UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of:)
)
PRICE-ANDERSON RULEMAKING)
)

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Place: Rockville, Maryland

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UNITED STATES NUCLEAR REGULATORY COMMISSION

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PRICE-ANDERSON RULEMAKING)
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Room 2F21
One White Flint North
Rockville Pike
Rockville, Maryland

Monday,
November 14, 1988

The above-entitled matter came on for hearing, pursuant to notice, at 9:10 a.m.

BEFORE: HONORABLE HOWARD S. BELLMAN
Mediator

APPEARANCES:

On behalf of the Nuclear Regulatory Commission:

STUART TREBY, ESQ.
FRANCIS CAMERON, ESQ.
Office of General Counsel
One White Flint North
Rockville Pike
Rockville, Maryland

Also Present:

IRA DINITZ, Office of Nuclear Reactor Regulation
JOHN TELFORD, Office of Research
NORMAN MCELROY, Office of NMSS
ERIC JAKEL, Office of General Counsel

On behalf of Hoffman-LaRoche:

ROBERT J. ROSS, ESQ.
1800 K Street, N.W. - Suite 600
Washington, D.C. 20006

APPEARANCES: (Continued)

Also Present:

ROY BROWN, Mallinckrodt
LINDA MCLEAN, Hoffman-LaRoche
BOB HARNEY, Hoffman-LaRoche
GASTON DE BARON, Hoffman-LaRoche

On behalf of National Association Nuclear Pharmacy:

ALVIN J. LORMAN, ESQ.
Baker & Hostetler
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036

On behalf of Syncor International Corporation:

WILLIAM KEMMEL, ESQ.
General Counsel
Syncor International Corporation

PROCEEDINGS

MR. BEILMAN: Let's bring the session to order. I am Howard Bellman, the convenor appointed by the Nuclear Regulatory Commission, pursuant to the requirements of Section 19 of the Price-Anderson Amendments Act of 1988. And this is the first session of the negotiated rulemaking procedures specified in the Federal Register of October 14, 1988.

I want to make some preliminary remarks about my intentions respecting procedure, although a great deal is already indicated in that Federal Register announcement, but before doing so, I would like to ask everyone here who intends to participate to state an appearance for the record. And we have also passed around, I believe, a sign-in document that will reflect everyone who is present here, whether they intend to participate or not. So, perhaps if we can just go around the table.

MR. TREBY: My name is Stuart A. Treby. I have been designated by the Commission to be the negotiator for the NRC Staff in this proceeding. My title doing my usual work at the Commission is Assistant General Counsel for Rulemaking and Fuel Cycle. In that capacity, I am the head of the division that is responsible for all of the rulemaking for the Commission.

With me, for the Nuclear Regulatory Commission is

Chip Cameron, who is also from the Office of General Counsel, Ira Dinitz who is from the Office of Nuclear Reactor Regulation, John Telford, who is from the Office of Research, Norman McElroy who is from our Office of NMSS and Eric Jakel who is also with the Office of General Counsel. The people I have just indicated constitute an internal team that is going to be involved in this negotiation.

MR. BELLMAN: Thank you.

MR. KEMMEL: My name is William Kemmel. I am General Counsel for Syncor International Corporation. We operate a system of nuclear pharmacies and we are a member of the National Association of Nuclear Pharmacies.

MR. LORMAN: My name is Alvin J. Lorman. I'm with the law firm of Baker and Hostetler and we represent the National Association of Nuclear Pharmacies.

MR. BELLMAN: Do I understand, Mr. Lorman, that you will be the chief spokesperson for the Pharmacies?

MR. LORMAN: That is correct. Well, for the pharmacies which are members of the national association, yes.

MR. BELLMAN: Thank you.

MR. TREBY: Could you clarify who those are?

MR. LORMAN: The National Association of Nuclear Pharmacies represents approximately 80 of the 125 nuclear pharmacies in the United States which are operated for

profit.

MR. ROSS: I am Robert J. Ross of the law firm of Ross & Smith and I represent Hoffman-LaRoche, duPont and Mallinckrodt. With me is Roy Brown, with Mallinckrodt, Linda McLean with Hoffman-LaRoche, Bob Harney with Hoffman-LaRoche and Gaston deBaron with Hoffman-LaRoche.

MR. BELLMAN: Thank you. Apparently there are no other appearances.

After the following, I will take any questions that my remarks may generate. As I am sure at least some of you know, the procedures specified and required by the Price-Anderson Amendments is not a typical negotiated rulemaking as contemplated by the Administrative Conference of the United States guidance documents that are actually cited in the amendments.

The Commission's Federal Register notice makes some reference to most of those discrepancies. And if you would like, we can discuss further how the remainder of this procedure will attempt to resolve those discrepancies further. It has seemed to me that a discourse on that point now might be gratuitous, but I want to make it clear that in the future, including this morning, if any of you want to discuss what I would refer to as reconciling the amendments to the Administrative Conference of the United States Guidelines, I'm happy to do that with you.

Perhaps the most difficult aspect of applying those guidelines to this matter has been the absence of any determination in advance of the number of participants. Under normal circumstances, the convener would survey the field of possible participants, make some judgments respecting which ones were required for our proper negotiations and recommend that they be invited or maybe even recommend that there are too many to conduct feasible negotiations or at least recommend how long the negotiations ought to take in order to allow for proper participation by the proper number of participants.

In this case, the amendments required the procedure eclipsing any question of feasibility and specified a time table making such a survey impracticable. On that basis, the Commission, after consulting with me and receiving my recommendations, simply invited all persons and entities belonging to a list of some 15 categories of interests potentially affected by this proceeding through its Federal Register notice and I believe reinforced that procedure by issuing some more specific invitations. And perhaps Mr. Treby will speak to that later.

In settling on that process, we contemplated the possibility of a very large number of requests to participate and on that worst case scenario basis selected many of the remaining specifications in the Federal Register

notice. For example, in order to insure that participation would be granted only to parties who were willing and able to participate substantially, the notice required that those who wished to participate file a notice of intent accompanied by a position statement specifying and addressing a number of material issues. In effect, a preliminary brief was required.

Also, the notice indicates that persons with similar interests are encouraged to consolidate and granted the convener the authority to require consolidation of participants.

And, finally, in this respect, the notice indicated that where a person did not wish to participate fully as a negotiating party, so to speak, or where the convener found that a request to so participate was insufficient, such persons would participate as members of the public. And I should say that it is my present intention to provide a formal opportunity at every session of these negotiations for the public to orally address the negotiators and that any member of the public may submit written statements for consideration by the negotiators throughout the proceeding.

This morning, although it certainly would appear that our fear of too great a number of participants has not materialized, I will rule upon the requests that have been

submitted, some of which are obvious from who is here and some of which are not, frankly.

Before doing that, however, I want to say that I am quite open-minded respecting modifying the procedures in view of the smaller number of participants and will be glad to hear everybody's suggestions about that. However, for the time being, I would not consider revising the calendar in the Federal Register notice. It may take us fewer days at each session. I'm not sure, however, I want to cancel whole sessions. At this point, I would be reluctant to do that.

On other matters, my current intentions are as follows. We will devote the first session, the session that starts today, to complete exposition of the parties' positions. In the current session, we will hear from each party, make sure everyone had received everyone else's preliminary documents and, if there is time, which seems very likely, ask one another some clarifying questions.

I had contemplated that the second multi-day session would allow for questioning of initial presentations and the presentation of rebuttal. I think that that should stand, but in view of the smaller numbers, I would also consider providing some time during that session for experts. Clearly, there may be some critical fact issues in this case. For example, respecting the availability of

insurance which may benefit from such presentations if we have time. And there may be some other such issues as well.

I do not want this to develop into a courtroom-like format, however. I would minimize question and answer processes, except perhaps in the examination of other party's witnesses. And even in that case, I would like to keep it as untrial like as I can appropriately.

I want to discuss this with you off the record, particularly after we have formally specified who the negotiators are. Perhaps as in a pure example of regulatory negotiations, we can even agree on some ground rules at the outset now that we see how few of us there are.

Speaking of off the record, I should say that I only intend to have a transcript made during the first two multi-day sessions so that we have that advantage in studying one another's statements. The subsequent sessions, which I've thought of as negotiation sessions, will be untranscribed. I understand that we all should be able to obtain transcripts within approximately two days of the session. I believe you are able to purchase copies of the transcript from the reporter. And let me say that if any of you want to make off-the-record statements, I would appreciate it if you would address that request to me and not to the reporter.

