
Public Hearing

before

ASSEMBLY POLICY AND REGULATORY OVERSIGHT COMMITTEE and ASSEMBLY HEALTH COMMITTEE

*“Testimony on cost-benefit, accessibility, insurance coverage of clinical trials
and the latest developments in pediatric and breast cancer research”*

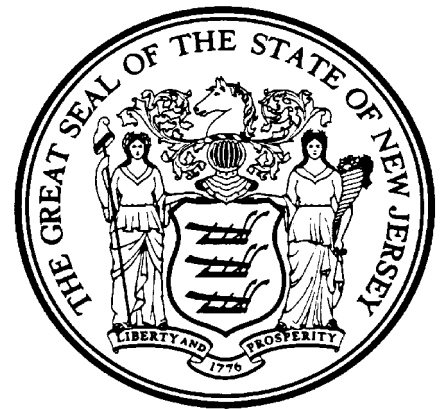
LOCATION: Auditorium
Hackensack University Medical Center
Hackensack, New Jersey

DATE: September 25, 1997
1:00 p.m.

MEMBERS OF COMMITTEES PRESENT:

Assemblywoman Rose Marie Heck, Chairwoman
Assemblyman Neil M. Cohen
Assemblyman Anthony Impreveduto
Assemblyman John V. Kelly

Assemblywoman Charlotte Vandervalk, Chairwoman
Assemblyman Nicholas R. Felice, Vice-Chairman
Assemblywoman Joan M. Quigley
Assemblywoman Loretta Weinberg



ALSO PRESENT:

Katharine A. Tasch
David Price
*Office of Legislative Services
Aides to the Committees*

Jon-Robert Bombardieri
Natalie Collins
*Assembly Majority
Committee Aides*

Dana Burley
*Assembly Democratic
Committee Aide*

***Hearing Recorded and Transcribed by
The Office of Legislative Services, Public Information Office,
Hearing Unit, State House Annex, PO 068, Trenton, New Jersey***

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ASSEMBLYWOMAN ROSE MARIE HECK (Chairwoman, Assembly Policy and Regulatory Oversight Committee): Ladies and gentlemen, we will begin. We are still awaiting several of our members, but since there are so many of you here at this particular time, we are going to begin the hearing with Dr. Rosenbluth of Hackensack University Medical Center, the Chief of Medical Oncology.

Doctor.

R I C H A R D J. R O S E N B L U T H, M.D.: Members of the Committee, ladies and gentlemen, on behalf of John Ferguson (phonetic spelling), President and CEO of Hackensack University Medical Center, on behalf of Northern New Jersey Cancer Center of whom I represent, I'm delighted to welcome you here this afternoon.

Just a few practical points, if I may. As you've probably noticed, there's a spread out there for those of you who wish to partake. The facilities are directly outside the door. Those of you who may have parked in the parking garage can pick up a parking voucher on your way out. Lenore will be sitting at the desk and will be happy to accommodate you.

And then a brief note of warning. At about 4:00, a whole bunch of elderly men will be showing up at our semiannual prostate cancer screen, so--

ASSEMBLYMAN KELLY: I'll be there.

ASSEMBLYMAN IMPREVEDUTO: Can I join? (laughter)

DR. ROSENBLUTH: I hope you'll be careful and not-- I hope there are as few of them as possible.

ASSEMBLYMAN IMPREVEDUTO: That makes two of us.

DR. ROSENBLUTH: Thank you very much.

ASSEMBLYMAN IMPREVEDUTO: Not too elderly, I hope.

ASSEMBLYWOMAN HECK: Ladies and gentlemen, this is a very important meeting we're having today and--

Charlotte, I'm going to ask you to open with your remarks, and then I'll go on to mine.

ASSEMBLYWOMAN CHARLOTTE VANDERVALK (Chairwoman, Assembly Health Committee): All right. Thank you.

I'm Charlotte Vandervalk, for those of you who follow these things. I Chair the Assembly Health Committee. Assemblywoman Heck and myself have had a series of hearings on cancer issues. We just feel that each one has been a real awareness -- really made some important strides and led to legislation. That's not our goal necessarily, but we feel an issue such as this needs to be addressed. There are so many issues related to it: incurring costs in clinical trials, what type of trials, who benefits-- One of the particular statistics that struck me, and I'll just share this one with you, is that when cancer is discovered in children, approximately 80 percent have already had advanced to such a degree that the cancer has traveled to distant sites in the body. That 80 percent compares to adults for 20 percent.

We have so many issues to look at. That one statistic tells you that there are so many variables, and we're not the technicians. We're not the people that can come up with these statistics, but we certainly are interested in them. We want to find out as much as we can about the subject so that we can do what we feel is best in the State of New Jersey and particularly with The Cancer Institute and its new designation. We think this is all important that

we work together on all different levels, and we really want to bring everyone together to hear the facts and move forward.

I particularly thank Assemblywoman Heck for really having a leadership role in this. Assemblywoman.

ASSEMBLYWOMAN HECK: Thank you. It's always a delight. We are the dynamic duo when we have these Committee meetings.

I have written remarks simply because I don't want to miss any important points and digress and noting that today is an important day for New Jersey's survivors of cancer and their families. Because the question on our minds happens to be "What can New Jersey do to encourage wider participation in clinical trials offered in New Jersey?"

The Assembly Policy and Regulatory Oversight Committee is holding this joint meeting with the Chair of the Assembly Health Committee, and we've done some good things in the past in areas that most people thought we were not going to be successful, but we've proven them wrong.

The hearing today will feature reports on the latest developments in pediatric and breast cancer research. Over 20 members of the public, cancer survivors, researchers, insurance and managed care representatives, hospital staff, and community advocates are here to testify today.

This is the third in the series of our joint hearings. According to the New Jersey State Commission on Cancer Research, the estimates nationally for all cancers indicate that 3 percent to 6 percent of eligible patients enroll in trials. The New Jersey Commission on Cancer Research estimates, from surveys of New Jersey's hospitals, that only 1 percent to 3 percent of eligible cancer patients enroll in clinical trials in this State.

The NJCRR Survey of Clinical Research Capabilities in New Jersey Hospitals indicated that 39 percent of reporting hospitals were involved in some clinical research and that 22 percent had plans to become active in clinical trials within the next year.

The Breast Cancer Summit Report highlighted the findings from the 1995 Summit. The numbers of breast cancer trials participation were very low. Although a number of breast cancer trials were available through New Jersey hospitals, only 174 women, or 2.5 percent, of all breast cancer patients within the State were enrolled in these trials.

Frankly, if New Jersey is so high in cancer rates, we must improve our participation in clinical trials. Since New Jersey is ranked first among the other state and regional registries of states in all female cancers, we must bring more women into clinical trial participation. We are third in breast cancer incidence for all New Jersey women. We are second in invasive cervix cancer for all New Jersey women. We are first for males and second for females in the incidence of bladder cancer. We are second for males and second for all females in the area of colon cancer. In fact, for all cancers, New Jersey ranks number one.

These figures were not created by me or by Charlotte. These figures were released by the New Jersey State Cancer Registry in April 1997, and they were reported in the *Cancer in North America, 1989-1993* publication. The chart is included in the informational package we have made available here today.

Our special thanks must be given to Ann Marie Hill, the Executive Director of the New Jersey Commission on Cancer Research--

Where are you sitting at, Ann Marie?

ASSEMBLYWOMAN VANDERVALK: Way in the back.

ASSEMBLYWOMAN HECK: Oh.

