ORIGINAL

RETURN TO SECRETARIAT RECORDS

NUCLEAR REGULATORY COMMISSION

IN THE MATTER OF:

PUBLIC MEETING

POLICY SESSION 78-12

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U. S. NUCLEAR REGULATORY COMMISSION

MEETING OF THE COMMISSIONERS

PUBLIC MEETING

POLICY SESSION 78-12

Commissioners' Conference Room
1717 H Street, N. W.
Washington, D. C.

Thursday, 2 March 1978

2:45 p.m.

COMMISSIONERS PRESENT:

Chairman Joseph M. Hendrie

Commissioner Richard T. Kennedy

Commissioner Victor Gilinsky

Commissioner Peter A. Bradford

STAFF MEMBERS PRESENT:

Assistant Secretary John Hoyle

Thomas Dorian

R. M. Bernero

R. E. Cunningham

W. Dircks

A. Kenneke

P R O C E E D I N G S

CHAIRMAN HENDRIE: Since we have a quorum, why don't we go ahead?

The Commission is meeting this afternoon for a briefing and discussion on medical uses of isotopes. I believe Dick Cunningham bears the principal responsibility. Bob Bernero apparently put his finger in the pencil sharpener. He can hardly be trusted with medical applications.

(Laughter.)

Let's see, who will have the lead? Dick, will you lead off, or Bill?

MR. DIRCKS: Dick has the lead, Mr. Chairman, but we just want to remind you that this is another one of those program comprehensive briefings we've been bringing down to you in recent weeks. We're trying to lay out not only what's going on in the regulatory area of medical isotopes, but at this time we bring forth a proposal, a staff proposal to the Commission, regarding the issuance of a proposed rule.

As you noted, Dick Cunningham of NMSS will present the briefing, along with Mr. Bernero, but I think we'd like to stress that this represents the views of all the program and staff offices of the agency. We do have other offices with heavy involvement in this particular area, including emphasizing the role of Inspection and Enforcement.

Whatever they're saying will represent the views of the other offices.

MR. CUNNINGHAM: May I have the first slide, please?

(Slide.)

Mr. Chairman, in November of 1976 we had a meeting with the Commission to discuss some issues dealing with nuclear medicine, some rather difficult policy issues, and at that time the instructions of the Commission were to develop policy guidance which will guide the course we take in subsequently developing regulations for nuclear medicine.

What we did was get public involvement in developing this policy. We have now done that, Mr. Chairman, and what we have today are some policy statements which we would propose to publish for public comment prior to adoption, in addition to some proposed rules that we would like to have published for public comment.

Before we go into the policy statements and the proposed rules, Mr. Chairman, I think we would like to take this opportunity to give you a background briefing on our medical licensing program. It is a rather large program in that it affects a lot of people, and it isn't one of those programs that are up before the Commission very often. We would like to take this opportunity to give you a background briefing.

May I have the next slide, please?

(Slide.)

When we talk about nuclear medicine, of course, or the medical radioisotope industry, it's necessary to start with the reactor that produces the radioisotopes. From there they're transported to the drug manufacturer, who changes these radioisotopes into a drug of pharmaceutical quality, and from there it goes to the hospital or nuclear medicine laboratory, where it is administered to the patient in one way or another.

COMMISSIONER BRADFORD: Dick, could you give me some idea of the numbers that go into each of those boxes, how many people produce radioisotopes?

MR. CUNNINGHAM: Basically there are only two reactors in the United States that were producing radioisotopes. Those were the GETR in Balacitos and the Union Carbide reactor in Sterling Forest. When the GETR shut down because of the seismic issues, a great deal of the slack was picked up by the high-flux reactor, HFR, I guess it is, in Oak Ridge, as well as Sterling Forest's reactor increasing their production.

In terms of quantity, the quantity of isotopes are a few hundred or thousand curies a week. It's not a lot in terms of the curie to radioisotopes produced.

COMMISSIONER BRADFORD: When Oak Ridge produces

them, that's at a Government facility?

MR. CUNNINGHAM: Yes.

COMMISSIONER BRADFORD: Do they then sell them just the way G.E. would?

MR. CUNNINGHAM: To my knowledge, they do. They sell them -- it's cost recovery, and I think they sell them just the way G.E. would.

The University of Missouri had a high-flux reactor that picked up some of the slack.

Some of these production procedures require a reactor with relatively high flux, and it does create a bit of a problem when these reactors go down. You can't stockpile the radioisotopes that are used in medicine; you have to keep the system full, so it does create some problems if you don't have the flexibility of shifting from one reactor to another.

COMMISSIONER BRADFORD: And how many manufacturers are there?

MR. CUNNINGHAM: There are, I would say, half a dozen major manufacturers that are the major suppliers of radioisotopes of pharmaceutical quality, radiopharmaceuticals. There aren't very many manufacturers.

So far as the medical users go, I do have a graph that I'll be getting to, but there are thousands.

COMMISSIONER BRADFORD: And they are all supplied

by those half-dozen manufacturers?

MR. CUNNINGHAM: Yes, essentially half a dozen. There are others in the business, but it's essentially half a dozen.

Incidentally, our reactors produce radioisotopes that are used -- practically all the medical radioisotopes used in Japan are produced in this country, as well as quite a few of the European uses of radioisotopes come from reactors in this country.

But for purposes of today's briefing, when I talk about the medical program, the people involved, the risks, the types of things that are going on, I'm directing my talk to the medical use, what happens in nuclear medicine laboratories, not any risk that might be involved in operating the reactor or in making radiopharmaceuticals or in the transportation among these groups. That's covered elsewhere, so really I'm talking about what's happening in the nuclear medicine laboratory.

May I have the next slide, please?

(Slide.)

Medical uses of radioisotopes can be broken down into two categories: diagnostic applications, where you try to determine what is happening in the body; and therapeutic applications, where you're trying to cure something.

May I have the next slide, please?

(Slide.)

Diagnostic applications are really four categories. In vivo, as you may recall, means inside the body as opposed to in vitro, which means that you take a sample outside the body and manipulate it somehow to get information.

In vivo function studies involve things like the rate at which the thyroid will take up iodine when you inject a quantity of radioactive iodine into the body and measure the thyroid. Renal function studies, blood volume studies and that sort of thing.

In vivo scanning studies are for the most part looking for tumors inside the body. The radioisotope most commonly used is technetium 99 metastable. It has a short half-life. Depending upon what chemicals you combine it with, it has selective uptake in various parts of the body and you can look for tumors in places like the brain, thyroid, liver, kidney, what-have-you -- almost anywhere you want to, really.

In vitro diagnosis, these are mainly radiobioassay studies that really are used to measure concentrations of things like hormones in the blood. They're used quite a bit. As a matter of fact, to show that somebody can still do something in this radioisotope business, Dr. Yahlo of the Bronx V.A. got a Nobel Prize this year for her work in developing radioimmunoassay procedures.

You can measure down to nanocuries per gram or picacuries per gram with these procedures, so they're very sensitive.

And the diagnostic devices: The bone mineral analyzer is a typical use. You just measure the density of the bone for various reasons.

Next slide, please.

(Slide.)

Therapeutic applications are basically three types, where you inject a large -- comparatively large quantity of a radiopharmaceutical into the body that goes to a selected organ. It's mainly used for thyroid cancer, hyperthyroidism, polycythemia vera, where you have an overproduction of red blood cells. You inject P-32. Metastatic bone disease, again P-32, where the phosphorous goes in the bone.

Teletherapy. This is using a cobalt 60 source that is used in a shielded container outside the body to try to irradiate tumors in the body.

Brachytherapy. These are interstitial implants that are sewn right into tumors, usually near the surface of the skin.

May I have the next slide, please?

(Slide.)

To give you some idea of the extent to which these

are used, there are about 15 million in vivo procedures conducted per year, 20 million in vitro procedures and about 7 million teletherapy procedures.

The significance of this is that there are a lot of people that are coming under the umbrella of the licenses we issue in nuclear medicine.

May I have the next slide, please?

(Slide.)

An idea of the size of the industry from a money standpoint. Of the $118.5 billion spent on health, about $2.2 billion is spent on nuclear medicine services.

May I have the next slide, please?

(Slide.)

Looking at the size of the program from the licensing standpoint, we have about 1600 licensees for hospitals to do diagnostic and therapeutic work; about 600 to physicians; 450 teletherapy licenses; and a fairly large number of people who register under general licenses to do very limited types of work.

I should say these are just NRC medical licenses. If you include the agreement states, you do a little bit better than double those numbers.

The number of people that are occupationally involved under our licenses we estimate -- and it's only an estimate, but we think it's about 30,000 people under these

medical licenses.

Now, in developing -- may I have the next slide?

(Slide.)

That is just by way of background. When we consider developing our policy to guide us in our future regulatory work in medical licensing, there are really two major considerations: what's the risk to the patient, general public and the workers; and, secondly, what are other people doing that are also involved in regulating or in somehow impacting on the control of nuclear medicine.

There are a number of subsets of questions you can ask about this. For example, in arriving at policy you have to ask yourself what regulations truly benefit the patient and the public and at what point do regulations really inhibit the physician's ability to make decisions on patient management to the detriment of the patient.

If you overregulate a physician, of course, he's not free to make judgments very quickly.

Another set of questions might be how much regulation is necessary to prevent misuse of nuclear medicine, where it might be used as a fad rather than a legitimate tool by qualified physicians, or the converse of that, at what point do we regulate physicians to the point that they avoid using nuclear medicine, again to the detriment of the patient -- make it so difficult for them that they'd rather

not get involved with it.

Finally, of course, you have the question of what can NRC regulate best and what should better be left to other people to regulate.

May I have the next slide, please?

(Slide.)

On the question of risk in nuclear medicine, in the first place the risk to the patient, in diagnostic procedures the risk is usually low. A typical scan using technitium 99 is about -- results in about a whole body dose of about 250 milligrams -- not a very large dose for medical purposes.