I also want to address the matter of ex parte

communication. Given my hybrid role as mediator and sort of arbitrator, up to a point, and the policymaking or legislative-like role of this proceeding, I believe that ex parte communications are appropriate, just as they always are between negotiators and a mediator or between a policymaker and an interested party. I would emphasize very strongly, however, that to the extent that I have to decide issues upon which the negotiators can't agree, I will do my very best to base my decisions on the record that you make together and not on ex parte communication. So, testimony and documents will be highly valued and assertions that can be documented, including assertions regarding congressional intent, should be documented.

As you know very well, the amendment requires an answer to the preliminary question: Should the Commission enter indemnity agreements with radiopharmaceutical licensees?

It is my present judgment that in order to make a more informed decision and in order to be as consistent with the normal regulatory negotiation format as is practicable, I should defer my answer to that threshold question until after our sessions.

I may likewise defer on some, if not all, of the scope issues raised, particularly in the preliminary document of the Commission.

It should be clearly understood that this deferral does not reflect a decision in favor of indemnification or any particular breadth of inclusion. I would think of it as tantamount to the conventional arbitration procedure of deferring decisions on arbitrability even where they are jurisdictional until the entire case has been heard. There are very similar court methods for accepting jurisdictional contentions without bifurcating proceedings.

So, following our first multi-day sessions, we will move to negotiation sessions where we will attempt to negotiate a rule even if one or more participants contends that there should be no rule.

I should tell you that I hope that we will be negotiating from a single text. That is from a proposed rule that one or more of you submits.

Let me ask on the record now if there are any questions so far about what I have said that you would like to put on the record?

(No response.)

MR. BELLMAN: I am going to go off the record for some informal discussion about participant status and other matters. I want you to understand that if you feel as though something that is being said off the record ought to be on the record, that we'll go back on at your request. It isn't my intention by going on and off the record to obscure

certain things. It is just to reinforce informality which I think ought to be bound in this matter.

So, unless there is something further that someone else wants to say on the record, let's go off the record.

(Discussion was held off the record.)

MR. BELLMAN: Shall we go back on the record?

I have a number of things to say for the record before we go ahead to the oral presentations. First of all, I would put on the record that the negotiating parties will be the Commission, the manufacturers as represented by Mr. Ross, and the pharmacies as represented by Mr. Lorman. So, we have three negotiating parties.

Another matter that we discussed were the particular efforts that the Commission made to insure that all appropriate parties were advised of this proceeding and maybe, Mr. Treby, you want to make a statement about your efforts to invite everyone?

MR. TREBY: Thank you.

Yes, the Staff besides publishing a notice in the Federal Register also took the Federal Register notice and mailed it to all of its licensees within the NRC so that they would receive a copy of it as opposed to having to read it in the Federal Register.

We also expanded the list of people that we would normally send such a notice to by including all -- including

representatives of the insurance industry to the extent that we could identify different ones, although I don't want to represent that we sent copies to every insurance company in the country.

Also, since many radiopharmaceuticals in other categories on the list in the Federal Register are licensed by states under the Agreement State Program between the NRC and the states, we insured that the representative of each of the agreement states received a copy of the notice so that they would be aware of it.

We also attempted to identify potential interested other federal agencies and sent them copies of it. And I guess we were somewhat successful since we do have an observer from another federal agency here today.

We also issued a press release. So, this is a summary of the various efforts that the Commission Staff undertook to insure the widest possible dissemination of its Federal Register notice.

MR. BELLMAN: Thanks. I understand that Mr. Cameron just had a discussion or a telephone conversation with American Osteopathic College of Radiology which had filed a letter. Can you report on that?

MR. CAMERON: Yes. I just talked to Pamela Smith who is the executive director of the American Osteopathic College of Radiography or Radiology, rather. And they were

mainly concerned with participating because they thought one of the issues was going to be the indemnification of physicians for malpractice or mis-administrations. I informed her that that was not one of the issues that would be on the table unless they wanted to put it on the table. They are against such indemnification. And she informed me that they would withdraw their request to participate. And I committed to informing her if there was any change at all on that issue that we would get back in touch with them and ask them to come in and participate. I don't anticipate that there will be any change, but they are satisfied with withdrawing their request for participating, although they may come as an observer.

MR. BELLMAN: Okay, thanks.

I would indicate for the record that while we were off the record, the parties agreed that there will be an opportunity for expert testimony at the December 5th meeting and that the advanced text of that testimony will be circulated here in Washington among them on November 30th. It is also understood that there may be some unanticipatible rebuttal offered during those sessions, depending on what the testimony provides, of course.

I would like to say for the record that I will ask for public input, if anyone wishes, at the end of this session whenever that turns out to be today. And, finally,

that we have agreed that we are now going to go ahead with oral presentation and that the presentation will be in the order of manufacturers, pharmacies, and the Commission, and between the presentations, there may be some questions based on the presentations. So, that is where we are as of the moment.

So, Mr. Ross, if you will?

MR. ROSS: Yes. I am Robert Ross and I represent the manufacturers of radioisotopes and radiopharmaceuticals, specifically, Hoffman-LaRoche and its subsidiaries, Mallinckrodt and E.I. duPont et de Nemours And Co., Inc.

We have filed our document in this case and I think it sets forth our positions on these matter, but let me run through them briefly.

First off, our interest is as manufacturers, of course, we would be if a rule were developed directing NRC to enter into indemnity contracts with radiopharmaceutical licensees, we would be the prime people who supply those radiopharmaceuticals and who stand at risk in the case of a potential law suit for releases from my clients' plants which manufacture radiopharmaceuticals.

I think in order to make a more complete record, at this time, I am going to ask Roy Brown from Mallinckrodt to describe a little bit what it is the manufacturing process for radioisotopes and radiopharmaceuticals is all

about.

MR. BROWN: My name is Roy Brown. I am manager of Regulatory Compliance at Mallinckrodt. The radiopharmaceutical manufacturers produce a couple of different types of products. First of all, they produce products that are used for diagnostic imaging. And, second of all, the manufacturers produce therapeutic products for treatment of various disorders.

The manufacturers ship these products both directly to hospitals and to nuclear pharmacies. The medical community uses these radiopharmaceuticals and medical radioisotopes both on a national basis and on a worldwide basis. It has been estimated that in the U.S., alone, there are 100 million nuclear medicine procedures each year.

The three manufacturers represented in this group comprise more than 90 percent of the radiopharmaceutical manufacturing market. Two more manufactures, a total of five manufactures, represent more than 99 percent of the market. So, this group of manufacturers is well represented. It represents the bulk of the manufacturing.

The manufacturers use both by-product materials and NARM materials. Several of the facilities have one or more cyclotrons on site to produce some of these machine produced or NARM products. NARM products meaning, N-A-R-M,

naturally occurring to the accelerated produced radioactive materials.

Due to the nature of the radiopharmaceuticals, many of the radiopharmaceuticals have a very short half-life, half-lives on the order of several hours. As a result of this, several of the manufacturing facilities are located in large urban areas. One need here is with the short half-life materials, you manufacture and ship the material one day and it has to be delivered to the hospital for use the following morning. This necessitates the manufacturing plants to be located in large urban areas close to major airports. Consequently, many of these plants are located in high population density areas.

Our manufacturing plants are highly regulated by NRC, EPA, FDA, DOT, DEA in some cases. We all have extensive environmental protection policies. We all have large professional staffs to do environmental sampling, environmental protection. The radiopharmaceutical industry does have a flawless safety record, operating for many, many year.

In summary, we just feel that the products we manufacture, the medical radioisotopes and the radiopharmaceuticals do represent an important nitch in diagnostic medicine and are used in the medical community, many lifesaving procedures worldwide.

MR. ROSS: As Mr. Brown has indicated, the risk to the public health and safety from the operations of these plants is extremely low. And, in fact, there has been an exemplary safety record established by the radiopharmaceutical manufacturing industry. However, that does not preclude such cases as Bennett v. Mallinckrodt arising when the public believes that it has been injured. This, we feel, is an indication of some of the future problems that we could face and, therefore, we would favor development of a rule directing NRC to enter into indemnity contracts with the radiopharmaceutical licensees and this is occasioned primarily because we are unable to obtain insurance in some cases or adequate insurance in others as reflected by insurance brokers that we have contacted and gone to.

I would hope by December 5th to have the testimony detailing that issue particularly in the hands of all the parties here.