Donna Bocco at the American Cancer Society, Donna, and Dr. Mary Todd from The Cancer Institute: Thank you for all your help. All of you, you've been wonderful. We've been working on this for at least six months. I want you to know that this is not a spur of the moment event.

I hope this hearing will draw attention to what we need to do in the legislative and executive branches to encourage patient participation in clinical trials and to encourage insurance companies in these trials. We need more men and women to participate, so we can apply the knowledge gained from their cases and be proactive in our goal to help save more lives.

One final note, I am challenging insurance companies, manage care organizations, and public policy leaders to find ways to finance clinical trials. I believe this could prove to be an important step in our prevention efforts and search for a cure.

In an article entitled "Bottom Line, Culture Clash Impeding Cooperation of Managed-Care Organizations in Clinical Trials," a sad trend was highlighted. Author Myrna Watanabe quoted manage care organizations as claiming that "clinical trial expenses are not part of their responsibility to provide cost-effective care." Another issue of importance is figuring out who is responsible on the funding or not funding of clinical trials. To quote the article again, "To participate in some clinical trials, patients must undergo tests to ensure that they qualify for inclusion in the study." Usually the expenses for those tests are billed to the patients' medical insurers.

While researchers argue that such procedures will be necessary for any practitioner to make a diagnosis, MCOs counter that these tests are part of trials and are considered experimental and refuse payment. If this is so, it is time for a change. Are these things happening in New Jersey? That's what we need to know, and we begin that journey today.

We're going to open with--

ASSEMBLYWOMAN VANDERVALK: Just so you-- I'd like to make some introductions here, so you know who is with us. Assemblywoman-- These are members of the Health Committee. Assemblywoman Joan Quigley, and Assemblyman Nicholas Felice; and sitting on my left is David Price, who represents the Office of Legislative Services.

ASSEMBLYWOMAN HECK: And of course, to my right is a man who usually sits at my right in caucus, Jack Kelly, and a dear friend Tony Impreveduto, who is a member of the Policy and Regulatory Oversight Committee.

Now we will begin-- And of course we have our members: Jon-Robert is here, and a number of our aides, Kate Tasch, who's done a lot of research.

ASSEMBLYWOMAN VANDERVALK: Natalie Collins.

ASSEMBLYWOMAN HECK: We're going to begin with William Hait, who is from The Cancer Institute of New Jersey, Professor of Medicine and Pharmacology from UMDNJ-Robert Wood Johnson Medical School, who's been with us before and has done an excellent job.

Thank you very much for taking the time to be here.

WILLIAM N. HAIT, M.D., Ph.D.: My pleasure.

I hope I have chosen the right microphone.

ASSEMBLYWOMAN HECK: You have.

DR. HAIT: Distinguished members of the State Legislature, ladies and gentlemen, my name is Dr. William Hait. I'm Director of The Cancer Institute of New Jersey. The first ever National Cancer Institute-designated cancer center in our State. It is my privilege to testify here at Hackensack University Medical Center, one of our finest affiliates of The Cancer Institute, on a problem that's near and dear to all of hearts: the horrific problem of cancer in our State and the critical issue of reimbursement for clinical research.

As you already know, New Jersey is the most densely populated State in the nation: almost 8 million people living in 7500 square miles, or over 1000 people per square mile. New Jersey is arguably the most polluted State in the nation with over 108 Superfund cleanup sites and several thousand additional sites registered with Federal agencies concerned about hazardous wastes.

New Jersey, as you already heard, suffers with one of the nation's highest incidence rates and death rates from cancer, ranking, as you've heard, at the top or near the top for all the major malignancies despite our best available treatments. Approximately half of all adults diagnosed with cancer will die from this disease. In fact, in children, where we do much better, approximately 20 percent of our children will also succumb from cancer once they're diagnosed.

Therefore, I hope that we can all agree that there is a lot that we need to learn about the treatment of cancer. Let me be a little more specific. Lung cancer is the leading killer of both men and women from cancer. When

lung cancer recurs following surgery and/or radiation therapy, it is an entirely fatal disease. Standard chemotherapy or standard therapy, therefore, is not only noncurative, but only an optimistic reading of the literature suggest that chemotherapy for lung cancer meaningfully prolongs life or palliates symptoms. Yet treatment with standard care chemotherapy for lung cancer is paid for by almost every insurer. In contrast, if new treatments become available which show promising results in early trials, preclinical trials, or early clinical trials for lung cancer -- have been shown to be safe in these early clinical trials -- insurers will not pay for the care associated with receiving these new treatments because they are only available for clinical trials. Therefore, it seems that in certain instances the insurance company would rather reimburse for therapies shown not to work rather than to pay for a new therapy that may or may not work.

Well, why is this the case. Well, one answer that we hear is “Experimental therapies are too expensive.” Well, the facts are that most experimental therapies are given free of charge -- at least the treatments are free. And only standard medical care that a good physician would provide regardless of the type of therapy is being billed to the insurance companies.

Number two, we often hear that these therapies are “unproven.” Yet in many instances, as you just heard, insurance companies are willing to pay for therapies proven not to work or not to work very well. This reluctance to support clinical research on the part of insurance companies has a devastating effect on the war against cancer. Modern physicians are hassled enough by the forms and precertification issues imposed by manage care to begin to negotiate for every patient eligible to receive an experimental therapy. Patients are fearful of receiving experimental therapies, not only due to the

unknown about a new therapy, but also due to the fear of being shouldered with huge medical bills if their claims are denied.

The pharmaceutical industry out of frustration is already turning to European countries to test their new drugs, since it is easier to recruit patients onto trials outside of the United States. As a result, Americans will no longer be the first to reap the benefits of new therapies developed by U.S. pharmaceutical companies or, in fact, the New Jersey pharmaceutical industry. No longer will the best and the brightest physicians travel to the United States for training, because the newest techniques will be developed elsewhere.

Clinical trials come in four major varieties. I'll just mention three. A phase I trial is a design to determine the safety of the new drug that has not before been given to a patient. A phase II trial is designed to determine how effective a drug is using the safe dose. A phase III trial is designed to compare a new therapy to a standard therapy to determine if the new one is better. Often in oncology, phase III trials are designed to determine which of two standard treatments is superior.

A real frustration for many patients is to go to a doctor, and they say, "Well, we don't know which treatment is better, CMF or CAF, for breast cancer." And as I mentioned, it would be ludicrous to deny coverage for a phase III trial since the insurer would pay for the same treatment if the patient was not on the trial. Therefore, many patients with cancer, the only hope is in experimental trial. Put in another way, the best available treatment is often experimental treatment. For insurance companies to deny access to this type of care is to cut off any reasonable expectation of hope for many patients with cancer and, for some, to deny potentially effective treatments.

If this meeting were to last two and a half hours, 161 Americans would be killed by cancer, 11 from AIDS, and 6 from murders. Clearly, our standard therapies have not been adequate. The Federal government invests about \$2.3 billion a year in cancer research. Yet it spends over \$240 billion a year in Defense Department research. For us to begin to accelerate the pace of discovery, we as a nation must get our priorities straight. The State of New Jersey has taken the lead in investing in cancer research through the New Jersey Commission on Cancer Research and the New Jersey Breast Cancer Research Fund.

This year, the State Legislature approved the creation of a Let's Cure Cancer license plate, whose proceeds will go to support cancer research, but this is a drop in the bucket compared to what it will take to eradicate this disease. I hope that the outcome of today's meeting will be to educate New Jersey residents and our State Legislature about the impact of managed care on the war of cancer, and as a society, we all can strive to get our priorities in better order. Thank you.