Therapeutic procedures, however, can be another story. There, of course, you're trying to actually kill certain cells in the body. In doing so you irradiate cells you don't necessarily want to irradiate.

Typical teletherapy exposures can range as high as 2- to 6,000 rem over a course of treatment. Now, when you consider that the LD-50 for radiation is somewhere in the neighborhood of 450 rem, you can see how important -- how a little error can produce very adverse results.

Patients receiving teletherapy treatment very often suffer the typical radiation, acute radiation syndrome thing. They vomit, they have erythema, they lose hair -- all these sorts of things happen to them. So there is a risk

in these therapeutic doses.

May I have the next slide, please?

(Slide.)

The risk to the public is pretty low. A typical surface dose from a patient for a very short time after he receives a diagnostic quantity of material is about 10 MR per hour, and that goes away very quickly. Of course, if you're giving therapeutic doses you hospitalize the patient if they're given internal therapeutic doses. Teletherapy treatment, of course, doesn't involve radiation inside the patient -- I mean administration of radioactive material inside the patient.

Again, when I talk of risk to the public I'm not talking about the whole nuclear medicine industry if you consider the risk of operating the reactor, making pharmaceuticals and so forth.

As for risk to the public who may be in or around a nuclear medicine laboratory, you always must remember that nuclear medicine laboratories are in hospitals and hospitals have people wandering around the corridors.

MR. DIRCKS: And it excludes transportation.

MR. CUNNINGHAM: Yes, it excludes transportation and all this sort of thing.

May I have the next slide, please?

(Slide.)

The risk to workers. There is some risk if good health physics procedures aren't followed, and there is some risk even if good health physics procedures are followed.

Every once in a while, for example, the shutter on a teletherapy unit will jam for some reason or another. Somebody has to go in and pull the patient out of the teletherapy treatment room. That's a risk.

Very often you have quite sick patients. You have emergencies on your hands. You can't follow the best procedure. You have to balance what happens to the patient against following all the nice procedures you would like to follow, so there's always that tradeoff.

In most nuclear medicine laboratories they handle a lot of technetium. When you generate or eluate to get the technetium, the vial, right after it's eluted, will be hundreds of R per hour at the surface of that vial. If it's picked up or mistreated it can result in problems.

Nevertheless, I think our surveys that we have conducted to try to find out what typical exposures are to medical workers, they're running around .5 rem per year; so it's not too bad on the whole.

That summarizes the risk to workers. Now I'd like to talk -- if I may have the next slide --

(Slide.)

-- a little bit to our interface with other people who

regulate nuclear medicine.

You can see here that we've drawn a little schematic of all these groups, whether they're regulatory groups or peer groups, what-have-you, who one way or another are involved in the regulation or setting standards of practice for the practice of nuclear medicine.

We have to define what we best can do and what can best be left to others.

Probably the two most -- well, three most important groups -- if I may have the next slide.

(Slide.)

These are just peer groups, all of which we have to work with. We have done quite a bit of work in the past to get the American Board of Nuclear Medicine established. We heavily supported that work a few years ago so we can get some standards, professional standards, of practice and physician qualification, although we're still looking at physician qualifications.

All of these are peer groups that in one way or another impact on the quality of nuclear medicine practice.

May I have the next slide, please?

(Slide.)

Again, state health organizations. States license physicians to practice medicine. They license paramedics, and in some instances they license pharmacies.

This is all relating to the quality of medical practice in one way or another.

And, of course, we have the agreement states, and I don't need to expand on that.

May I have the next slide, please?

(Slide.)

I guess our major interface in regulating nuclear medicine comes with the Food and Drug Administration. Food and Drug, FDA, controls good manufacturing practices. This is the control of the radiopharmaceutical manufacturer to be sure the drugs are good pharmaceuticals. There you're worried about things like sterility and that sort of thing -- drug quality.

They assure that the drug or device is properly labeled. That means that it has a label that says it's safe at applications for such a purpose, giving the indications on it, counterindications, dose range and so forth.

And they do control investigational use of drugs. This is the control of the use of drugs before they're ready to say it's safe and effective.

These investigational use laws, or the most recent ones, flowed out of the thalidomide scandal a decade or so ago.

Until very recently, within the past two years or so, we regulated for radiopharmaceuticals the investigational

use of drugs and decided when they should be put into routine use until FDA got staffed up and into a position where they could take this function over.

They have new legislation now covering medical devices, and they aren't yet in a position to completely regulate those. I'll get to that a little bit later, but that's one of the things coming up.

In developing a policy -- if I may have the next slide, please.

(Slide.)

As I said before, we were before the Commission in November of '76. In May of 1977 we held public meetings on questions of policy and the direction in which we should be going in policy to guide us. We also held a meeting with our Medical Advisory Committee. We now have a proposed policy statement.

I think in developing this policy what we want to do, of course we don't want to overregulate physicians and we don't want to underregulate physicians. If this policy is adopted, specific regulations that come in the future will be reviewed in the context of this policy.

May I have the next slide, please?

(Slide.)

So the three policy statements that we have, the first one is that we believe the NRC should regulate

the medical uses of radioisotopes as necessary to provide for the radiation safety of the workers and the general public.

This is practicing our role in just health physics, if you will, as we do in other facilities. This is one of the things that we know how to do, and we can do it, I think, fairly well.

May I have the next slide, please?

(Slide.)

Now, the next policy statement, we start entering into the qualifications of the physician to practice medicine and to the physician-patient relationship. This gets a little bit more difficult.

The next policy statement, though, is that NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

This implies that we will not regulate in areas where there are standards mandated by other agencies and these other agencies have competence to impose, or to enforce their regulations.

May I have the next slide, please?

(Slide.)

The third policy statement is that we will minimize our intrustion into medical judgments affecting patients and into other areas traditionally considered to be a part

of the practice of medicine.

I might say here that the AEC, and now the NRC, is the only Federal agency that ever regulated the quality of the practice of medicine. I don't know whether that's good or bad. Nuclear medicine has grown tremendously over the years, and we haven't had any major scandals. I don't know if they've done that in spite of us or because of us, but we are the only agency who has done that sort of thing.

Now, the question of how we implement the policy.

May I have the next slide, please?

(Slide.)

Looking at specific items of interest: physicians' qualifications. We have requirements, minimum requirements, I might add, for physicians' qualifications to practice nuclear medicine. We have repeatedly brought up this question to our Medical Advisory Committee and peer groups as to whether or not we should continue to license physician qualifications.

We got into licensing physician qualifications to practice nuclear medicine when there were no other standards and when nuclear medicine was new. This started long before the time, I guess, of any of us here in AEC, back in the late '40s when AEC was first formed.

Since that time a Board of Nuclear Medicine has been established. The Board of Radiology has subgroups

approving nuclear medical physicians. Nevertheless, the advice of our Medical Advisory Committee is to still continue this practice, not turn it over completely to the peer groups, because there has to be some mechanism for the approval of some physicians for certain things that the peer groups don't approve.

We accept with certain limitations board certifications as an indication of qualifications, but I have to stress that our criteria for physician qualification are minimal and about the best, probably, that we set for this is that it keeps people who aren't serious about this business out of the field. It doesn't let people dabble in the field.

Selection of patients, that's a medical judgment.

Selection of instruments to diagnose patients, that again, we feel, is a medical judgment.

Selection of drugs, we limit those to drugs approved by the FDA, approved for investigation by the FDA.

And selection of the procedures. That is the purpose for which the drug is used. We do this to a limited extent, and Bob Bernero will talk to you about that a little bit more.

Next slide, please.

(Slide.)

Selection of patient dose. That's a physician

judgment call.

Measurement of dose. We do require under our regulations -- we're in the process of doing this for teletherapy licensees -- that the dose be measured, so we are moving in that direction. That's just good practice, and we feel we can impose that.

Calibration of diagnostic instruments. We do require dose calibrators to be calibrated. The scanners and things like that, that's an open question.

There is a question whether or not we should pass on the qualifications of paramedics to assist in nuclear medicine laboratories. This is an open question. Lots of states do license their paramedics. There are paramedic certification programs, but nevertheless this is an open question. There aren't consistent rules, certification procedures, that can be applied.

It would be a difficult thing to do. In the first place, there are probably on the order of five to ten paramedics working in a nuclear medicine laboratory for each physician. That gives an increased workload. And the ways in which paramedics are used vary quite markedly from one laboratory to another, and their professional qualifications vary, too. A paramedic may be a technician with a high school education, or he may be a Ph.D. physicist. It depends just on how they're used.

If we get into this--we're exploring it, but we're not sure where we come out on this question.

Misadministrations, the reporting of misadministrations. This is a question that's been up to the Commission once. We've gone back to the drawing board, and we do have a proposed rule that Bob will discuss.

That really ends my presentation on the policy. There is one other thing I would like to bring to your attention in deliberating about these rules.

I might say that over the years the direction we have been going on licensing nuclear medicine is to exercise less control over the practice of nuclear medicine.

Two things are happening, of course. The field is maturing. We know what the problems are now much better than we did years ago. And there are other peer groups setting standards for practice, so the industry in a way can be self-regulated.

In addition to that, there are other agencies who can regulate some areas better than we can. For example, FDA in the quality of drugs.

I will show you one last slide before I turn this over to Bob, and that is the manpower we're expending on medical licensing. It's not very much when you consider the population of licensees we have, the population of people we are regulating and the population of people that are

receiving radioisotopes.

(Slide.)

Six people in our organization responsible for evaluating and issuing licenses; I&E has ten inspectors; and Standards is putting three manyears into regulatory effort.

I suspect that might even be a little bit high, but for the size of the population and the things that are going on in nuclear medicine laboratories, we feel that this is indeed a modest program.

If we were to do things like evaluate the qualifications of paramedics and do some other things, of course, the number of people that would have to be involved in this would have to expand.

If there are no questions on this, I'll defer to Bob at this point.

MR. BERNERO: What you've just heard is the policy question, the overall medical policy. That's one separate action that's put to you today.