I think there is another issue that we have a position on, also, and that is that if these indemnification agreements are entered into, we think they should include facilities in agreement states. We believe that congressional intent to that effect is fairly clear. And I would say that that finishes a brief synopsis of our position in this case.

MR. BELLMAN: Are there questions?

MR. TREBY: I have a few, if I may just for the purposes of the record.

MR. BELLMAN: Sure.

MR. TREBY: I wonder if you could explain to us what the difference is between a radiopharmaceutical and a radioisotope or whether there is a difference. I mean you indicated that you manufactured both of them. And I'm not quite sure I understand the difference.

MR. BROWN: Radioisotopes are various chemical agents tagged with the radio nuclide. For example, some compounds using C14 for labeling or tritium. Those are mostly used in medical research, both in hospital research and university research. Where radiopharmaceuticals are products that are licensed by FDA for use in humans either for diagnostic purposes or for therapy purposes.

MR. KEMMEL: Don't they cross over from time to time? In other words, something that was researched once winds up being --

MR. BROWN: Oh, absolutely. In some cases, the medical research that is being done using medical radioisotopes eventually will become a radiopharmaceutical or a radiopharmaceutical product.

MR. TREBY: But is the distinction the fact that a

radiopharmaceutical is licensed by the FDA for use in humans?

MR. BROWN: That's right. That's right. That's a distinction.

MR. TREBY: Also, you had indicated that there were five major manufacturers who made up approximately 99 percent I guess of the industry. Could you give us the rough percentages of what each one of them have? What percentage of the market just so we know, you know, whether there is one that is 80 percent or --

MR. BROWN: I can give you some numbers that we use. It's a difficult market to analyze because some of these products go directly to hospitals. Some of the products go to hospitals via nuclear pharmacies, but this is the breakdown that we use and this represents products going straight from the manufacturers to the hospital. These are all estimates. Mallinckrodt represents 40 percent of the RP market share. duPont 27 percent. Metaphysics or Hoffman-LaRoche 21 percent. Squibb 9 percent. Amersham 2 percent. And all others 1 percent.

Once again, these are radiopharmaceutical products going from the manufacturer directly to the hospital or what the market considers direct sales.

MR. TREBY: I know that duPont, for instance, is a very large corporation and all. I guess I don't know a

whole lot about Mallinckrodt. Could you tell us what other businesses Mallinckrodt has?

MR. BROWN: Mallinckrodt is a subsidiary of International Minerals & Chemicals out of Chicago. Mallinckrodt manufactures other chemical products, other pharmaceutical grade products and there is a division, a medical products group that manufactures these radiopharmaceuticals. The total, to give you a feel for dollar sales, we're looking at a direct market of somewhere around 225 million per year total market and a direct and non-direct market of around $400 million a year.

MR. TREBY: For radiopharmaceuticals?

MR. BROWN: For radiopharmaceuticals.

MR. TREBY: And radioisotopes.

MR. BROWN: Right.

MR. TREBY: In rough figures, what percentage of Mallinckrodt's business is radiopharmaceutical?

MR. BROWN: Roughly, it's 25 to 30 percent.

MR. TREBY: You indicated that the radiopharmaceuticals are manufactured I guess by two different means. One is to use by-product materials.

MR. BROWN: That's right.

MR. TREBY: And the second means is this -- the use of naturally occurring and accelerated produced radioactive materials, the so-called NARM materials.

MR. BROWN: Yes.

MR. TREBY: Do you have some sort of feel for the breakdown there, too? What percentage are from by-products and what percentage might be from NARM?

MR. BROWN: In terms of sales figures or curie throughput --

MR. ROSS: Use and manufacturing facility or sales or what?

MR. BROWN: We can certainly put some numbers together. There are several. In our written testimony there is an example of some by-product material products and some naturally occurring or accelerated produced materials. If you would like, we could go back and get a greater detail on either dollar figure breakdown or curie breakdown.

MR. TREBY: I think that might be helpful.

MR. CAMERON: I guess a critical question there that we wanted to clarify is whether you were asserting that the NARM material should be within the scope of the rulemaking.

MR. BELLMAN: Let me just put that directly. But before we do that, though, let me go off the record for just a moment.

(Discussion was held off the record.)

MR. BELLMAN: Back on the record.

I think there is a potential issue here or there

is an issue here about the coverage and whether it reaches these NARM materials and the by-product materials. The Commission's position seems to -- addresses that pretty directly in terms of your position on that. But let me just ask you about yours.

MR. ROSS: I would like to just have a small conference here, first.

MR. BELLMAN: Sure.

MR. TREBY: Well, let me just say something because I don't want to be indirect or to be viewed as trying to not put all my cards on the table.

One of the issues I think is the question of NARM. The Commission's jurisdiction is from the Atomic Energy Act and we do have jurisdiction to license by-product materials and the use of by-product materials. We are not -- we do not have any jurisdiction over NARM materials. Also, the Price-Anderson Act provides that we are to indemnify those things that are under our jurisdiction. And, so, the question comes up whether or not we would be able to even indemnify NARM manufactured materials. And that was why I was trying to get some sort of feel for the difference or the percentages of by-product materials and NARM materials.

MR. BELLMAN: All right. We'll go off the record so you can confer.

(Discussion was held off the record.)

MR. BELLMAN: We'll go back on the record.

MR. ROSS: We believe that even though there may be a gap in the Atomic Energy Act as far as NARM is concerned that we are going to try and make a case for its inclusion. We believe that the congressional intent was this way and, moreover, we feel that we're dealing here largely with matters of public perception. The public probably doesn't distinguish between NARM products and other radiopharmacies. And we feel that the overall public perception and public interest, as well as our own status in our facilities dictates that we will argue that NARM should be included.

MR. BELLMAN: Do you have any questions?

MR. LORMAN: No, but I'd like to answer --

MR. TREBY: I have some more questions.

MR. BELLMAN: I'm sorry. I asked you out of turn. Mr. Treby still has some more questions.

MR. TREBY: Right.

MR. BELLMAN: Go ahead.

MR. TREBY: The five major manufacturers that you listed, do they all hold licenses from the NRC or do they have licenses from the agreement states? Do you know?

MR. BROWN: Mallinckrodt has NRC license. duPont.

MR. ROSS: Metaphysics.

MS. MCLEAN: We have both NRC and state --

MR. TREBY: Just a second. We're getting too many people on the record here.

MR. ROSS: Yes. Metaphysics does hold an NRC and agreement state licenses. Squibb, NRC license. Amersham, I know holds an agreement state license. I don't know whether they hold an NRC license or not.

MR. TREBY: But it would be a fair statement to say that there is a mixture between NRC and agreement states.

MR. ROSS: Absolutely.

MR. TREBY: And even if Mallinckrodt has an NRC license, it also has an agreement license from one of our so-called agreement states as well.

MR. BROWN: Not in the manufacturing area, but in the radiopharmacy area, yes, we do.

MR. TREBY: And I assume that each of these or that some of these companies have facilities in more than one location and so that there would be a combination of NRC or agreement states depending on the location.

MR. BROWN: Possibly, yes.

MR. TREBY: I just have a couple of questions I guess dealing with insurance. One of the points that has been made is that insurance is not available. And just to clarify what your position is on that, I guess my first question is, Bob, do you know whether any of your clients

maintain insurance for this type of risk?

MR. ROSS: It has been my impression and my understanding after quite a bit of research into this area that they all have nuclear exclusions and that chronic releases are not covered by any of the three of my clients in their insurance policies.

MR. TREBY: All right. Well, just to clarify, when you say they have nuclear exclusions, they may have something called commercial general liability insurance, but that type of insurance has certain exclusions in it. Something called broad-form nuclear exclusions.

MR. ROSS: That is my understanding. And pollution.

MR. TREBY: And those -- is it your understanding that those exclusions cover by-product material?

MR. ROSS: Stuart, I'm going to have to -- I want to get back to you in more detail on that question.

MR. TREBY: Right. No, I understand that.

MR. ROSS: It is not an easy one just to say yes or no to. So, I'd like to be able to answer it, but it isn't that simple and I am going to have to go back to make sure that we have accurate statements on the record.

MR. TREBY: Well, let me just sort of indicate the kinds of questions or concerns I guess that the Staff has. And if you can answer them now, fine; and, if not, you know,

we are going to have another opportunity when you have your experts here.

MR. ROSS: We'll have several other opportunities, I think.