ASSEMBLYWOMAN HECK: Doctor, that was a most inspirational statement. You have copy -- at least a copy that we can make other copies of?

DR. HAIT: I have a whole file of copies.

ASSEMBLYWOMAN HECK: We need them--

ASSEMBLYWOMAN VANDERVALK: Wonderful.

ASSEMBLYWOMAN HECK: --because the data in there is very, very good, and some of it I've never heard before. I think it's so important for

us, as you said-- Each one of us might have a little piece that will be a drop in the bucket. But if we all become participants, we'll fill that bucket--

DR. HAIT: Absolutely.

ASSEMBLYWOMAN HECK: --one drop at a time. But sitting around doing nothing is not the way to go. So that's why, I think, there are many of us here today and some whom have met with us before that we're counting on to add, perhaps, half a bucket.

DR. HAIT: Well, we appreciate that.

ASSEMBLYWOMAN VANDERVALK: If I could have one question for you?

DR. HAIT: Of course.

ASSEMBLYWOMAN VANDERVALK: Your discussion about the advantages that Europeans have with the clinical trials that we don't have here in New Jersey, is there anything in the works in the recent legislation that was passed this week in Congress that will affect that at all?

DR. HAIT: I'm not really sure. We actually are very privileged today to have Bob DeLap with us from the FDA, and he may be able to comment.

ASSEMBLYWOMAN VANDERVALK: Thank you.

DR. HAIT: You're welcome.

ASSEMBLYWOMAN HECK: Any questions from any of the members of the Committees at this point? (no response)

You've been given copies-- And thank you very much. You've always been such a great help to us.

DR. HAIT: My pleasure.

ASSEMBLYWOMAN HECK: I appreciate it.

We are absolutely privileged to have Dr. Robert DeLap, the Director of the Division of Oncology Drug Products, Center for Drug Evaluation and Research in the U.S. Food and Drug Administration.

I know that Charlotte Vandervalk is very happy that you are with us today. Thank you for coming.

ROBERT J. DeLAP, M.D., Ph.D.: Thank you very much for that kind introduction. I wish my mother was here. (laughter)

Assemblywoman Heck-- Excuse me?

ASSEMBLYMAN FELICE: Your mother wrote it. (laughter)

DR. DeLAP: Assemblywoman Heck, Assemblywoman Vandervalk, and distinguished members of the Committees, and ladies and gentlemen, I'm delighted to be back in New Jersey. I actually resided in this lovely State until 1990, when I moved down to the Washington area.

I am Robert DeLap. I am Director of the Division of Oncology Drug Products at the Food and Drug Administration, and it's our responsibility to monitor the development and marketing of products for the treatment of cancer. I have a statement that I think will just take a few minutes, and I hope you will indulge me. Some parts of this will--

ASSEMBLYWOMAN HECK: It's most welcome, that's why we invited you here.

DR. DeLAP: Some parts of this will not be directly addressing the subject at hand, but I think it's all relevant. So I appreciate your indulgence.

The U.S. Food and Drug Administration is responsible for ensuring that medicines are safe and effective for their intended uses and that

foods are safe, wholesome, and honestly labeled. FDA also has responsibilities for regulating vaccines, blood supply, medical devices, radiation-emitting devices, cosmetics, veterinary drugs, and animal feeds. In all, the FDA's regulatory agency is responsible for monitoring products that are worth about 25 cents out of every dollar spent by U.S. consumers, or a total of over 1 trillion worth of products.

In the area of development of new medicines and monitoring of marketed medicines, The Food, Drug, and Cosmetic Act of 1938 established the requirement for the premarket safety testing and approval by the FDA before a new drug intended for human use could be marketed. This followed a public health disaster involved with marketing of a product containing sulfanilamides in a toxic solvent which killed hundreds of people. The 1962 Kefauver-Harris amendments to the Act added the requirement that new drugs must also be shown to be effective before they could be marketed.

The Food, Drug, and Cosmetic Act prohibits the introduction into interstate commerce of new drugs that have not been approved for marketing. However, the Act allows for exemptions from this prohibition for new drugs that are intended solely for investigational use by experts so that they can test new drugs and see if they provide hope for patients for diseases that are not adequately treated.

I've provided some additional information to the Committee in my written statement, but I'm not going to go through the whole -- all those details in the interest of time.

In addition to monitoring the progress of clinical research studies, members of the FDA scientific staff routinely work closely with drug sponsors

to assist in the design of drug development plans and to assist in the development of individual drug studies that may be of critical importance to the final studies of the drug. This is especially true for new drugs that are intended for serious or life-threatening conditions.

When a research sponsor believes that sufficient data have been obtained in preclinical and clinical studies to show that the drug is safe and effective for treatment of human condition, an application is submitted to the FDA for marketing, and we review these data that are provided by the sponsor. We very often-- In fact, for cancer drugs, we routinely obtain the assistance of external scientific review panels constituted of cancer specialists from around the country so that we can give these data the best possible review and reach determination as to whether the product is ready to be marketed. If the data are deemed adequate to establish product safety and effectiveness, then marketing approval is provided.

We, at FDA, continue to monitor safety and effectiveness of products after marketing approval. There may be some rare adverse experience that are first observed after the drug is marketed. There may be important interactions discovered with other drugs or with other factors in the patient's environment or genetic factors. New uses of a product may be discovered, and we like to see those evaluated and included in the instructions for use of the product. We receive a large volume of reports from firms, health care providers, and consumers that provide information about the safety and effectiveness of marketed products.

We have what's called a Med Watch Program where we obtain a lot of information from health care providers and from consumers and, as an

example of that program, receives about 150,000 reports per year that we review.

Recent FDA activities pertaining to cancer include some presidential initiatives that are intended to improve and streamline our regulation of products used in cancer. We have also -- not my area personally, but the FDA has -- developed programs for inspection and certification of facilities that perform mammography to ensure good quality in this important screening modality for breast cancer. There has been implementation of nutritional labeling for food products, and FDA moves to regulate the marketing of tobacco-containing products, which I think all of us are very well aware of from media reports.

Again, additional materials pertaining to FDA and to our activities in cancer research have been provided for the Committee for review, as interest and time dictates.

I understand that the subject of the hearings currently is the issue of coverage for patients who are enrolled in clinical trials. Before addressing that issue, I would like to mention that FDA does not have authority in this area to regulate policies and practices of insurance companies regarding coverage of patients in clinical research studies. And I would add that to my knowledge, FDA has not taken an official position on these matters. I know that many FDA staff have taken positions of research advocacy, I would call it, but we don't have an official position on these matters. So the comments that I'm going to make today really relate more to my personal beliefs than to an official governmental position.

ASSEMBLYWOMAN HECK: We'll note that.

DR. DeLAP: Thank you.

I have worked in the field of clinical cancer research for around 16 years, including work in the academic sector in the Cancer Division at Georgetown University, as well as a Research Director for two major U.S. pharmaceutical firms that sponsored cancer research. I just have a few points that I'm going to make from, again, my personal perspectives about coverage for clinical trials.

I think the first point I'd like to make is for cancer patients. It's my belief that enrollment in a well-designed, clinical research study represents the best standard of care. It is a common observation in the clinical trials literature that study participants tend to do better than patients who are not enrolled in clinical studies.

My second point is that I appreciate enrollment in a clinical research study often results in additional expense. The additional expense may include costs of an investigational drug, costs of administering the drug, costs of additional tests and evaluations needed by the study protocol, and costs of data collection and analysis.