And there are two other distinct actions. They are proposed rules which are developed consistent with that proposed policy, walking that line between underregulation and overregulation.

Now, the two parallel and separate actions that I will cover here relate to clinical procedures and

misadministration.

May I have the next chart, please?

(Slide.)

The clinical procedures, we'll cover that first. Our regulations, Part 35, are set up so that radiopharmaceutical licenses can be handled in groups where the activities involved are put into categories of increasing complexity, increasing demands in skills, in training, in procedures and in equipment.

Those licensing groups are listed here. Groups I to III are for diagnostic radiopharmaceutical uses and generators and kits. We're getting up to that level of complexity where the radioisotope is actually contained in a device, and the procedure is to get the material out for actual administration to the patient.

May I have the next slide, please?

(Slide.)

Groups IV through VI are for therapy and devices which are more complex, involve higher doses, more complexity, more difficulty to -- more demands of the skill of the user of the radiopharmaceutical material.

So what we are looking to here is a way to simplify our regulation on the diagnostic or lower risk side of these licensing groups.

May I have the next slide, please?

(Slide.)

The proposed rule we have here is to go into Groups I, II and III -- again, the diagnostic radiopharmaceuticals -- and to delete the clinical procedures from the regulations.

Let me have the next slide, please.

(Slide.)

What this really means, if we go into an example, in our current rule, currently Part 35.100, it would list, as you see here, for any given isotope at least several, a number of variations of the use of iodine 131. It would list for that one isotope a list of chemical forms, and associated with each chemical form is a procedure, a clinical procedure -- the measurement of thyroid uptake or a liver function study, or whatever.

The physician operating under that license is constrained to use that isotope in that chemical form for that clinical procedure, and he is constrained by the labeling on the radiopharmaceutical to the path of administration and the dose involved.

Now, the simplification we propose -- may I have the next slide, please?

(Slide.)

-- is to take out the clinical procedures and just have the rule cover the radioisotope in question and list the

chemical forms, the forms of this isotope, which can be used by the physician operating under this license.

Now, we would by that -- may I have the next slide, please?

(Slide.)

We would by that means leave the physician the option of using it for some procedure, some clinical procedure, which is not the direct approved, FDA-approved procedure. He would still be constrained to the same chemical and physical form, the same route of administration, and the dosage range. These are all covered by the labeling. But he has the freedom to practice medicine to the extent of his skill and to move out for a different clinical procedure within these constraints we hold him to.

Now, the reason for allowing this is, first of all, we're dealing with diagnostics, where the risk is fairly low; and by using an approved isotope in approved chemical form and route of administration we have already seen that the patient is provided with sufficient evidence of safety, and one is left with only a question perhaps of efficacy: Is the procedure he's using it for as effective as the approved one?

If we were to wait for approved clinical procedures only, as our regulations are presently constructed, then the physician would be constrained from an additional

use of this radiopharmaceutical until the FDA approval has been obtained. This could be very many years, and in the case of some radiopharmaceuticals, having obtained one FDA approval, the manufacturer may not be as inclined to invest the large amount of money and time to get a second or a third.

So by holding off the use of this radiopharmaceutical for another clinical procedure, we could be denying the patient a valid use of that radiopharmaceutical.

COMMISSIONER GILINSKY: Right now they are denied that?

MR. BERNERO: Yes, in effect right now Part 35.100 says you may use that isotope in that form for that purpose -- that liver scan or whatever it might be.

If that same liver scan would provide that physician what is to him an important and valuable insight into another organ, the regulation does not permit him to use it for that other purpose.

COMMISSIONER GILINSKY: So you're proposing to open up the use of these isotopes?

MR. BERNERO: Modestly. He still is constrained to use that isotope in that form, administered in that path -- some vein or whatever -- and in that dosage range. Those are not changed.

COMMISSIONER GILINSKY: And this is at the request

of doctors to make this kind of change?

MR. BERNERO: No. I believe this was staff-inspired originally.

MR. CUNNINGHAM: It's a combination of things. I think some physicians did suggest it. The FDA has supported this position, and the staff supports it simply because it certainly cuts down on the administrative burden of the work.

What you're really doing -- and the FDA has a policy position on that where they support this kind of thing -- but you're making a tradeoff.

On the one hand you're allowing the physician more flexibility to practice medicine as he sees fit within certain constraints. You know what the radiation dose is going to be.

What you're losing is the question of whether or not a drug used for a purpose other than for which the safety and efficacy has been established, you're losing something in knowing whether or not you would get a false positive or a false negative reading. We're not worrying about radiation risk, but if he tries to diagnose something other than what the label says to use it for he runs a higher risk of making a false negative or a false positive reading. This could be important to the patient if you miss a tumor or think something's there and operate on him and it isn't there.

MR. BERNERO: That's indeed been the medical judgment part. This change would be consistent with the FDA policy with respect to the drugs.

COMMISSIONER GILINSKY: What is the significance of FDA approval if you can go beyond it? Why is the FDA suggesting that we not pay attention to their approvals?

MR. CUNNINGHAM: The FDA has its own position on this. They did not suggest to us that we should do it. And the FDA has done it for some time.

MR. DIRCKS: But they're not opposed to it.

MR.CUNNINGHAM: Oh, no, not at all.

COMMISSIONER KENNEDY: They're not opposed, you say?

MR. DIRCKS: They're not opposed.

MR. CUNNINGHAM: They're not opposed to it, not at all.

That's a little bit hard for me to explain in FDA's case, more than it is in NRC's case, because what it really gets to is the safety and efficacy of drugs, which we think is an FDA question, not an NRC question.

It certainly does, to my way of thinking, circumvent some of the investigational drug rules, but the investigational drug rules, as I understand it, are for fairly large-scale investigations.

COMMISSIONER GILINSKY: But these proposed

procedures would circumvent those rules. Is that what you're saying?

MR. CUNNINGHAM: Well, FDA's policy circumvents their own investigational drug rules to some extent.

COMMISSIONER GILINSKY: The policy on what?

MR. CUNNINGHAM: That you can use a drug for a purpose other than that which is on the label.

MR. BERNERO: In effect the FDA, when it makes a finding on a drug, is saying that this drug is safe and efficacious for some purpose, administered in some way, concentrations and what-have-you.

They do not then say that under no circumstances can the same drug administered in the same way be used for some other purpose. They leave that available to the physician.

Of course, in that case the physician is going beyond the clear labeled and call it certified use of the drug, and he takes it upon himself or herself a much greater level of responsibility in the practice of medicine.

But FDA in their statements does not forbid that. It is not their policy.

COMMISSIONER GILINSKY: Do we have the views of some medical group on this?

MR. CUNNINGHAM: Yes, this was brought up before our Medical Advisory Committee and in the public meeting,

and I think all groups supported this. There was some discussion, but so long as we control the route of administration and the dose the only other remaining question would be the efficacy of the drug. They feel that for these diagnostic procedures the freedom given outweights any disadvantages that might accrue.

What we're really dealing with here, what we're really controlling in that case, is drug safety and efficacy, which we believe -- we agree with FDA that it's an FDA problem, and FDA is treating these drugs the same as they do any other drug.

I can read the statement here. We have it in the staff paper. There is a statement of the FDA position on this in which they say that there are reasons to do this and it would not be in violation of the Food, Drug and Cosmetic Act. It's on page 16, Enclosure 1, of the staff paper that was sent to you.

MR. BERNERO: In essence FDA is recognizing that the approved use of the drug may not be as up-to-date as it could be to be fully useful to the practicing physician, so the practicing physician can take the responsibility to be up-to-date and use this radiopharmaceutical in what is already an approved method. It's a question of the procedure and the purpose of the use.

COMMISSIONER GILINSKY: This is strictly in

diagnostic applications?

MR. BERNERO: Strictly in diagnostic. There is no attempt here to go into the more grave actions or quantities involved with therapeutic doses. It's strictly in diagnostic, so it's in Classes I, II and III.

COMMISSIONER KENNEDY: Where the quantities are very small.

MR. BERNERO: Yes, we're speaking of small quantities. What one is really weighing are the relative merits of what may be a superfluous or an unnecessary exposure to some small degree against what may be a medically useful thing for the doctor working with the patient.

COMMISSIONER GILINSKY: What sort of doses do you end up getting?

MR. CUNNINGHAM: Typically technetium is the most commonly used diagnostic isotope -- 20 millicuries on a diagnostic procedure results in about 250 millirem total dose.

COMMISSIONER GILINSKY: Millirem?

MR. CUNNINGHAM: Yes, millirem.

MR. BERNERO: Millirem quantities, not rem -- orders of magnitude difference with therapeutic.

COMMISSIONER GILINSKY: Say that again.

MR. CUNNINGHAM: About 250 millirem total dose for a diagnostic procedure. That's typical. It varies,

of course.

COMMISSIONER GILINSKY: That's a whole body dose?

MR. CUNNINGHAM: Whole body dose, yes.

MR. BERNERO: I'd like to go on to the next related paper, which I think may lend further insight to the judgments being made here.

This is on misadministration.

May I have the next slide, please?

(Slide.)

We're defining a misadministration here as is listed on the slide. It's the wrong act to the wrong patient through the wrong path. And we're inserting here a quantitative judgment to define sharply the difference in diagnostic uses and therapeutic uses on a percentage basis. It's a matter of judgment for us to define it to say a misadministration is more than a 20 percent error in diagnostic use and a 10 percent error in therapeutic use.

These numbers have been drawn based on the capability of measuring and administering these things, and they do reflect with the tighter constraint of 10 percent that therapeutic, of course, involves greater quantities, greater exposures.

May I have the next slide, please?

(Slide.)

The misadministration goes back a number of years. There was an original rule back in 1973. GAO did a study and recommended that AEC regulatory take action on that, and in implementing this GAO regulation there was a misadministration rule proposed then which would specify the activities that a licensee could delegate to others, the sort of training required for technicians, and it did bring up the subject of reporting misadministrations.