MR. TREBY: Right. You know, it is not my intent to cross-examine you.

MR. ROSS: Certainly.

MR. TREBY: But I guess one of the questions I would have is what type of insurance do your clients maintain for the risk from non-radioisotope pharmaceuticals? That is, you know, a company such as Squibb or Mallinckrodt must produce other types of pharmaceuticals and they must have some sort of insurance I would think for that kind of risk and what it is.

And whether these companies are self-insurers or not. With regard to that, I might say it is our belief that a lot of these very large companies, these multi-national large companies are self-insurers to some extent. And we wonder, you know, if we could have some more information or facts in that area.

On page 10 of your written statements, you had indicated that there was a concern about insurance coverage. And I guess we are wondering: Is your concern the coverage of risk from the chronic low level type of releases or is it to seek coverage from accidental releases or perhaps both?

You know, it is not clear to us what type of risk you're seeking indemnification from.

MR. PELLMAN: Let me -- I want to ask a question about that question. And that is are you making the distinction between behavior or emissions that occur that are in compliance and those that are not in compliance with regulation? You are asking him if he is seeking coverage for both of those categories in and out of compliance? Is that another way of putting it?

MR. TREBY: Well, I guess -- it appears to us there are perhaps three different types of situations.

MR. ROSS: Okay. I think this is very important to spell all of this out.

MR. TREBY: Right. One situation I guess is whether there is some sort of accident. And I'm not even sure whether that's a possibility or not, but we will assume for the purposes of our discussion here that there is the possibility of some sort of accident which results in releases which are far in excess of what PAR 20 says and you're seeking to get some sort of indemnification or protection against whatever claims might result from that.

Another situation for which you might be seeking protection is a release that is in excess of the Part 20 requirements, but it is not an accident in the sense of -- none of our accidents are the mushroom cloud type things,

but, you know, an accident that is unforese n or something. This is just some sort of release that exceeds Part 20 or our regulatory regime and you want some sort of protection from that.

And then the third category, which I guess is the situation that came up in the so-called Mallinckrodt case is where there are some low level releases, and by "low level", they are below what levels -- they are within the range that we say you can have such releases and it is impossible to have zero releases. And is that the type of --

MR. ROSS: We are seeking insurance for any release that is a potential liability to the plant where we cannot obtain commercial insurance or adequate insurance coverage. And I understand where you're coming from and we will answer for the industry in as much detail as we can in the next written testimony.

MR. BFLLMAN: All right. Let me just say -- and maybe we'll actually see this, but the same questions probably can be answered by the -- will have to be put to the pharmacies. From my perspective, in terms of meeting my responsibilities, I think it will be extremely valuable to me to be able to sort of crystallize the issues here and make sure that what is an issue is specified and what is not an issue is also specified as not an issue.

MR. ROSS: Right.

MR. TREBY: And no ships passing in the night here. I would think that that would be one of the ways of avoiding a terrible blunder on my part, which I presume we all want to do here.

MR. ROSS: I think this is a crucial issue for all of us. I mean this one probably is the most important one. The insurance coverage issue is the one that is going to drive the entire rulemaking, if there is one, or lead to the decision that there won't be one.

MR. BELLMAN: Okay. Other questions?

MR. TREBY: Yes. In your statement, you make reference to the fact that such cases as the Mallinckrodt case, are you aware of other cases besides Mallinckrodt? I ask that because we're not aware of other cases other than the one that the Pharmacies mention in their document dealing with --

MR. ROSS: I am aware of the cases that we mentioned and the cases that the Pharmacies mentioned and those are the only ones I'm aware of as well.

MR. TREBY: Well, one last question. I notice that Squibb and Amersham are not one of your clients.

MR. ROSS: Right.

MR. TREBY: Is that because they have insurance or they just didn't want to join in? Is there anything we should read into that fact?

MR. ROSS: No. For whatever reason, they didn't want to join in this particular effort. I can't second guess their motives. We certainly talked with them. And we have their support, but I have no idea why they didn't join.

MR. TREBY: Okay.

MR. BELLMAN: Do you have any questions?

MR. LORMAN: Several of your clients, Mr. Ross, also operate pharmacies as well as manufacturing facilities. I wonder if you would just identify the number of manufacturers that own pharmacies?

MR. ROSS: We don't have today the exact number of pharmacies connected with these people, but we can certainly tell you the names of the corporations that own them. We believe that it is Mallinckrodt, duPont and Medi-Physics which is a subsidiary of Hoffman-LaRoche that have the radio --

MR. BROWN: duPont does not operate pharmacies.

MR. ROSS: No pharmacies?

MR. BELLMAN: Let's go off the record.

(Discussion was held off the record.)

MR. BELLMAN: Back on the record.

MR. ROSS: Mallinckrodt and Medi-Physics, a subsidiary of Hoffman-LaRoche, do operate radiopharmacies. duPont does not. To our knowledge, Squibb does not and Amersham does not.

MR. LORMAN: Are you representing the pharmacies in this proceeding as well as the manufacturers?

MR. ROSS: I am representing the manufacturers primarily, and not the radiopharmacies except as the interest appears that benefits my client. And we certainly agree with the Pharmacies' position statement and in almost all regards. And we are certainly supportive of it.

MR. LORMAN: Will you supply us for the record either an estimate today or an actual number tomorrow or the next time we meet the number of pharmacies that are involved for Mallinckrodt?

MR. ROSS: Sure.

MR. LORMAN: Thank you. I have no further questions.

MR. BELLMAN: Why don't we go ahead with your presentation, then.

MR. LORMAN: For the record, my name is Alvin J. Lorman. I represent the National Association of Nuclear Pharmacies. I will not take a great deal of time to summarize my presentation, which I guess perhaps was the weightiest by weight, if nothing else, of the statements of positions that were submitted.

I find in reviewing the position papers of all the parties that in fact I think most of us agree on most of the issues, which I find encouraging. We agree with everyone

else in this room that the manufacturer and the compounding and pharmacies of radiopharmaceuticals is an extraordinarily safe procedure presenting virtually no risk to the public. We agree that the levels of radiation involved are extremely low.

Our concern, however, is that cases such as Bennett v. Mallinckrodt are a part of a public trend in the law toward environmental liability cases inventing types of liability which did not exist before, in many cases for which no insurance had existed because the liability was thought not to exist. And, frankly, it was a type of liability for which the nuclear pharmacies, themselves, did not have insurance. When that case became known to the nuclear pharmacy industry, inquiries were made of insurance carriers as to whether the CGL policies did indeed cover that kind of exposure and we are told that, in fact, the CGL policies that the nuclear pharmacies did hold did not cover it on two grounds. One was the general nuclear exclusion and the other was the new exclusions for environmental impairment. So, they get you one way or the other.

Nuclear pharmacies attempted to obtain or to ascertain the availability of insurance that would cover this kind of liability and as will appear later I guess in talking to some of the same people that the NRC Staff did, we were unable to determine that any such coverage was

available or available at a rate with coverage limits that would make it worthwhile having.

That remains the key issue to us. We believe it is a very important issue for two reasons. One, of course, business people feel very nervous about investing large sums of money in an operation which for at least one potentially very large area of exposure is uninsured.

The other thing is that we believe there is a public interest involved here. While we do not believe that this industry causes injury to the public, if at some point down the road we all turn out to be wrong, it would be comforting to know that there was some sort of fund to compensate the public. So, we believe it is more than just the commercial interests of the people at this table at stake here, but there is a public interest.

We believe that in passing the amendment in Section 19, that Congress determined that in fact if we demonstrate that insurance is not available, that the NRC should exercise its discretionary authority to, in fact, establish an indemnification program. Accordingly, we believe that the focus of this issue as it apparently is going to be is on the availability of insurance.

We also believe that Congress did -- and to answer the question that Mr. Treby will be asking later -- we also believe that Congress did determine that nuclear pharmacies

and other facilities as may be determined in the rule in agreement states would be covered as well. And that concludes my statement of position.

MR. BELLMAN: Let me ask you all whether there is disagreement among you as to the effect of the exclusions. I mean I realize there are differences among you as to the facts of the insurance market. And we're going to get some expertise here, I guess, on that point. But then you also recognize all of you that there are these exclusions in what is available, but are there differences among you as to what that means, how those -- what sort of those exposure those exclusions provide?

Maybe you could just describe why those exclusions from your perspective frustrate your need for coverage?