It's my personal view that these additional research costs that clearly would not have been incurred, absent participation in this study, should be considered the responsibility of whoever is sponsoring the research. It is also my opinion that the patient's routine health care costs that they would have incurred regardless of participation in the study protocol should continue to be covered by the patient's insurance plan. The fact that a patient has agreed to participate in a clinical research study should not absolve a patient's insurance carrier of responsibility of routine care costs.

I've provided some information for the Committee about charging for investigational drugs. In general, investigational drugs are donated by research sponsors. There are special circumstances under which companies may be allowed to charge for investigational drugs, and there is some discussion of that in the written testimony for the Committee. But again, in the interest of time -- it's a fairly detailed issue. In the interest of time, I think I will not repeat that orally.

There are just two other points -- I think, as Dr. Hait alluded-- It's not clear that coverage of patients in clinical studies cost more, less, or the same as coverage of patients who are not in clinical studies. Clearly, patients who are in clinical studies do not incur some expenses that they would have otherwise incurred. These patients are treated anyway. They receive some standard treatment, which is some marketed drug which may be quite costly. Some of the marketed cancer drugs are quite costly, and again, that cost is incurred if the patient is not enrolled in the protocol and is not incurred if the patient does participate in an investigation.

So, again, I don't know whether insurance carriers would pay more, less, or the same if there was a broad policy that they should cover the nonresearch-related costs from these patients.

My final point is that when patients are not enrolled in the clinical trial, again, they do still receive conventional treatment with marketed drugs. Aside from the considerations of whether there's any cost savings or not, as I just stated, it should be noted that patients who receive these marketed drugs or conventional treatment are receiving a treatment that is often known to yield unsatisfactory results. That is, if conventional treatment was so good,

there would be no need for the clinical research. Also, when patients receive conventional treatment, nothing of significance is likely to be learned from treatment of these patients. So, therefore, any benefit to future patients is lost.

In summary, my sense is that conventional treatment of patients rather than enrolling them in clinical trials is a poor way to use health care resources given the tremendous public health need for better treatments for most forms of cancer.

Thank you.

ASSEMBLYWOMAN HECK: Thank you very much, Doctor.

Any comments?

ASSEMBLYWOMAN VANDERVALK: If I may, I have-- Now, I want to state up front that I recognize that you're here in a particular capacity, and you may not have any control over the situation that I'm talking about, but I would like your thoughts on it.

I know of several individuals -- a doctor in one case and a small-business man in another case -- who have devices that they're trying to market, trying to get FDA approval, and they've hired attorneys who are expert in dealing with the FDA. But what they're saying-- I mean there are a lot of complications -- a lot of problems, as I'm sure you are aware. But the point I want to make is one of those problems is that they can't, even though they're dealing with experts, they can't seem to get a handle on exactly what is needed in the way of a trial, how many patients are necessary, what do they have to demonstrate, for how long a period of time. They can't nail down the specifics of what the FDA might be requiring, and they find this very troublesome. Obviously, this would lend itself to perhaps more trials in the future, more

costs, and a delay to those patients who could benefit from the end product. So I'm just throwing that out for your comment, if you will. Is this something you've heard before, or is this something new that, you know, surprises you? I've heard it from two separate sources, and I was surprised that there's this large gray area.

DR. DeLAP: It is-- The conduct of clinical trials to establish the usefulness of a new treatment is a very difficult-- It's a difficult area. There is a lot of variation from one person to the next in the course of their illness. So to understand what impact you've had on the course of a person's illness requires very carefully designed and conducted clinical trials.

We do work with research sponsors to the best of our ability to help them to design clinical trials that will answer the questions that need to be answered so that it can be understood whether the product or the device represents a true advance in the treatment of patients. Again, there are always questions related to -- are there special adverse things that can arise as a result of the product or the device? How does one evaluate those? There are adverse things that happen all the time, unfortunately, to people with these kinds of illnesses. So sometimes it is difficult to know if the product caused it or if it was just a natural course of the illness.

These are very complex areas. We work with-- It's our intent, and I will be the first to say that we do not always achieve that intent, but it is our intent to work with sponsors, particularly when we are talking about these key trials to get a product to the marketplace-- We try to work with sponsors to the best of our ability to get the best possible trial design so that they can get the best answer most efficiently, as possibly can be obtained.

I don't know that I can more specifically address this particular issue, but I know there is dissatisfaction periodically with these issues.

ASSEMBLYWOMAN HECK: Do you have a specific person or department that follows through on a structured trial or standards? Do you have one person who follows one specific trial from the beginning to the end--

DR. DeLAP: Each--

ASSEMBLYWOMAN HECK: --or does it just keep floating around?

DR. DeLAP: Each project has a designated project manager who is keeping track of what's going on with the company, what's going on internally at the FDA, as far as review to the product, to the extent possible. When we talk about scientific reviewers, we retain the same team, the same individuals for a given product throughout the course and development of that product. So we don't hand things off back and forth. Because, as the point that she raised, that that could be very--

ASSEMBLYWOMAN HECK: Damaging to the trial.

DR. DeLAP: --confusing and damaging. Yes.

ASSEMBLYWOMAN HECK: I think that Charlotte has brought up an important point, and now that we have met you, we'll be able to access him every time we get a question.

DR. DeLAP: Now, the folks at The Cancer Institute certainly know how to get in touch with me, and I'll be--

ASSEMBLYWOMAN HECK: One of the things that I was pleased to hear you say that we cover conventional methods, which we know are not really improving the well-being of a person. And then you said that

certain cancer patients would receive the best standard of care if they became involved in clinical trials. I think that's significant, and I think that's one of the reasons we're here today.

Now, have you heard of any other states moving aggressively in the area of coverage for clinical trials?

DR. DeLAP: I have not. I must admit that's not an area that I follow as closely as I might.

ASSEMBLYWOMAN HECK: Well, maybe we can find out through the course of our discussions with others.

I thank you very much.

Any questions? (no response) No.

Thank you very much.

DR. DeLAP: Thank you.

ASSEMBLYWOMAN HECK: Sherry and Ashley Boone, mother and daughter, pediatric cancer patient and parent, Hackensack University Medical Center.

ASHLEY BOONE: Hi. My name is Ashley Boone. I'm thrilled to be here with you. Tomorrow's Children's Institute has asked me to be here today to put a face on the problem of insurance funding of clinical trials.

In May 1996, I was diagnosed with acute myelogenous leukemia. Within two weeks, my doctors determined that I would need a bone marrow transplant. Because of the rapid progression of my illness and no family match, the only available option was a stem cell transplant from a baby's umbilical cord blood. This procedure has only been performed since 1988. The results are promising.

My family and I prepared for the ordeal of transplant physically and emotionally. My pets were sent to my grandparents' house. Mom and I arranged for home tutoring, and I looked forward to the day when I felt better again.

In late August, Mom and I sat in radiation therapy waiting for my first dose of radiation to kill my bone marrow. Dr. Gillio (phonetic spelling) and Mary Fleming (phonetic spelling), social worker for TCI, came and sat next to us. Dr. Gillio said, "Your insurance company is refusing to pay for Ashley's transplant." He assured us that radiation would begin the next day, that TCI would find funding, which they did.

The next day funding was in place, but our battle was not only with cancer, but with the insurance company. Dr. Joel Brockstein (phonetic spelling) took up the sword to challenge the insurance dragon.

I even wrote a letter to Hillary Clinton hoping that she could use her influence to change their minds. Three weeks later, after my transplant was well underway, the insurance company agreed to pay for the procedure.

Now, I'm a good patient, not very demanding. I do what I'm told. Had I not been a good patient, I would be pretty upset that my doctor was spending time with the insurance company and not with me. His place is to read lab results, not insurance statistics. One year later, as a result of the insurance company that called it unproven medical therapy, I'm here with you cancer free.