That proposed rule back in 1973 had in it a proposed requirement to report misadministrations to the patient or family of the patient. That was a staff-inspired change, not a GAO recommendation.

Now, that proposed rule got a lot of comment.

May I have the next slide, please?

(Slide.)

There was a lot of comment at that time, and, of course, the medical policy was in a state of evolution since the Government regulatory policy was in some state of evolution at the same time.

The principal comments, of course--many of them you could expect to see--misadministration reporting, especially involving patient notification, brings up the idea of self-incrimination.

COMMISSIONER GILINSKY: Is this on the part of the doctors?

MR. BERNERO: Yes, inviting the increase of malpractice suits.

Our legal advice is that it's really not self-incrimination. The question here is not one of Fifth Amendment or anything like that. We're not dealing with a felony here.

COMMISSIONER KENNEDY: But we're dealing with malpractice suits, though.

MR. BERNERO: Yes, but that question is certainly a substantial one, challenges on -- interfering or meddling in medical ethics and pointing out that where are comparable requirements on other drugs -- why should radiopharmaceuticals have this unique requirement.

So this was the general thrust of all the comments on that.

Well, with this new policy, this presently proposed policy we have here -- may I have the next slide?

(Slide.)

We have a new NRC proposal on misadministration by which we would withdraw the 1973 proposal and require that the licensee keep records of misadministrations as defined on that earlier slide -- wrong act, wrong place and so forth, and using those quantitative limits -- and we would further require by this rule that the licensee report to NRC all the therapy misadministrations -- all therapy, because

it's a grave matter. There are high doses, large quantities. And all serious diagnostic misadministrations -- serious being where one is dealing with clinically detectable adverse effects.

It's an almost undefinable thing to say a serious diagnostic misadministration is exactly this or exactly that. There is a great deal of medical judgment involved in judging or reading what is serious.

COMMISSIONER GILINSKY: Well, let me ask you. Suppose the wrong patient got one of these diagnostic doses we were just referring to. Would that fall in this category?

MR. BERNERO: Not unless there was a serious effect, a clinically detectable adverse effect.

COMMISSIONER GILINSKY: You mean after-the-fact?

MR. BERNERO: After-the-fact. But if it were merely the wrong patient, it would be a recordable misadministration. I'm speaking of a diagnostic act, not a therapeutic act.

A diagnostic administration that went to the wrong patient -- you know, two people named Brown sort of thing -- that would be a recordable misadministration, not a reportable one, unless it had an after-the-fact adverse effect.

COMMISSIONER GILINSKY: You really have to get

up into many, many rems before you got an observable effect.

CHAIRMAN HENDRIE: I think the clinically observable is more likely to be a chemical pharmaceutical effect.

MR. BERNERO: Yes, an allergic reaction or something like that.

By their nature the diagnostic procedures are relatively mild and are not likely to induce any serious effect, but if the wrong patient got it and there were some allergic reaction to the drug, some purely chemical thing, it would at least bring that out as an immediately reportable misadministration.

COMMISSIONER GILINSKY: Well, let's take this case here. I don't know what form the material comes, but suppose he got a dose which was too large by a factor of 100. Would that fall in this category?

MR. CUNNINGHAM: By a factor of 100?

MR. BERNERO: Oh, yes.

COMMISSIONER GILINSKY: Would there be an observable clinical effect?

MR. BERNERO: Excuse me. You don't need both. If--let's take one patient. It's not the wrong person. We're dealing with the right person, and that patient is supposed to get a diagnostic procedure of some number of millicuries that would give him a dose of 250 millirem. And

the technician, or whoever caused the mistake, doubled the dose, 100 percent increase -- that would be a --

COMMISSIONER GILINSKY: I asked about a factor of 100, but you go ahead.

MR. BERNERO: That would be a recordable misadministration, but it would only be reportable if the patient reacted to it.

COMMISSIONER GILINSKY: That's what I'm asking. What would require a report to the NRC?

MR. BERNERO: If the mistake was made on a therapeutic, a defined mistake made on a therapeutic, or on a diagnostic where there is a clinically detectable adverse effect, and only there; all of them are recorded for NRC scrutiny.

You see, the distinction really is how quickly will we learn of the event. The recordable one waits for the inspector to show up to read it; the reportable one bypasses the inspection process and time by notifying us promptly.

COMMISSIONER GILINSKY: Then what do we do with it when we get it?

MR. BERNERO: Well, I'll get to that. There are a variety of things we can do with this.

May I have the next slide?

(Slide.)

MR. DIRCKS: I think an issue that should be brought out is now we're not getting any reports, reportable or recordable.

COMMISSIONER GILINSKY: Right now?

MR. BERNERO: Yes. The West Virginia and all of those things are by guess and by gosh picked up. There is no regulation that says those have to come in.

COMMISSIONER KENNEDY: An interesting point that you didn't cover on the other slide, which I gather is also new -- or is it? -- is that you'd be requiring the licensee in those reportable cases to at the same time report the fact to the attending physician.

MR. BERNERO: Yes, indeed.

COMMISSIONER KENNEDY: Who may not be the same individual who was supervising the procedure.

MR. BERNERO: Typically isn't. The licensee is typically a licensed radiologist or someone like that, and he would be required in reporting to us to report to the physician, the real doctor for the patient.

And then the referring physician is the one in the position to determine should the patient be told, would it be unnecessarily alarming, or how should the patient be told: should the wife or the husband or whatever.

COMMISSIONER KENNEDY: Is that physician in a position to make that kind of a judgment? I know he is

vis-a-vis the patient himself, but does he know the level of seriousness? Is he able to assess that?

MR. BERNERO: Well, he's in a position to know the patient and to consult with the radiologist and any other authorities he deems necessary to make a judgment of whether some sufficiently grave consequences are involved that he should inform the patient.

Now, the choice there, of course, is a broad one. We could go to the one extreme and leave it to the doctors. Current medical practice is that the licensee would be reporting to the referring physician; that would be the typical medical practice, and we could just not require anything. Or we might go even further.

COMMISSIONER KENNEDY: If that is regular practice, why would we require it by regulation?

MR. BERNERO: Perhaps as a matter of clarification, to show what we feel is an appropriate requirement on our part with respect to this misadministration.

The question logically comes up: Should we not require the licensee to report to the patient? That's one alternative that was discussed at great length: Just be adamant about the thing; go down there and report that to the patient.

The obvious challenge can be raised. You could take a person who's already ill and unnecessarily alarm them

with a relatively minor thing.

Another alternative is to insist that the licensee report to the patient subject to the veto of the referring physician. That gets sort of complicated. And how much different is that from just giving it to the referring physician?

As a matter of clarity, the rule would say report to NRC these defined misadministrations and report them to the referring physician, and leave it at that; leave it for the referring physician to determine.

COMMISSIONER GILINSKY: Do physicians typically report this to a patient?

MR. CUNNINGHAM: They're supposed to. I think that it hasn't been followed in all cases.

COMMISSIONER KENNEDY: Isn't that a matter of patient-doctor relationship?

MR. CUNNINGHAM: Yes.

COMMISSIONER KENNEDY: Isn't that a matter of the medical judgment of the doctor himself?

MR. CUNNINGHAM: That's right.

MR. BERNERO: Yes. And the issues that people raise are, "Well, won't he protect his colleague from a malpractice suit?"

COMMISSIONER GILINSKY: Well, it's more than a colleague here. I mean, it's somebody to whom he referred

the patient.

MR. BERNERO: Oh, yes. He referred the patient to that radiologist, whatever the licensee is.

MR. CUNNINGHAM: Are you talking about liability of the referring physician for something another physician does or fails to do?

COMMISSIONER GILINSKY: Well, he's involved in the matter.

MR. CUNNINGHAM: Yes, I think so.

MR. BERNERO: Yes, there's a level of involvement.

MR. CUNNINGHAM: The fact is that the referring physician is the one that's managing the patient and should be the one to make the medical judgments necessary.

Now, if he doesn't follow medical ethics, that's a problem we can't do a whole lot about; but he's the one in the best position to make those kinds of judgments of what's best for the patient.

MR. BERNERO: You know, in a way it's like filtering out the selfish acts. We can look at the licensee and say we expect him to report it if he makes such a mistake, but in order to filter out those who won't to protect themselves we will apply the filter of requiring, having a license requirement that they be reported.

We could apply a second level of filtration and

go to the referring physicians and say let's make sure that they're not charlatans either, and so we get a fraction of a fraction thereby removed. There is a matter of degree, how far we can go.

COMMISSIONER GILINSKY: Well, it's not a matter of charlatans, I think, here. It's a question of whether there's some obligation to the patient that he be informed.

MR. BERNERO: Yes, and whether that responsibility for deciding on that reporting should be held by us, delegated to the licensee as far as we're concerned, or delegated to the referring physician.

And our recommended choice is in effect to delegate the decision to the referring physician, the one closest to the patient and well removed from the fault, from the misadministration responsibility, removed by one step.

COMMISSIONER BRADFORD: Why is it ever going to harm the patient to be told that there was a misadministration? Why would that information ever be withheld?

COMMISSIONER KENNEDY: Because doctors typically withhold a great deal of information on the simple assumption that to provide it to the patient would do him more harm than good, from a psychological if no other point of view. It's a rather typical thing, to make a judgment about whether informing the patient is going to help him in his recovery or

hinder him or make it impossible, which is also possible.

MR. CUNNINGHAM: I think it's fairly easy to construct some instances where you don't want to tell a patient this. If you have a patient that has a bad cardiac -- a pulmonary embolism or a cardiac patient or somebody who has just had surgery and you tell them, "Well, we made a mistake and your thyroid's been burned out," this may add some shock that really doesn't do the patient very much good at that time.

COMMISSIONER BRADFORD: Well, nobody has said anything about the timing of when you tell him, but what's the other side of that coin? Is it possible for a patient who has been in some way overexposed and doesn't know it to be traveling or move to another part of the country and to expose himself or herself far more than they would if they knew that they'd been overexposed before?