MR. LORMAN: We have a very simple answer. Our insurance carriers told us that the exclusions worked to prohibit any coverage for the kinds of incidents that we're talking about. So, whether -- we don't have any -- I don't have any independent expertise in the area of insurance, but our insurance carriers told our pharmacies that the nuclear exclusion works as a bar as well as the environmental impairment exclusion. So, we are knocked out of the ball park, at least according to our insurance companies, on both grounds.

MR. TREBY: I think there may be a difference. I

don't profess to be an expert in insurance, but in talking with members of the Staff who are more knowledgeable than I, they seem to think that there may be a distinction in these exclusions with regard to those people who operate nuclear facilities, such as a power plant that produces electricity and those who are using by-product materials or source materials to do something. And that the exclusions go to those who are operating nuclear facilities. Since a by-product -- use of a by-product material is not within this term of art, "nuclear facilities", then it appears that perhaps the exclusions don't apply.

However, I want to make sure I add my caveat that I'm not an expert on insurance. And it is an issue that I think needs to be resolved before this group.

MR. BELLMAN: It seems to me it almost as important as the whole notion of market, itself, because, clearly, insurance is available with the exclusion. So, we need to determine, it seems to me the importance of those exclusions.

Mr. Lorman, I take it your position is the same as the manufacturers, not only with regard to the coverage of agreement states, but also with regard to this NARM by-product dichotomy.

MR. LORMAN: I hate to do this, but I don't agree. My client agrees with the NRC with that. NARM material is

not covered, with the understanding that as long as the NRC is not at this point seeking to expand its jurisdiction to cover such material, we agree it is not covered under the present statute and, therefore, should not be covered under Price-Anderson as well.

MR. BELLMAN: And with regard to the issues that Mr. Treby indicated about accidents and compliance and noncompliance, could you address that, please?

MR. LORMAN: Yes. I can answer those questions quite simply. You gave us three scenarios: an accident, a release of excessive of Part 20 limits that was not an accident, and chronic complying releases. We believe that insurance on all three of those events should be provided.

MR. TREBY: Can you think of other scenarios to go with those three?

MR. LORMAN: No.

MR. BELLMAN: Do you have any other questions?

MR. TREBY: Yes. I have just a few, I guess.

You indicated that you were representing radiopharmaceuticals, about 80 of them, I guess.

MR. LORMAN: Yes.

MR. TREBY: As in the case of the manufacturers, do they hold both NRC licenses and agreement state licenses and some combinations?

MR. LORMAN: Yes.

MR. TREBY: Are these 80 different outlets, are some of them associated with each other in the sense that they may be outlets of one company?

MR. LORMAN: Yes. The largest number are part of an organization called Syncor, Inc., International which is the successor firm to a merger of two prior chains of nuclear pharmacies, Syncor and Nuclear Pharmacy, Inc., which merged some years ago. Syncor is the largest member and represents the bulk of those membership in the NANP.

MR. TREBY: Does Syncor, itself, have a license? Do each of the subsidiaries --

MR. LORMAN: The pharmacies are licensed in one of two ways. Some of them hold individual licenses, either the NRC or an agreement state. There are a group of Syncor pharmacies which in fact are covered by a master license from the NRC. So, there is one license that covers more than one pharmacy.

MR. TREBY: Do you know whether these companies have insurance of any sort at this time? I assume they must have some insurance for their non-radioactive program.

MR. LORMAN: My understanding is they have the CGL policies to cover their businesses, but that does not include the kind of coverage we are concerned about here.

MR. TREBY: Also, do you know whether any of these companies are self-insurers?

MR. LORMAN: My understanding is that none of them are.

MR. TREBY: Well, again, it is my view and I think it is probably the consensus around the table that the availability of insurance is the central issue. So, to the extent that you can give us any more information about things like self-insurance and whatever kinds of other insurance they have, I think that would be helpful.

MR. LORMAN: I guess you could call them self-insured if you call the absence of insurance, self-insurance. But by definition, no.

MR. ROSS: Perhaps I could get a Staff definition of what he means by self-insured because that's not -- well, may I have one?

MR. TREBY: Sure. My understanding of a self-insurer are companies who set aside some reserves to take care of contingencies such as self-insurers or else have some surety bond or letters of credit or some other financial means whereby in the event they're hit with a claim and then they have to pay some monies, there is a source to meet that obligation.

MR. BELLMAN: It is something much more affirmative than crossing your fingers.

MR. TREBY: Oh, yes. And it is much more than just saying, "Well, we have x-amount of money in our

treasury and, you know, if we have to pay, we have to pay."

It is some sort of separate fund that is set up for the purpose of meeting these kinds of obligations.

MR. LORMAN: We have no problem with your definition. The answer is still, no.

(Laughter.)

MR. ROSS: Stu, in your definition, would you say that self-insuring would mean that whatever this plan is you're describing has to be funded before there's a loss? Is that within the ambient of your definition?

MR. TREBY: I don't think that's critical to the definition. It could be either, either funded or not funded.

Well, I guess one other question that we would have although you may not be able to answer it now and that is to what extent your clients have looked into some sort of captive insurance type things. Some pools made up by the individual members who would provide some insurance or some of these companies that provide specialty type insurance.

MR. LORMAN: Reserving the right to have an expert speak to that in two weeks, our preliminary looks have determined that we're not a big enough industry to do that. There aren't enough people involved to spread the risk that it ultimately is not really called insurance. But we will bring in someone to address that issue.

MR. BELLMAN: Mr. Ross, do you have any questions of Mr. Lorman?

MR. LORMAN: No, I do not.

MR. BELLMAN: I guess we are ready for the Commission's presentation.

MR. TREBY: In the Commission's Federal Register it sets forth six issues and I intend to briefly address each of them. I have, on behalf of the Staff, submitted a written statement as have the other two speakers before me. And I assume that they will be made part of the record. Maybe as a part of the housekeeping process when we're finished, we can consider how we want to get that into the record, whether we have it attached to the transcript or just provided to you. Something like that. I don't intend to read my statement.

I have been designated by the Commission to serve as the Staff's negotiator in this proceeding and authorized to represent the Staff in this proceeding. The nature of the Commission's interest that may be affected by this rulemaking is that under Section 81 of the Atomic Energy Act of 1954 as amended, the Commission is authorized to issue licenses for the medical use of by-product material. And, as indicated in the Staff's written statement, the Commission has under license approximately 2800 licensees doing various things. Not all of those are

radiopharmaceuticals. There is a variety of things that we set forth in our statements.

Under Section 170(a) of the Atomic Energy Act, the Commission has the discretion to require financial protection of and to extend an indemnity coverage for these activities licensed by the Commission. And I would note that the Commission has been requested to exercise this discretionary authority in the past for the licensees who are before us today and has not chosen to do so. And, in fact, has only exercised its discretionary authority to require financial protection of and extend indemnity coverage to certain persons licensed to possess or use plutonium in plutonium processing and fuel fabrication activities.

Of course, the 170(a) makes it mandatory that we extend indemnification to the construction and operation of power reactors and research reactors.

With regard to the nature and the extent to the risk to the public health and safety posed by the activity of concern, I think I agree -- or I know I agree with Al when he stated that all of the participants here are in agreement that the activities of concern pose low risk to the public health and safety. For the Staff's part, based on considerations of potential risks and consequences due to the amount of by-product material in the inventories which

are listed on Table 1 of the Staff's written position. The half-lives of the radioisotopes, the frequency and methods and use of these radioisotopes and the low likelihood of an accident based on historical experience at radiopharmaceutical licensee facilities, the Staff believes that there is adequate safety with respect to these activities.

I might say if we didn't think so, we wouldn't have issued the licenses. But I think that is one thing that we probably have agreement on that there is very low risk to the public health and safety.

Whether financial protection for such risk is available to licensees from commercial sources, this is the central question and the one where there appears to be the greatest disagreement amongst the participants.

As the staff indicated in its written statement, it believes financial protection is available from the commercial sources. I provided a little earlier this morning a list of telephone conversations that Mr. Dinitz had had with various insurance representatives to verify the Staff's belief which it has held for some time that the possibility of commercial insurance exists. And the list indicates a number of telephone conversations that he had with different representatives. These representatives included the largest excess and surplus insurer in the

United States or one of the larger casualty property insurers in the U.S. writing medical professional liability policies, the large casualty -- one of the largest casualty companies, et cetera. And I intend to provide a copy of this listing with the written statement and I don't need to read through it all here. But in summary, it seems to indicate that a lot of these companies indicated that they had never previously been asked to provide this coverage, but if asked, they would consider writing the coverage. Now, that's not an ironclad agreement that they would provide it, but, apparently, they would certainly consider it and they appear willing to evaluate the possibility of providing that coverage.