I attend Wallkill Middle School full-time, and I'm now missing eighth-grade honor science. I ride my bike and play with my cat and dog.

Some day I hope to return to Hackensack University Medical Center as an anesthesiologist.

ASSEMBLYWOMAN HECK: That's wonderful.

ASSEMBLYWOMAN VANDERVALK: Thank you for sharing that with us.

ASSEMBLYWOMAN HECK: Thank you very much.

ASSEMBLYWOMAN VANDERVALK: Good luck to you.

ASSEMBLYWOMAN HECK: That was a point well taken, and we're glad you came here today.

ASSEMBLYWOMAN QUIGLEY: I think, on behalf of the Committee, we should also commend you and your family for your bravery in pursuing the treatment and the insurance company.

ASSEMBLYWOMAN HECK: Assemblyman Cohen would like to--

ASSEMBLYMAN COHEN: Yes, after that nice presentation-- All the members on this Committee had supported me when I was trying to get through legislation, which ultimately did go through, which would require health insurance companies to require as part of their coverage--

ASSEMBLYMAN KELLY: Bone marrow.

ASSEMBLYMAN COHEN: --bone marrow cancer treatment. We added in, as part of it, the stem cell transplant. The Governor signed that two years ago. It only took me five years to get even that through.

ASSEMBLYMAN IMPREVEDUTO: And the death of a friend.

ASSEMBLYMAN COHEN: It generated out of a friend of mine, who had breast cancer, was supposed to go to the hospital, was approved to go

into a hospital in Boston for bone marrow cancer treatment. Forty-eight hours before she was going in, after preparing a long time for it, the insurance carrier called up and said they had changed their mind. And the hospital said, "Well, if you can't come up with \$60,000," which was then one-half of what the process was, "you would not be able to come to the hospital." Fortunately, between six or ten family members came up with money to at least put down the money for one-half to give her a chance at life.

Back then, in 1990, when I was trying to deal with this situation, I was told that the stem cell transplant process was not proven to be of any worth, and the insurance companies opposed that addition. Our argument then was that as things change with technology and scientific discoveries, the then \$120,000 cost for a bone marrow transplant procedure would ultimately save money over the long haul, in terms of the medication, chemotherapy, radiation, and other longer-term process of treatment.

Now the cost, at least as far as I know, is about \$60,000 to \$65,000 for a bone marrow transplant. In fact, Dr. Bacorra, I think was part of Hackensack, helped me on some things. Insurance companies have a profit line margin. That has to be dealt with from citizenry and from legislators. I mean, on the legislation we got through-- Charlotte Vandervalk, Nick Felice, who were then on the Health Care Committee, helped me a great deal, as well as Assemblyman Kelly and Assemblywoman Heck, to get this through. But what this points out is that what gave you the opportunity for a chance at life, five years ago, they were saying was foolish for me to include in a law. They didn't heed our warnings that this process through clinical trials would develop so that it would give people a chance at a much fuller life.

You're a very courageous little girl, and I wish you a full life.

ASSEMBLYWOMAN HECK: Very nice.

Anyone else? (no response)

Allan-- Dr. Allan Frutchik, I believe this pronunciation is, Chairman, Patient and Family Services Committee, American Cancer Society, New Jersey Division, Member of Board of Trustees.

A L L A N N. F R U T C H I K, M.D.: Thank you very much, Chairwoman--

ASSEMBLYWOMAN HECK: Pronounce your name for me.

DR. FRUTCHIK: Allan Frutchik.

ASSEMBLYWOMAN HECK: Frutchik.

DR. FRUTCHIK: It's a pleasure to be here and to speak here today. I serve two roles. One is as a private practitioner in the treatment of cancer patients as a Medical Oncologist and secondarily as a representative of the American Cancer Society.

Firstly, my experience with clinical trials has always been positive in that I have benefited immensely from the educational input that these trials allow one to garnish information from. Secondly, the patients have always benefited. In particular, even their pathology has been reviewed and changed as a result in participating in the clinical trial which has led to improved, high-quality care.

I'd like to share one brief example of an experience I've had with a managed care company recently. There's a 52-year-old woman who I'm treating now for advanced cancer that has involved her liver which is inoperable. She has been advised by myself to enter into a program that was

recently published in a highly regarded journal stating that this treatment at this time is the standard of care for this disease. Subsequently, I had to obtain approval from the managed care company before the patient could be admitted. I was told by the medical director that this treatment is experimental, and they will refuse to pay for the treatment. The patient could not possibly afford to be held responsible for the several thousands of dollars that this would require. After a heated exchange with this physician, they ultimately agreed to pay for this treatment. Subsequently, I might add happily, the patient is showing definitely clinical evidence of this treatment working at this point in time and is happy to be here to say that to me.

Now I'd just like to just address a few issues as a representative of the American Cancer Society. Firstly, the American Cancer Society and other experts believe that the average cost of care for the cancer patients enrolled in clinical trials may actually be lower than the average costs for those with the same cancer diagnosis who are treated outside the clinical trials. Anticancer drugs, as was stated earlier, are generally paid by the research sponsor rather than the third-party payer.

Secondly, there is not uniformity in State and Federal laws to provide for the coverage of patient care costs in clinical trials. The conflicting or unclear policies may discourage patients from participating in these trials because they are unsure of the costs that will be paid. Medicare beneficiaries face unclear and inconsistent guidelines on whether patient care costs will be covered when enrolled in the clinical trial.

The only state in the union that has thus far passed the law is Rhode Island, requiring private, individual, and group health insurance plans

to cover new and investigational therapies -- be provided during phase II, phase III, and phase IV clinical trials. The American Cancer Society is tracking 1997 legislation in four other states, Illinois, Massachusetts, New York, and Pennsylvania. California has also passed an experimental treatment law to provide patients with an appeals process to review their coverage of care while in clinical trials.

Thank you very much.

ASSEMBLYWOMAN HECK: Thank you very much, Doctor.

Do you have a copy of that to give to staff, so we can make extra copies?

DR. FRUTCHIK: Yes, we do.

ASSEMBLYWOMAN HECK: Thank you very much.

Any questions?

ASSEMBLYMAN IMPREVEDUTO: If I may, Madam Chairman.

ASSEMBLYWOMAN HECK: Sure.

ASSEMBLYMAN IMPREVEDUTO: I guess it's no great secret, and it been written-- I read it in the *Bergen Record*, and I read it in one of the papers here that one out of every three people will be diagnosed with some form of cancer at some point in time. I have had the unfortunate situation to lose my mother and her sister to breast cancer at age 60 and my father, six months ago, with prostate cancer. My brother has just been diagnosed with esophageal cancer and is currently undergoing clinical trials at Sloan Kettering.

I guess the question -- and I don't know if it should be directed to you or to some of the other oncologists -- is-- First of all, when it happens, I mean, the first thing you're in a quandary and you don't know what to do.

The first thing for the family and certainly for the patients is fright: "I want to get this thing out of me. I want to get started into doing something." And when you talk about clinical trials, then the next question comes. "Well, if I go into a clinical trial, is it a clinical trial whereby someone gets nothing and someone gets medicine? Is it something where someone gets a weaker medicine and someone gets a stronger medicine?"

I guess my question is: Is the patient ever in jeopardy of not getting the fullest of treatment in a clinical trial?