MR. CUNNINGHAM: It's hard to imagine that being very much of a problem.

COMMISSIONER GILINSKY: Let me ask a related question. Suppose you went from one doctor to another doctor and started a new radiation therapy. Would they be required to inform the new doctor of the maladministration?

MR. BERNERO: Well, let's reconstruct that a little. The original referring physician has a procedure done or asks for a procedure to be done. A misadministration

occurs. The original referring physician knows about it and perhaps chooses not to tell the patient.

The patient now goes to another physician altogether, and the new referring physician is in charge of the case. Typical medical practice is he immediately consults with the original referring physician.

Our regulation wouldn't speak to that issue, but the choice is clearly left with the original referring physician to advise him of the medical history "as I knew it and saw it, and this is where I left the patient."

(Simultaneous discussion.)

COMMISSIONER BRADFORD: Why should that be a choice at all? Whatever there is to be said for not telling the patient, surely there's nothing to be said for not telling the second physician?

MR. BERNERO: Oh, no. It's just that our regulations don't speak to that sort of thing. That's typical medical practice to do so, the full explanation.

For instance, the second physician might be told by the first physician that "I've been giving this a patient a lot of placebos to keep her from worrying," and he won't tell the patient that because it would defeat the whole purpose of what he's prescribing. That's medical practice.

Our regulation doesn't speak to that issue. It gets too complicated to set up these hypothetical situations.

But we do speak to this question of informing the patient or family, and we stop short of that in the recommendation.

COMMISSIONER GILINSKY: Why not have some formulation whereby the patient would be informed unless the doctor would say -- you know, unless he would certify to NRC that it would be harmful to the patient to be informed?

MR. BERNERO: Well, this is the one option that was ventilated in the paper and we considered, and that was that we would require the licensee to report to the referring physician and with some tag lag, some conditional character, report to the patient and/or family subject to a veto.

Well, this raises some complicated questions. One is timing and administration so that the thing is properly handled. A timely report and yet a timely opportunity for the referring physician to make a judgment.

Secondly, what would be the level of veto? How would one go about doing this without really getting awfully deep in the doctor-patient relationship?

Would we judge the referring physician criteria, motives or logic for saying yea or nay?

COMMISSIONER GILINSKY: Well, this is off the top of my head. You might not judge it at all. In other words, you might leave it up to the doctor, but he would at least have to certify that was the case. If it came up

sometime later there would be a record of it.

MR. BERNERO: There would be a bias on the act in the sense that there would be a pressure to inform where his action would be to stop it as against no pressure and his action to pass it on.

COMMISSIONER GILINSKY: That's right.

MR. BERNERO: And, of course, I agree there would be a record later on that he formally said, "No, don't tell him."

COMMISSIONER KENNEDY: What would that record do for whom, other than being interesting?

MR. BERNERO: In a malpractice suit.

COMMISSIONER GILINSKY: Well, if it were abused in some way.

CHAIRMAN HENDRIE: Well, you have a record in the other case.

MR. BERNERO: Yes, there's a record of the mis-administration.

COMMISSIONER GILINSKY: Except the patient doesn't get informed.

CHAIRMAN HENDRIE: If the patient is not informed, you know the information went from A to B and didn't go to C. So that's a matter of record.

MR. BERNERO: The record is there with the requirement to inform the referring physician.

COMMISSIONER BRADFORD: First of all, by whom are these kinds of issues handled with regard to other, non-radioactive drugs? Is this a Federally handled matter, or is it normally handled at the state level -- or not handled at all?

MR. CUNNINGHAM: They aren't.

MR. DIRCKS: It's a regulation of medicine which no one really has approached.

MR. CUNNINGHAM: As far as we can tell, there are ethical practices that physicians are supposed to meet. This is one of the issues, of course: Why is NRC getting into this business when no other field of medicine requires such reporting?

MR. BERNERO: We're uniquely deep into the doctor-patient relationship already.

COMMISSIONER GILINSKY: Well, not yet.

MR. KENNEKE: In this respect.

MR. CUNNINGHAM: In the way we regulate nuclear medicine, we are. As I said earlier, we're the only Federal agency that gets involved in the physician-patient relationship.

COMMISSIONER BRADFORD: What does the FDA do? Do they approve a drug for use and once it's approved it's fair game?

MR. CUNNINGHAM: Actually, FDA is tied to ICC

rules. What they do is approve -- their approval says the drug is labeled in accordance with the way it's going to perform; it's safe and efficacious if used in this dose range, for this purpose, with these indications, with these counterindications. It's allowed to be introduced into interstate commerce.

They have no direct regulatory control over the physician except in the case of investigational drugs, and there a physician is required to file an investigational plan.

MR. BERNERO: When we look to requiring misadministration recording and reporting, what we see that we would do with the information is look for some generic implications, misadministrations that may be a serious problem in many institutions and might call for some sort of publicity or advice campaign.

COMMISSIONER KENNEDY: Or an institution which seems typically to be involved in the misadministration syndrome.

MR. BERNERO: Then one can look to the licensee: Are the corrective actions appropriate? Is this licensee responding in a proper way? Do we see a trend here of perhaps sloppy practice, of too many misadministrations at one licensee?

These are valuable tools for the inspector, for

the licensing body to have this information for an individual licensee.

But we're not using the misadministration reporting or recording for a direct action with respect to particular patients. The focus is more on individual licensees or licensees as a class. The focus is not on the single patient.

COMMISSIONER GILINSKY: Do we have any idea of what the rate of misadministration is?

MR. CUNNINGHAM: I'll try to answer that. When this issue first came up, we looked at some studies that had been done in medicine. The misadministration rate, as I recall, was something like about 5 percent.

CHAIRMAN HENDRIE: This is generally.

MR. CUNNINGHAM: Generally. Now this can include such minor things as the nurse giving a pill to the patient before dinner instead of after dinner, giving the wrong pill to the patient, or very serious things, like giving the wrong blood type to a patient, which could kill you pretty quickly.

It covers a vast range of things, but it's somewhere around -- some estimate 5 percent and some estimate it as high as 12 percent.

We think nuclear medicine, because we have in fact been involved in this because of its special nature,

that probably the misadministration rate is much lower than that.

There have been some fatalities from misadministration of radiopharmaceuticals, however.

COMMISSIONER KENNEDY: Radiopharmaceuticals?

MR. CUNNINGHAM: Yes, sir. It has happened.

CHAIRMAN HENDRIE: Pharmaceutical overdose sort of thing?

MR. CUNNINGHAM: No. I could give you an example. Most of these are just human errors that are hard to explain.

One patient I recall a few years ago. One treatment for cancer patients is to give a colloidal phosphate.

CHAIRMAN HENDRIE: Oh, this is a therapeutic?

MR. CUNNINGHAM: Yes. And they gave the wrong -- they gave a soluble phosphate. So things like that happen.

Actually, hospitals aren't all that safe places to be. Avoid them if you can.

(Laughter.)

But we think that the misadministration for radiopharmaceuticals is low.

CHAIRMAN HENDRIE: If you feel ill, gentlemen, ask to be taken to your nearest nuclear power plant.

(Laughter.)

COMMISSIONER KENNEDY: We'd be safer than coal- or oil-fired plants, because the President of the United States

just said so.

CHAIRMAN HENDRIE: At least safer than hospitals.

MR. CUNNINGHAM: Well, things do happen, but we think the misadministration rate of radiopharmaceuticals is lower than the general average; but we can't prove it. We have no reporting requirement.

CHAIRMAN HENDRIE: Let's see, should we perhaps proceed onward with this briefing, which I suspect has not nearly run its full course?

MR. BERNERO: I would like to terminate the portion I've been covering and turn it back to Dick Cunningham to give you the broader perspective of how this relates to all the other medical policy things and things you're going to see in the near future.

MR. CUNNINGHAM: May I have the next slide, please?

(Slide.)

We can just wind this up in about 2 minutes probably.

There are some additional rule changes coming up. The teletherapy calibration rule was published as a proposed rule and will now be up to the Commission as a final rule.

Measurement of doses, there's a minor rule change.

Plutonium powered cardiac pacemakers -- again, this was a proposed rule and is coming to you as a final rule.

FDA recently -- well, within the last couple of years, I guess -- got new legislation over medical devices, which covers everything from sutures to heartpumps, to regulate medical devices in the same manner they do drugs. They're trying to get geared up to do this. It's a tremendous undertaking. When they do, we will develop some Memorandum of Understanding with them so that we don't overlap in our work. I would assume that they would be taking over some of the things that we are currently doing when they're properly staffed to do it.

And the qualifications of paramedical personnel is one that requires some more staff work to find out where we are on that.

CHAIRMAN HENDRIE: That comes up -- what? In terms of training, for instance, for nurses or laboratory technicians --

MR. CUNNINGHAM: Yes, sir.

CHAIRMAN HENDRIE: -- who may be preparing for administering these things?

MR. CUNNINGHAM: That is correct. Paramedics may be the technicians that run the scanners, the technicians and nurses that administer the drugs, people that do the

calibration work, or it may be a physicist who does the calibration on a teletherapy unit -- a whole raft of things.

CHAIRMAN HENDRIE: Isn't that establishment of qualifications much better placed in the professional groups in the field rather than fall under Government regulation?

MR. CUNNINGHAM: Certainly this is the opinion of very many medical groups. There are certification organizations. This is one of the issues we're looking at.

The question was originally raised by GAO in one of their reports. We think that a lot has happened with certification of paramedical people since that GAO report came out.

If our work finds that professional organizations are doing a job that appears to be adequate, we certainly don't want to get into it. Among other things, it will be costly for us.

CHAIRMAN HENDRIE: I was going to say, with the greatest affection and respect for our good friends in GAO, they do have a tendency to swing first, saying, "Boy, you ought to get in and really fix this up," and then five years later they come along and say, "What? You've got a thousand people working on this on the Government payroll? That's outrageous. How dare that happen!"