With regard to what our position is, I guess our position can be summarized as stating that, first of all, we believe that there is a low risk to public health and safety from the pharmaceutical licensee's activities and, furthermore, in the unlikely event that an event does occur, the potential liability for offsite damages resulting from such an event would be within the insurance coverage that the Staff believes is available.

The Staff also would note that one of the primary objectives of the Price-Anderson Act was to remove the deterrents of the private sector participation in atomic energy activities presented by the threat of potentially

enormous high liability claims in the event of a catastrophic nuclear accident. And that was one of the principal incentives for the initial Price-Anderson Act back in 1954.

We believe that this objective retains its validity for application to the issue of whether radiopharmaceutical licensees should be indemnified. And, therefore, we believe that in addition to demonstrating that commercial insurance is unavailable, the Staff believes that those supporting indemnification must also demonstrate that indemnification is necessary to maintain participation in the radiopharmaceutical industry in order to insure that the public will not be deprived of radiopharmaceuticals.

We would note that we're not aware of any instance where a radiopharmaceutical licensee has ceased operation because of the threat of uninsured liability. And this is an industry that has existed for 30 to 40 years so far.

The last area that I would like to address is other facts pertinent to the indemnification issue. And under this category, I'd like to raise this issue of the coverage of agreement states. As I stated earlier in my presentation, the NRC in the various categories that we enumerated in our written statement cover about 2,800 licensees. We understand that the 29 agreement states cover approximately 5,000. So, there are many more licensees

covered by agreement states than covered by the NRC. The question is whether or not the NRC has the authority under Section 170 of the Act to require financial protection and indemnification of radiopharmaceuticals from an agreement state.

We believe that the record on this issue is ambiguous. The amendments act does not provide any explicit authorization for the Commission to indemnify agreement state licensees. And, as I said, a reading of the current language of the Atomic Energy Act would indicate that we can only -- that is the Commission can only cover its own licensees. We do recognize, however, that there was some language in Section 19 of the 1988 Act amendments that extended Price-Anderson and contained Section 19 which indicated that this negotiated rulemaking should cover both persons licensed by the Commission and by the agreement state. Frankly, we're not quite sure what that means, whether Congress was implying that we should have the jurisdiction to extend it to agreement states or whether after we conducted this rulemaking activity we would then go back through Congress with the results of our activity and say, "Yes, there ought to be indemnification. And in order for us to extend to agreement states, you need to give us some additional jurisdiction."

We believe that this ambiguity needs to be

resolved in some way in the course of this proceeding. It should be one of the issues on the table here and one that the negotiating committee should address.

We suggest in our written statement that perhaps we could defer addressing that until after we had reached some sort of position as to whether or not indemnification should be provided because if the answer is indemnification should not be provided, then it's somewhat of a moot point. And I guess I don't need to say anything further on that issue. I have already discussed the NRC's staff position with regard to NARM and I don't think I need to elaborate any further on the position covered in our written statement.

With regard to the scope of the licensees to be covered, as we said in our written statement, we thought that it should be somewhat limited from the very broad coverage that we initially stated in the Federal Register notice. The purpose of the Federal Register notice was to give the widest possible dissemination of notice to potential participants in this proceeding. And because we listed various categories, that did not necessarily mean that the Staff agreed that all of those would fall within Section 19.

As I believe I stated earlier, we thought that there should be two tests, initially, as to the scope of

licensees covered, first, to look to Section 19 and, secondly, who sought to participate here. Certainly, the Staff does not disagree that the -- who are the parties to this proceeding at the moment: the manufacturers and the radiopharmaceuticals would fall within the scope of Section 19. And they certainly have sought to participate here. And we would think that they are within the scope of whoever should be included in any rulemaking that would take place. So, I guess our position would be or our position would be that at this time, they are the only categories that we would see being covered by any rulemaking that might result from this proceeding.

In the event that we get to the point that we think there should be some rulemaking and some indemnification, we would like to identify a couple of other matters that we believe need to be covered in such negotiations. First amongst these would be the amount of coverage and financial protection to be provided. Section 170(c) of the Act requires that the Commission must provide indemnity coverage in the amount of $500 million. Given the very slight risk that we have identified from these categories of licensees and the very small half-lifes, et cetera, we raise the question whether even if indemnification is found to be appropriate, whether it should be in that amount or some other amount. That seems

to be a very large amount of money and perhaps some lesser amount might be appropriate. In any regard, that is an issue that we think needs to be discussed amongst us.

Secondly, pursuant to Section 170(b) of the Act, the Commission may require that those licensees who are indemnified have and maintain some amount of financial protection of the type specified in Section 170(b) of the Act as a first step. That is with regard to power reactors, for instance. I believe there is a requirement that they have to provide a certain amount of insurance first before they indemnification thereto.

The issue is, again, if we were to provide in this rulemaking for some indemnification, should there be a similar type provision with regard to these licensees.

Finally, a subject that appears to be very close to the heart of Congress and I guess therefore must be close to the Commission's heart is the question of fees with regard to all people to whom an indemnification agreement would be executed. And we would like to put that subject on the table, also.

These were the items that we identified in our initial consideration of the problem of some things that should be considered when we meet in the negotiation phases of this proceeding. And we wanted to alert the other participants of our thinking. And that concludes our oral

statement.

MR. BELLMAN: Let me say with respect to the last three items Mr. Treby just specified, how much insurance should the insured maintain on its own, the amount of coverage that the law might provide and the fees that -- I would hope that each of you would have a specific position on those three issues.

With regard to the matter of the lack of evidence that companies are withdrawing from the market because of their exposure, the point you made of people being in this business for decades and nobody seems to have left, what sort of demonstration are you talking about? What sort of evidence are you talking about? I know what an absence of evidence is, but I don't know what you might see as affirmative evidence.

MR. TREBY: I guess the type of affirmative evidence that we would be looking for is some -- I don't want to create a self-fulfilling prophecy, but, you know, some statement by either the manufacturers or the radiopharmaceuticals that due to the lack of some sort of protection this is going to be the factor that determines that they're going to go out of business, that this is such an important matter that this determines whether they remain in business or not.

When one reads the congressional record and reads

some of the statements, at least on the Senate side, it appeared that some of the Senators seemed to be concerned with the concept that the radiopharmaceuticals industry and the manufacture of those radiopharmaceuticals was a very important public service. And that is something that the Staff agrees with. We think that radiopharmaceuticals are very important and very worthwhile to the public health and safety. And they seemed to be concerned that this industry was going to disappear unless it got some sort of protection.

Our concern is that this is an industry that has existed for a long time without that protection. And we frankly don't know where this concern comes from that the people involved in the industry are going to go out of business. I guess the type of evidence would be some sort of indication of that.

MR. BELLMAN: Well, I just want to say that although it seems to me that what you're raising is relevant and material and all that, it calls forth a sort of rhetoric that can only be grounded sort of in the hearts of the stockholders or something. And I don't know exactly. I mean it's a perfectly plausible issue, but it is a difficult matter of proof here.

MR. LORMAN: Would Mr. Treby be persuaded by sort of evidence by analogy, such as what's happened in the

vaccine industry in the United States where DPT manufacturers one by one fell off the boards because of product liability concerns until there literally was a risk of no one in this country being willing to make a DPT vaccine or the evidence that until Congress passed the Swine Flu vaccination scheme, no one would manufacture Swine Flu vaccine in this country. Is that probative evidence to you? Or do we have to get up and say, "We're going to go out of business."

MR. TREBY: Well, that's why I said I am concerned about the statement saying, "I'm going to go out of business." It is easy to say that and I'm not sure how probative that is, but maybe some information by analogy would be helpful to show the extent of the concern. I think as a representative of the Commission, I sort of have two hats. One hat is as an advocate of the Staff's position, but the other hat I wear is a person who is responsible and concerned with how we go about rulemaking and how we can protect our rulemaking if we are ever challenged in court. I am concerned about developing records, too. And I would like there to be some sort of record developed that, you know, there was a need for the particular rulemaking and it fell within the ambient of what of Congress said Price-Anderson was all about.