DR. FRUTCHIK: I think the answer to that would be twofold. Firstly, most clinical trials are clearly using an agent or agents that are either as good or better than the standard of care. I think that was alluded to earlier. So in no way would a patient ever receive inferior therapy. When there's absolutely no effective standard therapy that has any statistical significance in benefiting the patient's life, then it may be appropriate to have a new agent, say in the phase I trial, developed that will be compared to no treatment or the best supportive care. And this was a lead that came out of lung cancer treatment trials where patients were treated with only the best supportive care compared to chemotherapy. The trials seemed to indicate that the patients who received chemotherapy had a better quality of life. Obviously, we need a long ways to go in terms of drugs. But I don't think in any situation or scenario would a patient ever receive lesser-than-adequate treatment.

ASSEMBLYMAN IMPREVEDUTO: I guess the next question, logically following in my mind, is that we have spent -- the State of New Jersey, the United States, the public -- zillions of dollars on research for cancer cures, and we should continue to do that. Should we also be looking at -- and I

suspect that we are -- but maybe more attention needs to be paid on the early diagnosis of the markers. When your family is devastated, as mine has been, you want to go for body scans on a weekly basis. I don't even know if there is such a thing as that, if you go for a test and you say, "Look, my father had prostate cancer, I need to get the proper testing," or, "My sisters need to get the proper breast cancer testing." And there are some tests that I know that may not be exactly what the insurance companies want to see you get.

And I know that there are gag orders -- although those in the insurance industry will deny that-- I know for a fact that the gatekeeper in many HMOs are told to tell the patients that they are serving certain things and not other options that they may have, because those other options may be more costly. And I need to know for a fact if that is true. I've been told this. If anyone here can highlight that, I'd be very appreciative. I do have legislation in prohibiting that kind of thing. But that, if in fact is true, that's criminal.

DR. FRUTCHIK: I think the thrust today should not be centered just around trials related to cancer chemotherapy, but the American Cancer Society and, I think, others here will agree that clinical trials also includes early diagnosis and preventative trials. So that should encompass all of what we're talking about today, and I think that would address your issues.

ASSEMBLYMAN IMPREVEDUTO: Yes, I think the insurance companies need to look more at paying for well care and be ahead of the game. Preventative medicine oftentimes is better than trying to catch up to it later on.

DR. FRUTCHIK: Absolutely.

ASSEMBLYWOMAN VANDERVALK: Assemblyman, if I may just add to the question on the gag orders-- The recent legislation that was signed by the Governor, the Health Care Quality Act, which Neil Cohen and myself were sponsors, that prevents gag orders and goes further in saying that the doctor has a responsibility to tell the patient all forms of treatment, not only those covered by the insurance company. However, as proud as I am that that passed-- However, it does not cover every insurance policy in the State, because there are ERISA plans that are controlled -- the self-funded plans -- that are controlled only by Federal legislation. So, you know, there are two answers to your question.

ASSEMBLYMAN IMPREVEDUTO: Yes.

Thank you.

ASSEMBLYWOMAN HECK: Any other comments? (no response)

We'd like to welcome Assemblywoman Weinberg.

ASSEMBLYWOMAN WEINBERG: Thank you. My apologies.

ASSEMBLYWOMAN HECK: No problem.

Thank you very much, Doctor.

We have Dr. David M. Goldenberg, President, Garden State Cancer Center.

DAVID M. GOLDENBERG, Sc.D., M.D.: Good afternoon. I'm David Goldenberg, President of The Garden State Cancer Center, in Belleville, New Jersey.

ASSEMBLYMAN FELICE: Can you use that microphone, too?

DR. GOLDENBERG: I'm sorry. I'm David Goldenberg, President of the Garden State Cancer Center, which is an independent cancer research center in Belleville, New Jersey. I've been in New Jersey with my research group for 15 years. Originally, we were on the campus of UMDNJ in Newark, and we are now independent in our own facilities, supported approximately 95 percent by National Cancer Institute grants. I believe we're probably the highest-funded institution in New Jersey from the National Cancer Institute.

Our mission is really to develop new technologies to diagnose treatment. (audio feedback)

ASSEMBLYWOMAN VANDERVALK: I think you'd better push that away from you. (referring to PA microphone)

We've had a technician run to the back, so he helped out. Thank you.

DR. GOLDENBERG: Our mission has been to develop new technologies for the early detection and diagnosis of cancer, in addition to develop more selective therapeutics.

I'm very pleased to hear from the Assemblyman the question about earlier diagnosis. In your introductory remarks, you talked about the fact that most cases are diagnosed when they're very advanced. And yet, I agree, unfortunately, there is not enough effort being made to develop better and more specific detection and diagnostic approaches. I'd like to tell you a little bit, before I conclude today, about some progress we've made in breast cancer that is perhaps not very well known because our publication is under review now and it has not appeared.

I think our experience in developing new technologies is very relevant to the question here today. I've been engaged in cancer research for more than 30 years, and I've watched many different attempts to solve the very basic question of how does one develop and actually then fund quality clinical research. And I think one of the questions that you're going to have to resolve is, once we do get some reimbursement, who's going to judge what is quality clinical research. If every doctor in every hospital says, "I want to try this new approach," is that automatically reimbursable, or should there be some sort of standards or peer review as to what is legitimate clinical research? I, for one, find that that is going to be a very difficult task.

When we started our work in New Jersey, we had two to three clinical trial protocols approved by the NCI, National Cancer Institute, and the FDA, and this enrolled approximately 200 patients a year. These involved research protocols and colon-rectal cancer, lung cancer, breast cancer, and numerous other cancers -- the major killers -- and some rare tumors, too, for example, liver cancer in children, a very rare disease, but it was an area of extreme interest to us. We now have 15 protocols in operation, but we're only investigating 500 patients. Now, why is this the case?

First, one should clarify, as was already stated here, that there are different phases of protocols. There's a phase I, which is very early, and then there's a phase IV, which is when something is already proven to be efficacious. We are rarely engaged in almost exclusively phase I and II trials because every agent at our institution has been developed at our institution. It's not been taken from another company or another organization, but we are the innovators of our own technology.

Because of managed care, we went from a 70 percent reimbursement rate for the noninvestigative-related costs to today 30 percent. As a result of that, although we have perhaps seven times as many protocols -- all approved and funded by the National Cancer Institute and approved by the FDA -- we don't have seven times as many patients in these trials. So what was the solution if we were going to maintain our NCI grants.

I now have protocols in operation, stemming from The Garden State Cancer Center, in Germany, in Sweden, in Italy, and in perhaps three or four other countries where we are exporting technology and reagents so that we can get research results from patients in other parts of the world. Now, that's true international research, and I support that very much because some of the patients that come to us also come from other parts of the world -- as far away as India, as far away as Russia, and elsewhere -- and that's the internationalization of good science. Yet it is unfortunate that there are patients maybe 10 miles away from Belleville who are not getting access to this research, but there are patients that we allow to get into our protocols 3000 to 5000 miles away. And that is really an unfortunate dilemma.

And the problem is not only -- and I must be frankly honest with you because I've been in this research area so long that I have nothing to gain by not being frank-- It is only partly an issue of reimbursement. We, in the medical profession, have a problem of educating each other to foster more and earlier referral from the primary care physician, from the oncologist to the research center. We have to go out and actually proselytize our colleagues to try to get patients into clinical trials earlier, when we all recognize -- and you've heard testified today -- that the best care is often the research protocol. And

so we are very pleased that we have established an affiliation with the St. Joseph's Hospital and Medical Center in Paterson where we exchange patients and technology. We've set up a similar relationship with, in fact, the University of Pennsylvania, which is a comprehensive cancer center, because we can add something to what they can give to their patients.