I think what we've seen is the first swing. And, sort of in line with some of the general thrusts of our

standards-setting activity, I would think we would be better off, if we're not altogether pleased with the professional group certifications, to encourage them to do a little better. If we are going to write anything into our rules that covered it, it would probably much better be to put some mild requirement that administerers of these things be certified by the professional group, but then on the other hand you would encourage the professional group to upgrade the standards rather than going into NRC licensing and testing and so forth.

MR. BERNERO: We don't want to add it to Part 55.

MR. CUNNINGHAM: Certainly, Mr. Chairman, this is the direction we're going. I hope to see within the next few years that we can get out of looking at physician requirements to practice medicine, also. We're moving in that direction. We have made progress, although our advisors say, "Don't do it yet."

MR. DIRCKS: I think we might want to mention some of the related issues.

MR. CUNNINGHAM: Oh, yes, there's one more slide, Mr. Chairman.

(Slide.)

There are some related issues, of course. There's the fertile women question.

COMMISSIONER KENNEDY: We discuss that once each

year at about this time.

MR. KENNEKE: In the spring.

MR. CUNNINGHAM: It's important here, because of that 30,000 population of workers under the medical licenses, a large percentage -- I suspect over 50 percent -- are women, which isn't typical of the other industries.

Transportation question -- very important. Medical pharmaceuticals, or radiopharmaceuticals must be transported on passenger-carrying aircraft. The half-lives of these materials are short. Cargo services in the United States just won't get them to the hospitals in time.

This is an issue that has been raised now and again. It is covered in the GEIS on medical transportation.

MR. BERNERO: Yes, NUREG 0170 identifies this.

MR. CUNNINGHAM: But it has been subject to a lot of question.

Then we have NARM, which stands for Naturally occurring Radioactive Materials. There is a question whether or not we should --

CHAIRMAN HENDRIE: Let's see, it's Naturally Occurring and Accelerator Produced Radioactive Materials.

MR. CUNNINGHAM: Yes. Some hospitals are going to greater and greater use of accelerators. We will see more of it, I guess, as time goes on. The agreement states have raised this question, and it will be something we will

be coming up to you with, with some recommendations.

And, of course, we have the occupational exposure. I left that for last even though it's first. We are trying to apply the _____ Principle to medical uses of radioisotopes.

I think that covers what we had, Mr. Chairman. We have the proposed policy for publication for public comment, and we have these two rules that Bob has gone over with you for publication for public comment.

CHAIRMAN HENDRIE: Al, I had a note that you want to make a comment on 68.

MR. KENNEKE: Across the board, Mr. Chairman, we think the policy statement is moving the Commission in the right direction. The staff job is well reasoned and fully sound, and, as Dick and Bob have pointed out, it's a continuation of a trend of thinking that's been going on for some time.

We would, however, point out that it seems that the reluctance to go beyond the diagnostic, changes with the diagnostic list, seems somewhat inconsistent with the policy statement you're about to issue, which is to say that you are going to minimize intrusion into the physician-patient relationship.

As Dick and Bob have both indicated, the residual

rules that would exist even after your approval of the changes to Part 35 will maintain a strong degree of NRC involvement in the physician-patient relationship by going beyond what FDA itself requires with regard to the use of these materials.

So you might wish to consider what more might be done or what further steps you might take to examine moving still further in the direction of being fully consistent with the policy you're about to issue.

The other point that we wish to make was on --

CHAIRMAN HENDRIE: I didn't understand that last one.

MR. KENNEKE: Assuming that you approved this policy, then the change that's being made to Part 35 --

CHAIRMAN HENDRIE: Perhaps doesn't go as far as you might want to go?

MR. KENNEKE: As far as the policy seems to indicate it would go.

CHAIRMAN HENDRIE: I see.

MR. KENNEKE: The other point that we would suggest might be looked at a little bit in terms of a few word changes in the policy statement is, to improve the response for the 90 or so commenters about the rule on misadministration, to better describe, as has been done here today and is done in Paper No. 70, the reasons why these

changes in fact don't intrude into the physician-patient relationship. We think in that case a somewhat better description could be provided to foreclose that. Much of the discussion that has gone on here is indication of that.

MR. CUNNINGHAM: If I may make a point, Mr. Chairman, as I indicated earlier, we do have a Medical Advisory Committee that is quite active in giving us advice. It assists us on applications and has guided us through a lot of these policy issues over the years.

In our consultations with not only that committee but with various peer groups that I have listed, one senses -- well, they state quite emphatically that they don't want NRC to completely withdraw from physician qualification, physician-patient relationship entirely, because that opens up the field of nuclear medicine to people who aren't serious about it.

Nuclear medicine has developed with tight control without these major scandals, and I think people recognize that. We are phasing out, but I don't think anybody that I've talked to wants it to be precipitous.

This policy will point us in the right direction, but it recognizes we aren't completely out of it yet.

CHAIRMAN HENDRIE: So you think in fact that, although indeed Al's comment is correct, that the Part 35 changes proposed do not back all the way out, but at this time

it's a little premature to do that.

MR. BERNERO: We're not ready to justify getting out of Classes IV through VI there.

CHAIRMAN HENDRIE: And with regard to improved language in response to comments, I take it you're always glad to receive suggestions for improved language.

COMMISSIONER GILINSKY: Let's see, the 98 comments were on what?

MR. BERNERO: The 98 comments were back on that '73 rule, which was misadministration and delegation of authority and qualifications of technicians.

COMMISSIONER GILINSKY: They're rather old comments?

MR. BERNERO: Yes, they're dated, and now it's a fresh slate. That history is available, but it is better now to have this singular rule on misadministration.

MR. DIRCKS: And we're going out for comment.

MR. BERNERO: All of this is proposed to go out for comments, and in a sense it's in light of this new proposed policy: Here's the correlary proposed rule for misadministration and the correlary proposed change to part 35.100. So we would go out for comment on all three.

COMMISSIONER GILINSKY: Who sits on your medical advisory group? Are they all doctors?

MR. CUNNINGHAM: Well, we have four physicians.

We're right in the process of rotating some members.

COMMISSIONER GILINSKY: No patients?

MR. CUNNINGHAM: No patients. These are chosen strictly for their medical credentials.

COMMISSIONER KENNEDY: Hopefully you'd have to rotate those pretty rapidly.

(Laughter.)

MR. CUNNINGHAM: The Advisory Committee has, I think it's six physicians really, one medical physicist, and we also have a radiopharmaceutical consultant plus another medical physicist consultant.

Incidentally, I think we spent $11 thousand in fees, services, travels to the meeting and everything last year for this committee, and I think it's one of the best bargains NRC gets.

CHAIRMAN HENDRIE: How much?

MR. CUNNINGHAM: Eleven thousand dollars.

CHAIRMAN HENDRIE: How much does it cost us to run the ACRS?

MR. BERNERO: No invidious comparisons intended.

CHAIRMAN HENDRIE: Let's see, we have your recommendation on the policy question and the publication of the proposed policy statement in the Federal Register inviting public comment and so on. This matter, I guess, is before the Commission at the moment.

MR. DIRCKS: Yes, sir.

MR. BERNERO: All three. There are three separate actions in effect.

CHAIRMAN HENDRIE: I'm prepared to have limited objective right at the moment.

Let me first ask about the 68, which is the policy statement that the Commission is concerned and does propose to regulate the radiation safety of patients where justified by the risk and where voluntary standards or compliance with these standards is inadequate, and to publish in the Federal Register the policy statement, statement of considerations, for public comment.

I wonder if it's at a stage where you might be able to vote it up or down or would like to consider further?

COMMISSIONER GILINSKY: I'd like to consider it further, just to get a better feel for what it implies for the other items.

CHAIRMAN HENDRIE: Okay.

COMMISSIONER BRADFORD: I was going to say something more limited in the same way, which is you can't separate it from Number 70 because Item 10 in here overlaps with the -- it contains a commitment to publish the misadministration standard concurrently. Or, if you published a different misadministration standard, you'd have to change

Item 10 in 68.

CHAIRMAN HENDRIE: Okay.

COMMISSIONER GILINSKY: On the misadministration paper --

CHAIRMAN HENDRIE: Well, I'm going to hold on a vote for that and ask for discussion on the other items.

COMMISSIONER GILINSKY: I notice that there are some offices that favor informing the patient, and I wonder if we could hear from those.

MR. DORIAN: There is one office that favors the veto procedure. It's the Legal Director's Office.

COMMISSIONER GILINSKY: Well, let's hear about that.

MR. DORIAN: We think that there will be more of an inclination for the doctors to tell the patients if something goes wrong if the NRC stands in the middle of that, that is, if we say please inform the patient unless the doctor thinks there is something wrong with that. If there is a veto relationship, the doctor would be more inclined to inform the patient.

COMMISSIONER KENNEDY: Why? That would imply his medical judgment would be affected somewhat?

MR. DORIAN: It might imply that we think --

COMMISSIONER KENNEDY: Isn't he going to tell the patient what he thinks is wise from the point of view

of patient care? Isn't that what his obligation is?

MR. DORIAN: He might think twice as opposed to simply dismissing it in a cursory way. He might be more inclined to think of it knowing that someone may be peering over his shoulder.

COMMISSIONER KENNEDY: I hope you guys don't come around when I have another case of heart surgery. I could die waiting for them to get around to deciding.

CHAIRMAN HENDRIE: Unless you propose that in making the veto you're going to ask physicians in general to sit down and develop elaborate briefs as to why they chose not to pass the information on. I presume that's not the intention -- or is it?

MR. DORIAN: The intention is that we don't want to make more work for lawyers on this one.

(Laughter.)

COMMISSIONER KENNEDY: You could have fooled me. I can't see who else it's going to help.

CHAIRMAN HENDRIE: If the referring physician simply decides on the one hand that "Yes, I'll pass it on, because the patient can know and it's not harmful to him," that's one way of doing it. On the other hand, if he simply says, "I decide to veto," unless you're going to require some elaborate -- let me take the word "elaborate" out -- some procedural step of substance on the veto side, I find

them indistinguishable and I find the former procedurally easier.