MR. LORMAN: I guess our response would be we will

certainly attempt to satisfy your curiosity in that regard, but our legal position is that Congress satisfied your curiosity for you by directing this proceeding. We agree with you: Let Congress determine that this is an important industry whose future is important to the American public and that in directing this proceeding, Congress made the judgment that the issue is insurance, not whether we are going to go bankrupt without it.

MR. TREBY: Well, perhaps that's another issue that needs to be considered at our table, too. I have read the various congressional statements and all, and, certainly, there are many statements on the Senate side that indicate just what you have indicated. However, there are a number of statements, particularly on the House side, that indicate that Congress may not have reached a final conclusion on this matter but may view this rulemaking activity as a direction to the Commission that it engage in rulemaking and that it did not preordain what the result would be and that it was nothing more than an urging that we undertake this stuff since Congress, itself, was unable to resolve the matter when it was before them.

MR. BELLMAN: Let me just say on my own behalf that I think it is uncontroversial that fundamental questions were not disposed of by the Congress because if they were, we wouldn't be here. I mean they disposed in

many ways of this issue by shunting it to this process, not the normal course of events. I mean it is unprecedented to my knowledge, this what we are going through here. That doesn't mean that they didn't express some very strong opinions about other things or that some of them didn't express strong opinions.

Now, I think that in addition to recognizing what they didn't dispose of, I agree with anyone who wants to be sensitive to whatever broad opinions did seem to be evident in their debates, in their discussions and consistent with something that I think Mr. Treby just said. I presume that we want the outcome of this process to float. That is to say we don't -- not only do we want to do the right thing here, not only do we want to do what we are requested to do, but we also want to do something that will be sustained. Whether it is a matter, as he suggested, of making an appropriate record to withstand challenge subsequently, or whether it is a matter of doing that which political leadership in the best sense of those words will accept. I think we want to do all of that, and I certainly do.

MR. LORMAN: We don't disagree with you at all. Solely on this issue of whether or not the industry goes under without insurance, I think that is our disagreement. I don't think that's an issue. Did Congress consider it? I don't think it's an issue, frankly, that is really

appropriately before this group for negotiation. Prudent business practice dictate that businessmen either have insurance or an alternative to insurance. That people don't sit around saying, "Shall we go out of business if we don't," most of the time. You do in extraordinary circumstances, such as in the vaccine areas. Granted, we don't sit here with as much horsepower behind us without a $20 million judgment against someone sitting in this room as we would in the vaccine area. But once we have had that judgment, it is sort of closing the barn door after the horse has escaped. Our position is prudent people have insurance, otherwise, they don't do business. Just as no one here, I suspect, has no insurance on their automobile. And we don't sit and engage in lengthy discussions about the wisdom of not having insurance on your automobile.

MR. SCHWARTZ: Let me just get back to some other points. You were asking the other parties about these three scenarios of yours. And I want that you address them yourself regarding your own position on that, on those.

MR. TREBY: I guess the first point is that our current position, subject to overwhelming -- well, not overwhelming, but evidence to the contrary is that they can get insurance that cover all three possible scenarios. However, as to whether indemnification should cover all three scenarios, I guess I'd like to think about that.

Certainly, it should cover the accident one and the releases above Part 20. I think I would like to defer until the next time as to whether or not it should cover the releases that are within regulatory guidelines.

MR. BELLMAN: With regard to your position on scope which it seemed to me there were three elements, the by-product, NARM, dichotomy, the federal versus state licensees dichotomy and also the matter of only the participants here. With regard to the -- I understand, although I'm not sure what sure to do next with regard to this notion of ambiguity. I know what you mean by ambiguity there with regard to the federal-state licensees. With regard to the by-product NARM element, is your position a position of policy or a position of legal strictures.

In other words, are you saying it would somehow bias the law to go beyond your position?

MR. TREBY: Yes, it's a legal stricture. We just don't have the authority under the Atomic Act to cover --

MR. BELLMAN: So that if my recommendation, for example, or our consensus did that, it would be an illegal, it wouldn't be a proper rule.

MR. TREBY: At least with regard to NARM. To be very candid, the subject of whether or not the Commission should take jurisdiction over NARM comes up from time to time and the Commission was briefed a month or two ago on

that very subject. And, you know, I can't predict if the condition at some point is going to take jurisdiction over NARM materials. The issue comes up from time to time, particularly with regard to disposal because some of these materials are in our low level burial sites. But at the present time, we don't have jurisdiction over it and it would be illegal to extend Price-Anderson to it.

MR. ROSS: When I indicated you were going to make arguments with regard to NARM, I believe I started by agreeing that in fact there is that hole in the law and that NARM is not presently covered.

On the other hand, we want to certainly be inclusive and if, in fact, we get to a point where some indemnification results from this, we want to have raised it on the record and in our documentation in case the Commission does take it up in the future.

MR. BELLMAN: I just think that for purposes of consensus building and the kind of objectives that I would like to have here, it is important for all of us to know when positions are known on discretion and policy judgment as opposed to readings of the law because presumably none of us is interested in reaching an agreement that is not legal.

MR. LORMAN: I would like to ask, Stuart, when you say the Commission has been briefed on whether to take jurisdiction over NARM, do you believe that the Commission

has the statutory authority to do so or would the statute need to be amended --

MR. TREBY: The statute would need to be amended. But I think the Commission pursues legislative agendas, too, and this is something that the Commissioners appear to be interested in. We have had subject as to whether or not that is something they ought to go back to Congress and ask about. In particular, the agreement states, some of which do regulate NARM are always pressing the Commission to do something in this area.

MR. BELLMAN: But that needs to be sorted out. I mean we're not here to develop a legislative agenda.

MR. TREBY: That's right.

MR. BELLMAN: I mean we can give some gratuitous advice here.

MR. TREBY: I didn't mean to muddy the waters. I just wanted to provide full disclosure that while it is my view that it is clearly not something that the Commission can do now.

MR. LORMAN: I would just like to clarify our position, then, in response. We agree with you that the Commission does not have legal authority to regulate NARM at this point, but we also agree with Mr. Ross that should the Commission assert authority over it one way or another, then we would like it covered as well.

MR. ROSS: We certainly wouldn't want to go back through this just for NARM in case it came up. So, there must be some way we can allow for that contingency in the future.

MR. BELLMAN: Well, give that some thought because it's not immediately apparent to me anyway. Do you have any other questions or any questions?

MR. LORMAN: I don't. Well, I guess I do. Perhaps this is an improper question, but since, without divulging it today, the name of one of the insurance companies on here is the name of the very insurance company that we have been unable to extract the policy, quote, from for some time. I am wondering whether in connection with our next session, you are planning to bring in people that we can ask about these things or is this basically the kind of evidence we're going to see, because, quite frankly, I don't know how to cross-examine this when it's the same company that won't give us a quote.

MR. TREBY: Well, I guess I have two answers. I think, first of all, with regard to the apparent different views, I think it may be a matter of talking, one of us talking to some sort of headquarters group in a different location and another one talking to a regional office or something like that. I think we just spoke to different offices. I am not prepared to resolve the difference here

now.

With regard to whether we're going to bring in people, well, we're working towards the best we can do. We've been seeking to interest the insurance industry to tell us what their views are one way or the other. And we may look at getting an expert. It depends on what we can do.

MR. BELLMAN: Without being too lawyer-like, as I say, I suffer a lapse once in a while and I think that we all appreciate the value of being able to cross-examine and we all appreciate the lack of value in hearsay. So, I mean if we're going to have competing evidence, some of it may be more persuasive than other evidence because it is direct and subject to cross-examination. I don't know what else to say about that. We're going to get together for as many days, really, as I'm sure it's going to take. And you all have your own ways of putting these presentations on. I think in many ways, the value of this document that shows the efforts so far by the Commission or some of their efforts is to forewarn the rest of you about the basis for their position.

Do you have any questions?

MR. ROSS: Yes, I do.

Stuart, on this list of telephone conversations with insurance representatives, I know that most of it says, "... would consider writing such coverage." Frankly, that

doesn't help me a great deal. Almost any insurance company that you call probably would consider writing some coverage. Did your people or you, if you made the calls, get any more specifics out of these people, such as: Are these claims made policies, occurrence policies? Were there limits that you considered? Were any of the premiums brought up? Was deductibility part of what you asked them? Is there a need for engineering studies prior to these companies considering issuing a policy? Questions of that nature. Were any of those asked? Do we have the answers to any?

MR. TREBY: These telephone conversations were conducted by Ira Dinitz who, as I earlier indicated, is our expert in NRR who deals with Price-Anderson issues all the time. Perhaps the most efficient way to answer your question would be to have Ira provide the answer to you. So, I would ask Ira to respond.