But what I would like to see is a network of affiliations throughout New Jersey where, when you develop new technologies, when you do phase I and II trials, they can all participate either by establishing the resource in their own hospital or, if that's not feasible because of the nature of the hospital, referring the patient to the specialized center and then letting the patient go back home for management by their local physician so that the difficulties of being sent away from home can be avoided.

That's our mission and we're trying to do this in as many places in this State as possible. What I sometimes see-- It's easier to do an affiliation with the University of Pennsylvania, with Staten Island University Hospital, the New York Hospital in New York than with many local hospitals. And I ask myself, why? And I sometimes find out the competition within the medical profession, which has resulted from managed care, is also something we should all address and not only look to the question alone of reimbursement, because I think both need to be tackled.

Thank you. Sorry, I don't have any prepared remarks because I only knew yesterday that I would be here.

ASSEMBLYWOMAN HECK: Doctor, but if indeed you could just synopsise what you reported and send it to one of us, we'll make sure the entire -- both Committees receive it.

ASSEMBLYWOMAN VANDERVALK: Doctor, if I may just follow up on your comments. I think it's very sad, as you mentioned, that our local residents in New Jersey cannot avail themselves of these trials that Europeans are, and that goes to part of my problem with the way the FDA is structured. Now, with the proposed changes in law that are on the table right now in Congress, it seems to be, in my opinion, a very welcome change. But will this affect what you're talking about? Will it make the trials be located in our country as opposed to European countries?

DR. GOLDENBERG: Absolutely not. I'm sorry the FDA person left the room, because I would have loved to have a public debate with him since I've had debates with the FDA, publicly and privately. I have recommended and suggested, and it has not been, of course, adopted, but I think we need the political system--

I do not believe that phase I and II clinical research trials at reputable, academic institutions, that have certainly sustained peer review by the NCI, require FDA approval for those trials. I think FDA should get involved with phase III trials, trials supported by corporations that are developing new products. But academic institutions are being very much delayed in the progress they're making in all fields of medicine -- but particularly cancer research -- because of very onerous requirements that are really duplicatory to what we have as institutional review boards that are empowered by the NIH.

And so we have, as an NIH-supported institution, institutional review boards that involve doctors, ministers, lawyers, patient advocates to ascertain what is proper research. We then have to go through a FDA review

which can delay us sometimes years. And I have cases in my own clinic where we had a response, a major response, in an untreatable or relapsed lymphoma, and we had to go back to the FDA to ask for an amendment to the protocol because we didn't expect in the phase when we would get that response, and it took us three months to get an approval to retreat that patient who had an 80 percent or 90 percent disappearance of her lesions. She came to us from Georgia because there was no other place to go. I felt very badly that I couldn't get her retreated a month later because of this system. And if we don't attack this at a national level, we're spinning wheels.

ASSEMBLYMAN FELICE: Madam Chairperson, if I may?

Just a question, Doctor. What we're saying the bottom line is there's much more latitude for clinical trials by sending some of your technology and research to other countries.

DR. GOLDENBERG: Absolutely.

ASSEMBLYMAN FELICE: So you are getting a lot more input back from other countries that have that much more latitude that we could be doing here.

DR. GOLDENBERG: Without compromising the quality of medicine. The quality of medicine in Sweden, Germany, and the other countries that I referred to I know personally are outstanding.

ASSEMBLYMAN FELICE: Thank you.

DR. GOLDENBERG: I want to just close with one example that I mentioned about breast cancer. We do about 20 million or 30 million mammographies a year in this country. This is the finest approach for

screening and early detection, in addition to, of course, the Pap smear and cervical cancer.

We also have among that population about 1 million women who have an abnormal mammogram but is not abnormal enough to be called cancer. And there it becomes a dilemma, then, of what do you do, and about 750,000 or more go to biopsy. Without discussing the trauma, the emotional issue, the cost of that is about \$4000. We have been developing at our institution diagnostic tests to improve the, what we call, specificity or find out how many are really true negative that would avoid biopsy. We're just in the process of reporting that we have a true negative rate in those women who have an abnormality that you cannot feel, a nonpalpable lesion, of 97 percent. So we calculate that we could probably spare 500,000 unnecessary biopsies in this country if this methodology we're developing will finally become available, which in dollars means \$2 billion a year.

Now we are struggling to get this technology into as many clinical trials as necessary, funded, and so on. Everyone knows the efforts that you need to take to develop something, get it funded, and then go out and proselytize to your colleagues. But the point I'm trying to make is that this is not therapeutic research, it's diagnostic research. And because it's diagnostic, it doesn't have the appeal and the attention that many of the things we've heard about today. And I for one I am not an advocate of the next drug that is toxic, that has very little bit more effect, but to develop new technologies.

And that's why our institution is very focused on biological therapies using cancer-related or specific antibodies to deliver phytotoxic agents more selectively with less side effects, and the very same agents to do

earlier diagnosis where you can find lesions down to one or two millimeters, which are not found by current diagnostic methods. And therefore, we're very different in the sense that we are not interested in the next me-too drug that's going to have a little side arm that's a little different but will still give you some major side effects that will make life not as quality life, as we've heard about today.

ASSEMBLYWOMAN HECK: We appreciate all your testimony in moving into that area. But again, I would really respectfully request that you put this in writing so we can analyze it and take some action on it.

And thank you very much.

ASSEMBLYWOMAN QUIGLEY: Madam Chairwoman?

May I ask one question?

ASSEMBLYWOMAN HECK: Yes. Oh, yes.

ASSEMBLYWOMAN QUIGLEY: Doctor, I know you can't give us specific answers, but as a general statement, what happens to people while they are waiting for insurance approvals or for FDA approvals? If you've got somebody who needs to be treated or retreated within 30 or 60 days, and it takes 90 days or 2 years, how many of those people are suffering serious adverse affects?

DR. GOLDENBERG: Your question's very complicated. It's not a single question. Let me give you some answers to what I think you're after.

Patients who are able to find interesting protocols are already a selected group of patients. We have patients who find us on the Internet because our protocols are listed in various surveys. We have patients that are so wealthy, they can find anything going on anywhere in the world and then

select it. And then we have other patients who are just average-- I know someone just recently from Livingston, who is a dentist, who would not accept the ways that I told him we would have with the FDA, and he got on the phone, and he called someone about the third level below the commissioner. And I saw him do wonders, and I asked him, if he could survive his cancer, to please come work for me, because he made calls to get his own treatment changed overnight. And the very same physician at the FDA who told me, "No, we couldn't pretreat at this time," reversed it, and the next day told me we could.

So, if you are lucky enough to have either the political -- and you're an aggressive person and you will not demand a no, then you can overcome some of this. But the average person who doesn't have the resources, the capability, who is just lucky to be able to cope with the disease does not have this advantage. And anyone who tells you differently is not telling you the truth.

ASSEMBLYWOMAN QUIGLEY: I was afraid you were going to say that.

Thank you.

ASSEMBLYWOMAN VANDERVALK: Thank you very much.

ASSEMBLYWOMAN HECK: Thank you, Doctor.

Dr. Joseph Singer, Chief Medical Officer, First Option Health Plan.

JOSEPH SINGER, M.D.: Good afternoon.

Dr. Todd asked me to come to speak to you because of the relationships that First Option Health Plan has developed with The Cancer Institute of New Jersey and how we deal with clinical trials.

I cannot speak for other insurance companies, other HMOs, other managed care plans. I can only speak for how we look at things from the Medical Affairs Department at First Option.