MR. DORIAN: Well, the idea was that -- to make the doctor think twice as opposed to simply thinking once.

COMMISSIONER GILINSKY: Well, let's see, isn't there a difference --

CHAIRMAN HENDRIE: I find it splendid that lawyers think doctors ought to think twice.

COMMISSIONER KENNEDY: I think doctors ought to think that about lawyers.

COMMISSIONER BRADFORD: I'm sure they do.

COMMISSIONER KENNEDY: More often, I would add, and with good cause.

COMMISSIONER GILINSKY: Well, suppose a doctor did not tell the patient and there really wasn't any good reason for not having done so.

COMMISSIONER KENNEDY: But is that our business?

COMMISSIONER GILINSKY: Well, it's a question of what the obligations are to a patient.

COMMISSIONER KENNEDY: Well, that's his business.

CHAIRMAN HENDRIE: I don't find in the Atomic Energy Act a requirement that we regulate physicians' obligations to patients.

COMMISSIONER BRADFORD: It's just in the public health and safety, I think.

COMMISSIONER GILINSKY: I mean, you're licensing that stuff, and it seems to me that telling people when the stuff is abused is a requirement.

Now, the only reason, it seems to me, for not doing it is in the peculiar circumstances when you're dealing with sick people and it may be in some circumstances more harmful to tell them. You could imagine circumstances like that. If it were not for that, it seems to me the obligation would be to tell them. That's the only factor here which would hold you back from insisting that the patient be told. And the question is how one deals with that situation.

MR. BERNERO: Perhaps I should have emphasized it more when I was talking on the subject. The distinction of our focus of attention in regulating nuclear medicine is on the prospective safety of the patient, to see to it that the patient is being treated by qualified people with appropriately selected procedures. When we look at misadministration reporting/recording and what-have-you, our attention is focused on prospective uses of it, to protect the next patient and the next one after that, and not on the carrying out of due process and justice for the patient who may have suffered a misadministration.

COMMISSIONER GILINSKY: Let's say there are releases from reactors. You could apply the same logic there. You could say, "There's a release; let's focus on preventing

the next release and making sure that people around another reactor are not going to be subjected to the release that people were around this reactor.

The fact is that some of these people are going to have heart conditions or whatever, and it may not do them much good to know that the reactor in their neighborhood had a release; yet we insist on telling them. I don't think the situation here is all that much different.

Now, it may be useful to put in some safeguards for special circumstances. But it seems to me the first obligation is to the party.

MR. KERR: Mr. Chairman, our office was one of those, also, who commented on this state program. We feel the patient should be informed in those cases where a report is to be made to NRC.

We feel the person that's most affected is the patient. He should know if the regulator is going to be told.

COMMISSIONER KENNEDY: That would argue equally for not telling the regulator.

MR. KERR: Perhaps. Now we also suggested in there that if the patient is not able to absorb the shock, in those cases where it might be injurious to his health, that a responsible relative be informed.

COMMISSIONER KENNEDY: There is a matter of patient relationship there, isn't there? If I understand

medical ethics, and maybe even the law -- and I certainly would not suggest that I understand the law -- I think the patient himself, if he's able to do so, would have to authorize a doctor to tell a relative.

MR. KERR: I think doctors do tell relatives a number of things.

COMMISSIONER KENNEDY: Some things. But there are well understood relationships which have to be carefully guarded there.

MR. KERR: I think our point is that the patient is the one that is the most directly affected.

COMMISSIONER KENNEDY: Someone has to decide which of those relatives is the responsible one.

MR. CUNNINGHAM: If I might go back just a little bit, we've come full circle on this issue before us. We have no reporting requirement now. We do have a limited objective with our reporting requirement, as Bob said, and that is to correct something before the next patient.

It is also true that something might be done for a patient after exposure. The way we developed this rule, it was not intended to specifically address that problem.

It has been discussed many times with our Advisory Committee, with all these peer groups, with the public in public meetings, and we get about as many ideas on how this

should be handled as people you talk to about it.

COMMISSIONER KENNEDY: What did the public say in public meetings on this point?

MR. CUNNINGHAM: Well, the public meeting was really two sets of people: the various medical practitioner groups was one segment of the public, and then strong state, agreement state mainly, representation. And I think it would be fair to say that the medical people aren't overly enamored with this rule, because it does put an obligation on them that they don't like particularly. They can point to things such as hospital ethics committees and what-have-you that address this very problem of what the physician should tell the patient and so forth.

The state, agreement state, people, I think Wayne Kerr just reflected the sentiment of the agreement state groups, who probably tend to -- would like to assert a little bit more control over the physician and the physician-patient relationship than we do.

COMMISSIONER GILINSKY: Are their comments included anywhere in your paper?

MR. CUNNINGHAM: They are. They're summarized in 60-68.

MR. DIRCKS: They're in Enclosure Number 3.

MR. CUNNINGHAM: Yes, Enclosure Number 3 has comments of various groups summarized -- page 4.

MR. BERNERO: And then Enclosure 3 of paper Number 70 has a summary of comments on the old rule.

MR. CUNNINGHAM: I think the point is that this rule as it is intended is to solve generic problems that may have resulted in these overexposures. It isn't intended to take care of the one patient that got overexposed specifically.

And, as I say, there are other --

COMMISSIONER KENNEDY: May I ask a question? The individual has been overexposed.

MR. CUNNINGHAM: Yes.

COMMISSIONER KENNEDY: What is necessary then is -- there are at least two things that I can think of. One is that he doesn't get further exposure, at least until some measurable period of time.

The second is, if circumstances suggest, he ought to get some sort of medical treatment.

MR. CUNNINGHAM: That's correct.

COMMISSIONER KENNEDY: Now, what does telling him do about either of those? The doctor would be the one who would give him the medical treatment, prescribe it anyway, wouldn't he?

COMMISSIONER GILINSKY: He might want another doctor.

MR. BERNERO: Yes, that's the point. The patient

would say, "You guys are butchering me. I'd better go somewhere else. It's that option that exists.

When we say report to the referring physician, the misadministration was an act of a therapist.

COMMISSIONER KENNEDY: Somebody else, that's right.

MR. BERNERO: When we say report to the referring physician, we take it away from the one who committed the fault and put it in the hands of the medical judge in the matter.

There is a secondary question of, "Well, you're the one who referred me to him for this treatment. Aren't you in some way responsible?" That's a rather derivative responsibility. We just don't consider it that type or grade.

MR. CUNNINGHAM: I might also add, for the medical management of the patient, whatever is done in most cases has to be done pretty quickly for the patient's benefit in the case of a misadministration, and all this reporting business to the referring physician catch up.

I think there was a case not too long ago where they gave a therapeutic thyroid dose to the wrong patient, and it did destroy -- or could have destroyed part of his thyroid. They had to give an injection of some blocking solution pretty quickly. Things would have to be done immediately.

COMMISSIONER GILINSKY: Well, presumably if you have to report to a patient, you're going to be more careful about administering these doses.

MR. CUNNINGHAM: I don't agree with that, Commissioner. I think that these hospitals do exercise controls. Again, if you look at how misadministrations occur, they are hard to explain. They just seem to be human errors. The things are difficult to explain.

We don't think that would improve the misadministration rate. It might improve subsequent care of the patient. I don't know about that. But I really can't believe, from what I understand of how these misadministrations occur, it would lower that rate.

CHAIRMAIN HENDRIE: Let's see, the inclination would be as recommended?

COMMISSIONER GILINSKY: I would go with the proposal concerning the reporting requirements.

CHAIRMAN HENDRIE: The veto option.

Peter?

COMMISSIONER BRADFORD: I'm inclined in that direction as well. Is there a way to publish 68 in a way that leaves -- the only thing standing in the way of publishing 68 is that Item 10.

MR. CUNNINGHAM: I'm sure we could split it out.

COMMISSIONER BRADFORD: There's probably some way

to --

COMMISSIONER HENDRIE: I think 69 is not controversial.

COMMISSIONER BRADFORD: No, 69 is no problem at all.

COMMISSIONER HENDRIE: That I know of.

COMMISSIONER KENNEDY: Why can't we publish both as alternatives and let the public comment on them?

COMMISSIONER BRADFORD: You mean on 70?

COMMISSIONER KENNEDY: No, 68, on Section 10, or whatever it is.

MR. BERNERO: We're requesting comments on the issue, and we could make it sufficiently conditional if it isn't already.

COMMISSIONER KENNEDY: What I'm saying is you have clearly inferred here, and in the staff indeed, there are two rather different views of this. Why not put them out to the public? What we want is public comment, so why don't we ask for public comment on those particular questions?

MR. BERNERO: In fact, as presently constructed it's not conclusive in Item 10. Item 10 is reporting to NRC, the patient, and/or the patient's physician. It's a string of options. It's sufficiently indefinite, I think, as to be inconclusive.

COMMISSIONER KENNEDY: Make sure the statement

of considerations -- that point is brought up. Why not do that?

MR. BERNERO: It doesn't foreclose anything.

COMMISSIONER BRADFORD: That's the language on page 2 of -- look at page 22, the last paragraph.

(Pause.)

MR. BERNERO: The last paragraph of the page?

COMMISSIONER BRADFORD: Yes.

COMMISSIONER KENNEDY: That's the statement of what they were proposing.

MR. BERNERO: It's a factual reference to what is there. We could emphatically alter this statement, this public statement, to make very clear our emphatic request for comments.

COMMISSIONER KENNEDY: That's what I'm suggesting.

CHAIRMAN HENDRIE: Depending on what one wanted to do -- let's see, one could rewrite that last paragraph on page 22 and not say that there is a new proposed rule for this reporting requirement elsewhere in the Register. They could say that the Commission is contemplating one of two general pathways: One of them as described here, and the other one in which the radiographer, whatever, report serious, reportable ones to the NRC and the patient unless the referring physician recommended against that.

