that our comments will assist you in your review of the Senate bill extending the Price-Anderson Act. We would welcome the opportunity to meet with your staff to elaborate on our views or to discuss additional concerns that you may have.

Sincerely,

Lando W. Zech, Jr.
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cc: Rep. Manuel Lujan, Jr.

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88-05100060-12

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