MR. BELLMAN: Okay. He can do that. Does anybody have any objection?

MR. ROSS: No.

MR. BELLMAN: That's fine. Okay.

MR. DINITZ: I think our initial thought was that we wanted to see from the industry as to whether or not they had ever been approached by the radiopharmaceutical manufacturers or radiopharmacies directly.

It's funny, because I normally read Business

Insurance and I see ads from various insurance companies and one ad that caught me a little by surprise was an ad by the Home Insurance Company that said, "We are willing to write radiopharmaceutical -- I'm sorry -- pharmaceutical companies and other high risk," I can't recall the other high-risk type, "or all other product liability companies. Give us a call." Which is what I did.

And one of my first contacts was with the Home Insurance Company and they are a very large writer of casualty and property insurance policies within the country. And I asked them have they ever been approached by the radiopharmaceutical manufacturers or radiopharmacies to write or to consider writing insurance. And he said, "No."

And I said, "Well, I will take you at your word in your advertisement that you would be interested in at least considering it." And, of course, I should preface this by saying, no one told me or could tell me over the phone that they are willing to write any type of insurance. They have to make a determination or underwriters have to make a determination as to the nature of the risk, the coverage in the policy, the deductibles in the policy. These are underwriting decisions that no one could give to you over the phone.

Our basic need, however, was to find out just what kind of canvasing of the market -- we wanted to determine

what kind of canvasing of the market that the radiopharmaceutical manufacturers or radiopharmacies accomplished.

I also called one of my initial contacts, as you see on there, was with the Lexington Insurance Company. In a number of my conversations and, of course, I converse very, very regularly with American Nuclear Insurers, the larger of the two pools writing nuclear liability insurance. From early on, they had indicated to us that they do not write this type of insurance for radiopharmacies or radiopharmaceuticals because of the ability, they have indicated to us and as well have indicated to the Congress numerous times, that this insurance they believed and certainly indicated to me was available in the conventional market. Therefore, we thought it was incumbent upon us to just do an initial canvasing of the market to see if that, in fact, was correct.

One of the companies I did contact early on was the Lexington Insurance Company, the largest of the excess and specialty insurance markets. The indications from Lexington were that this is an area that they would be interested in looking at. They had never been approached by any of the participants to consider writing this type of coverage, but they were in the business to write this type of coverage and they certainly would welcome inquiries from

the radiopharmaceutical industry on this issue.

As I got into more of the telephone conversations, that seemed to be a pattern that developed and a number of the companies that I contacted indicated that they had not been approached to write this type of coverage, but the conventional insurance market was the area that the coverage should be written in. And there was agreement that it should not be written with American Nuclear Insurers, but the CGL policy, the Commercial General Liability policy that was being written for across the board for thousands and thousands of companies would be the policy that should be written for radiopharmaceuticals and all of the companies that I contacted indicated that they would be willing, at least, to consider whether or not to write this type of coverage, given the fact that they couldn't make any other commitment to me over the phone until they actually had specifics on what we were talking about.

MR. ROSS: And you didn't give them a hypothetical client or anything like that and say, "Could you just kind of run this through your system?" Or would they even do that for you?

MR. DINITZ: They wouldn't even do that. I think we all know insurance companies --

MR. LORMAN: They don't do it when you submit it.

MR. BELLMAN: One at a time because the reporter

is going to have difficulty.

MR. DINITZ: You're right. They don't like to deal in hypothetical situations, especially, you know, insurance underwriters don't deal with hypotheticals. They said that, "If we were approached, we certainly would consider writing it."

To give just a follow-up on what Stu said, I had spoken to Gary Lewis in Mallinckrodt about the insurance. Of course, I guess early on, it had been alleged that Mallinckrodt had not maintained and was not able to maintain a CGL policy. And we were a little surprised to find out that they were maintaining the policy. The gentleman I happened to speak to at Liberty Mutual, just to give you an idea as to what we were running up against, the one official in the company saying insurance was available, and the other saying it's not, the Liberty Mutual gentleman I spoke to wasn't even aware that they were writing Mallinckrodt.

So, there are -- these are very large insurance companies. Headquarters operations, regional operations. And it is certainly very well possible that one official in the company does not know what other officials of the companies are doing.

I tried in my contacts to speak to the people in this area that were directly responsible for the pharmaceutical and these type of high-risk operations,

rather than speaking to the people writing the casualty and property policies for fire and theft and the usual risks.

MR. ROSS: Other than that, I don't think I have any other questions.

MR. BELLMAN: Let me pursue one other matter that the Commission's position raises. And that is the coverage by this proceeding -- our proceeding here, of categories of actors who are not among us, the position of the Commission being, I understand, that they should not be covered by this proceeding. I mean I presume that allows us to say neither yea nor nay with regard to whether they ought to be. They're just not here and not germane.

Is there any dissent from that view of the Commission? Is there any other category that you want discussed here besides your own?

No? Okay.

MR. LORMAN: Not on behalf of the pharmacies.

MR. ROSS: Other than, of course, Squibb and Amersham aren't directly represented here --

MR. BELLMAN: I'm not talking about companies.

MR. ROSS: Other than that, no. I agree with that.

MR. BELLMAN: Are there any other further questions that any of you have of one another here?

(No response.)

MR. BELLMAN: Is there anyone here from the -- anyone else here, not at the table, who wishes to say something? I think I recognize everybody here, having been here all along.

(No response.)

MR. BELLMAN: All right. Let's go off the record, please.

(Whereupon, a brief recess was taken.)

MR. BELLMAN: Back on the record.

This is my attempt, subject to everyone's correction, to recite for the record a list of issues and agreements with respect to certain factors and some points with respect to evidence that is regarded as important to provide.

The first issue is the need for insurance, which is divided into three subsets: the need to address liability, the need to address litigation costs and the need to address potential disincentives to investment.

Next, there are issues with respect to availability of insurance which includes kinds of insurance, amounts of coverage, and the cost of insurance. All of which factors go to a question of whether acceptable insurance is really available. Or, as it was put: What kind of insurance can a participant in these industries hope to purchase and is it reasonable to expect them to accept

that kind of insurance?

Then there was some discussion with respect to the need for insurance and the period of time that has passed in the present state of affairs where it is asserted there is a lack or absence of insurance.

How does one account for decades of operation in that situation, given that it is not conventional to expect an enterprise to operate without coverage? In fact, were there decades without coverage is another question. Or have some kinds of insurance which were available become unavailable?

Also, the question was asked what types of insurance and other insurance-like devices are now held or engaged in by these companies in these industries.

There is the question of the importance of the nuclear or pollution exclusions and what effect or importance should be attached to insurers' advice to these companies with respect to the importance in effect of those exclusions.

And the question of if these exclusions are applied more broadly than simply these populations of companies, why should these companies receive special treatment from the government?

I think that we agreed that whether that the public would suffer were these companies to leave their

business, but -- and we also agreed that we cannot -- ultimately, we cannot determine whether not being indemnified will cause them to leave. What we know is that the parties have varying opinions and it is difficult to bolster any of those opinions with specific evidence.

Finally, with respect to insurance, there is the issue of how much insurance for indemnification should be provided if any is going to be provided.

Secondly, there is the issue of whether agreement states are or should be covered and it was indicated that it would be helpful to know how these companies are distributed between federal licensing and agreement state licensing.

Thirdly, there is the issue of NARM coverage. And, finally, it was agreed that the discussion here encompasses releases within Part 20, releases that exceed Part 20, and what we have referred to as "accidents."

That is my representation of what I think we have agreed are the issues here. I mean I really do encourage you to refine that if I have -- I take no pride in authorship here.

(No response.)

Hearing none, thank you all very much. And I will see you in a couple of weeks.

(Whereupon, at 2:15 p.m., the hearing was adjourned.)

CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission in the matter of:

Name: PRICE-ANDERSON RULEMAKING

Docket Number:

Place: ROCKVILLE, MARYLAND

Date: November 14, 1988

were held as herein appears, and that this is the original transcript thereof for the file of the United States Nuclear Regulatory Commission taken stenographically by me and, thereafter reduced to typewriting by me or under the direction of the court reporting company, and that the transcript is a true and accurate record of the foregoing proceedings.

/s/ Joan Rose

(Signature typed): JOAN ROSE

Official Reporter

Heritage Reporting Corporation