COMMISSIONER KENNEDY: There you will have to put a statement in that Commissioner Kennedy disagrees. I don't think the radiographer ought to report to the patient at all.

If the matter is going to be reported to the patient, it seems to me it's got to be reported to the patient by the patient's doctor.

CHAIRMAN HENDRIE: We can't do it. We can't regulate down a whole tier of people.

COMMISSIONER KENNEDY: We can't have radiographers, who see a patient for 20 minutes on one day --

CHAIRMAN HENDRIE: They're the licensee.

COMMISSIONER KENNEDY: I know, but he has no relationship with the patient. He's a technician essentially as far as the patient is concerned. The patient doesn't even know this guy.

If the patient is going to be told that something has happened to him that may affect his health, it is his doctor who's got to tell him that.

CHAIRMAN HENDRIE: Well, that's a view when you're going out for public comment.

COMMISSIONER KENNEDY: That's right. If you want to say no, it must be the radiographer who's got to do it, all I'm saying is I insist that a statement be put in saying Commissioner Kennedy prefers the following, or suggest it as another option. That's all. I'm perfectly

prepared to get public comment on it.

CHAIRMAN HENDRIE: The proposal is to put it out as two options.

COMMISSIONER KENNEDY: No, you dropped an option, which is the option that was recommended in the first place.

CHAIRMAN HENDRIE: To the contrary. That was option Number 1.

COMMISSIONER KENNEDY: But that doesn't get to their option.

CHAIRMAN HENDRIE: Of course not. That's why I've got option Number 2. And we can comment and wrangle about this --

COMMISSIONER KENNEDY: We need option Number 3.

CHAIRMAN HENDRIE: -- and later on you can say you agree with this one or not, or with that one or whatever.

COMMISSIONER KENNEDY: I want three options, Mr. Chairman. I respectfully suggest. One is the option which they put forward in the first place, in which the decision to convey this information to the patient is entirely with the doctor, the patient's doctor, referring doctor.

The second option is the one that our colleagues are suggesting, a perfectly reasonable point of view, which is no, that referring doctor, having been told this, must provide the information to the patient unless --

CHAIRMAN HENDRIE: I'm sorry, that's not -- I don't

regard that within the proposition.

COMMISSIONER KENNEDY: That's what I thought their option was.

CHAIRMAN HENDRIE: Please hear me out. I would want ELD's opinion on that, and the General Counsel's, whether in fact this Commission through the Atomic Energy Act can regulate the general practice of medicine in that fashion. The referring physician is not a licensee.

MR. BERNERO: Excuse me, Chairman Hendrie, if I could interject.

What we're bogging down on here is more of a procedural question. We do indeed license the radiographer, whoever he is. That's the licensee. He is the one we can put a condition on: "You will do this and you will do that."

We would be having a requirement that he would report to the referring physician, and it is a procedural matter that, if we required him to report to the patient, it would be done in conjunction with the referring physician in some way.

It is clearly not sending this guy down into the room saying, "Guess what? I zapped you." It's a procedural matter.

We can't lay a license condition on the referring physician because we don't license him.

COMMISSIONER KENNEDY: We are now really in the

practice of medicine.

MR. KENNEKE: We're already there with the dose rate.

COMMISSIONER KENNEDY: This is going to put us there in a way we've never been.

MR. DIRCKS: It's a different cup of tea when you regulate dose limits than when you regulate the behavior of the physician to the patient. It's much different.

COMMISSIONER KENNEDY: A physician who is not the patient's physician.

MR. KENNEKE: You're already restricting the physician's ability to treat the patient.

MR. CUNNINGHAM: Wait a minute. Let's make one thing clear. We don't regulate doses to the patient.

MR. KENNEKE: You restrict them to the label.

CHAIRMAN HENDRIE: And we do license the nuclear medicine specialist, but we don't license referring physicians, who may be the general run of medical practitioners. You can't go out and lay requirements on people who aren't licensees.

COMMISSIONER KENNEDY: We can't interfere with their patients, either.

COMMISSIONER BRADFORD: To the extent that that was what I had in mind, I think you're probably right.

COMMISSIONER KENNEDY: I thought that's what you

did have in mind.

COMMISSIONER BRADFORD: I thought that's what I had in mind, too, but I hadn't thought of that wrinkle.

COMMISSIONER KENNEDY: The other wrinkle is a very serious one. That one I can understand. It's the other one I can't.

CHAIRMAN HENDRIE: It's an administrative problem in terms of how do you handle the regulation with the people, and I just don't see how to do it.

COMMISSIONER BRADFORD: I see the point, unless OELD or the General Counsel feels differently.

CHAIRMAN HENDRIE: You can lay a condition on the radiographer which says, "Radiographer, if there is a reportable incident, send a notice to the patient; however, before you do that, you send a letter to the referring physician. If you don't get one back that says, 'God, don't do that,' send it to the patient."

That's all a set of conditions you lay on the licensee, and you can do things through that.

COMMISSIONER KENNEDY: Can we see that, all that procedural matter written up so we'll know what we're talking about, please?

CHAIRMAN HENDRIE: I don't want to be ingenious and then find out we're now in some fashion licensing a quarter of a million general practitioners with regard to

their referring patients to --

COMMISSIONER KENNEDY: We're not doing that, but what we're doing is stepping into their practice.

CHAIRMAN HENDRIE: I think there's a problem just with the practical regulatory aspects of that.

COMMISSIONER GILINSKY: I'd like to have OELD take a look and see what they come up with.

CHAIRMAN HENDRIE: Well, with regard to being able to go forward here, we could either rewrite this paragraph to say the Commission will soon publish and not indicate what it is. That's Option 1.

Or the following statement, policy statement, could be published in the Register which would include both of these options, provided some reasonable procedural arrangement for the veto option could be worked out.

I don't have any objection to going either way, but having come this far and spending two hours on the briefing, and having raised our understanding sort of above some minimal threshold so we're beginning to grasp the elements, I hate to lose that. If we could indeed act to get these published here, that would be desirable.

MR. BERNERO: These are all proposed policy statements and amendments.

If we could commit to a clarification of that paragraph on page 22 of the following paper so as not to be

so definitive and that's all it is --

CHAIRMAN HENDRIE: Well, I think we could in fact decide which of the two ways that would leave the option open would be desirable. One way, as Bob says, would be not to in effect state the thrust of the proposed rule here but just to say that there will be soon published for comment a rule. That would be one way to handle it, and that would allow this thing to go.

I assume we could also do the 69 paper, too, since I think everybody agrees on that.

Now, the other way to fix this would be to say, "Look, we're considering two paths, and we'd be interested in comment." One of them is as written out here, and the other one is the one with the veto arrangement; however, that will require some language that ought to circulate back to us so we can agree it's a practical regulatory scheme.

COMMISSIONER KENNEDY: Who is it who has to render this veto in your scheme?

CHAIRMAN HENDRIE: The referring physician.

COMMISSIONER KENNEDY: The referring physician.

COMMISSIONER GILINSKY: Well, either one is acceptable to me.

CHAIRMAN HENDRIE: Any preference? Let me recommend leaving this in a form which says the rule will

be published, without -- and keep it general enough so that both these things fall under the umbrella.

I think the sort of thing that you could possibly note there, since it would be true in either case, would be that the referring physician would . . . .

MR. BERNERO: Addressing the issue. You know, the policy paper is not the forum wherein we ever intend to make the decision. It's addressing the specific issue, and this paragraph on page 22 associated with the policy should be speaking -- and a rule will be published addressing that issue, considering the range of options, words to that effect, without attempting to tip to a final balance. It's the wrong forum.

CHAIRMAN HENDRIE: Would you like to see that paragraph?

COMMISSIONER KENNEDY: The way Bob's talking about it right now, I'd sign off now without seeing it again.

MR. BERNERO: The paragraph would be altered so as to state that a rule will be published which addresses misadministration and attendant recording and reporting requirements, considering issues such as whether to report at all, whether to report to referring physicians and whether to report to the patients, but not by any stretch attempting to set up in this forum the decisionmaking.

COMMISSIONER KENNEDY: As far as I'm concerned, I don't need to see it again.

CHAIRMAN HENDRIE: Does it sound all right to you, Peter?

COMMISSIONER BRADFORD: Yes.

CHAIRMAN HENDRIE: In that case, with the understanding that page 22 will be thus perfected, and any other language in the proposed Federal Register statement will be also perfected to go with it, that that be done, may I ask for a vote of the Commission?

(Chorus of ayes.)

So ordered.

Before you go, and while you're in a voting mood, I recommend that we accept the staff recommendation in the 69 paper on that --

MR. BERNERO: Clinical procedure.

CHAIRMAN HENDRIE: -- clinical procedure.

(Chorus of ayes.)

So ordered.

MR. BERNERO: And you want 70 back with the --

CHAIRMAN HENDRIE: You'd better, then, circulate back 70 with this alternate language. I think you see the problem: Who can you tell what things to do? And let's try to keep in mind reporting requirements and so on and try to arrange these however we come out so that it's a

minimal procedural burden both on them and on us.

COMMISSIONER KENNEDY: Let us not forget that the purpose of this exercise is medicine, not reporting. Can we possibly do that?

CHAIRMAN HENDRIE: Look, if you're going to raise whole new issues at the last minute . . . .

(Laughter.)

Okay, I must say that I found the briefing on a subject that I'm not very familiar with, and it has a good many twists and turns in it, to be an exceptionally clear-cut one, a very admirable piece of work for which I congratulate all the staff concerned. It put the issues, I thought, fairly forcefully out in an understandable and simple way. I very much appreciate the quality of your work.

MR. CUNNINGHAM: Thank you, Mr. Chairman.

CHAIRMAN HENDRIE: Everybody else, I guess, can wander out and have a fine Thursday afternoon, but the Commission has to stay right here and carry on its labors through an affirmation session.

(Whereupon, at 4:40 p.m., the meeting was adjourned.)

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