We've come into a situation where the availability of new technology precedes documented appropriateness and efficacy of therapy. There are new drugs coming out on a monthly basis, and it is very, very difficult for us to really understand the benefit of some of these drugs. What we have done as an organization is we have developed consultative teams with The Cancer Institute of New Jersey, with people out at Fox Chase Cancer Center, and other organizations where, when our patients are requested to go into clinical trials, we send them for a second opinion.

Through the research we've done financially, I can't tell you whether it's more expensive or less expensive to treat a patient on a clinical trial with great precision. But anecdotally, it is not more expensive. People need to receive care. They need certain blood tests and X-rays. They need physician services. And whether it's done with a clinical trial or whether it's done with a standard "therapy," it's essentially the same.

It's my belief and with discussions I've had with Dr. Todd that it is probably less expensive to treat members in a clinical trial simply because there are very prescribed protocols of diagnostic studies that people go through. And they don't get an extra CAT scan or MRI here or there. It's a very well developed, very thought-out process.

We've had many, many patients go through phase II and III clinical trials at The Cancer Institute of New Jersey, at Fox Chase Cancer Center, at Cooper University Hospital, and we've found it's been a very, very reasonable and appropriate thing for us to get involved with. The biggest issue and my biggest concern is that patients get involved with the appropriate clinical trial. And that's the one caveat if I can offer any advice at all.

There are many, many physicians that are independent oncologists, independent practitioners that wake up in the morning and think that they have a new idea how to treat cancer. And these are individual events and individual hospitals. Unless something is really organized where we can do reasonable outcomes analysis to determine if in fact the course of a disease has been modified that -- we're really not doing individuals or the community, as a whole, a service. So what we have adopted as our decision-making guidelines is we look at whether there's any type of published literature that supports the stance of the clinical trial. We look for the trial to be part of an NCI or multicentric trial so that we know that a very sophisticated analysis will be done with the results, the data that are obtained from the trials. And then we allow our members to go through them.

ASSEMBLYWOMAN HECK: So you're using standards by which to cover those costs?

DR. SINGER: Correct. Correct.

At this point, we have the standard language and our certificate of coverage as most insurance plans do, but we go beyond that and really look to the quality of care and the outcomes that we can achieve.

Someone with a malignant melanoma that has very, very poor outcomes potentially-- You know, we've entered into different monoclonal antibody studies that are phase II clinical studies because--

ASSEMBLYWOMAN HECK: And cover those?

DR. SINGER: Yes. Fully.

ASSEMBLYWOMAN HECK: Assemblywoman.

ASSEMBLYWOMAN QUIGLEY: Madam Chairwoman, I'd like to know if Dr. Singer would be able to make available to the Committee copies of those decision-making guidelines. It might help us if we decide to draft up something later on--

DR. SINGER: Sure.

ASSEMBLYWOMAN QUIGLEY: --to know what's already in place.

DR. SINGER: Sure.

What we do is we review every case individually. We've got a group of six or seven full-time physicians at First Option, and then an advisory group of oncologists that we deal with on a daily, if not weekly, basis to discuss these individual situations. But basically, the requisites that we have are that it be -- there's some published literature justifying that we're not going to harm someone with these new drugs and that there's clinical and medical reasonable appropriateness that they'll do what we think they're going to do.

ASSEMBLYWOMAN HECK: Necessitates it.

Assemblywoman Weinberg.

ASSEMBLYWOMAN WEINBERG: Just out of curiosity, Doctor, when you say you review each case individually, how long does that review

take? And when you send people for second opinions, how long does that take?

DR. SINGER: I've got an agreement with Dr. Strayer (phonetic spelling) and Dr. Todd, The Cancer Institute of New Jersey, that I can have it done within five business days. As far as our organization, we can do these research and make these decisions, 48 hours. We're not talking about months. I mean, that's ridiculous.

ASSEMBLYWOMAN HECK: Yes, we agree.

DR. SINGER: It really is. I mean, the stress that you place an individual under is tremendous, and the amount of--

ASSEMBLYWOMAN HECK: And the damage done in the time lapse.

DR. SINGER: --progressive damage from the disease, depending upon which disease you're talking about, can be significant if you wait six months to do things. So an appropriate, timely response is what's critical.

Just to touch base on a slightly different topic, to facilitate the access to appropriate screening studies is very, very critical. The earlier that you identify a malignancy, the higher the likelihood of a successful response.

ASSEMBLYWOMAN HECK: It's refreshing to listen to you, Doctor.

DR. SINGER: I mean, in our organization, for example, with mammograms, we don't require preauthorization for mammograms. Some HMOs, insurance companies, women need to be 45 to start mammograms. As long as a physician feels it's medically appropriate, whether they're 18, 25, or 50, we honor that clinical response. You have to look at the diagnostic study,

the efficacy. There's no point in denying it. There's no woman in the world who would undergo a mammogram if she didn't need to have it done.

ASSEMBLYWOMAN HECK: Agreed.

DR. SINGER: For men with prostate cancer, it's fairly controversial where their PSAs are helpful or not in diagnosing prostate cancer and whether they add anything to the treatment. We have no restrictions on that. If we feel an urologist needs it done or family physician wants it done, they can do it. It creates some problems down the road because then we have to deal with studies that are borderline in how we deal with them. But access to early diagnostic studies is critical.

ASSEMBLYWOMAN HECK: That's wonderful.

Now are you giving us some written testimony, today?

DR. SINGER: I will. Unfortunately, I don't have it with me.

ASSEMBLYWOMAN HECK: Would you please?

DR. SINGER: Sure.

ASSEMBLYWOMAN HECK: We'd appreciate it.

DR. SINGER: And just outcomes measurement is the biggest thing that-- Really if you are going to set up criteria for people to mandate reimbursement for clinical studies to be involved with the national data analysis outcome study program is critical.

ASSEMBLYMAN IMPREVEDUTO: Madam Chairwoman.

ASSEMBLYWOMAN HECK: Yes, certainly.

ASSEMBLYMAN IMPREVEDUTO: In cases of very rare cancers like esophageal cancer, which is one of the rarer ones, there aren't too many people doing studies in that field. If in fact a person is going to a cancer

institute or a research institute like Robert Wood or Sloan or some of the others -- Columbia Presbyterian -- are you still requiring a second opinion?

DR. SINGER: It depends on where they're going, what the process is. When we have patients that go primarily to The Cancer Institute of New Jersey, I don't require a second opinion. If they go to Sloan, I don't simply because of the people that are cutting edge that understand the nature of the disease and therapeutics best. There are a lot of hospitals that are setting up their own stem cell programs -- community hospitals. It's a technology that's involved to the point where it's relatively inexpensive to set up nowadays. We have hospitals that are community hospitals that do not have fellowship programs in oncology there that are doing stem cell transplants in New Jersey. And if they're not part of an established protocol, I have great concerns about the quality care that's being delivered. If it's coming out of Columbia Pres., Sloan Memorial, Fox Chase, The Cancer Institute of New Jersey--

ASSEMBLYWOMAN HECK: Where the histories are known and available.

DR. SINGER: Exactly. I have a much greater level of comfort in dealing with those organizations.

ASSEMBLYWOMAN HECK: Is that it?

ASSEMBLYMAN IMPREVEDUTO: Yes, I just wanted to--

ASSEMBLYWOMAN HECK: Thank you very--

ASSEMBLYWOMAN WEINBERG: Can I just ask one more question?

How typical is what -- I know you said you can't speak for other insurance companies, but how typical is what you allow your patients to do with any other managed care company or insurance company?

DR. SINGER: I think it's fairly atypical.

ASSEMBLYWOMAN WEINBERG: Fairly atypical.

DR. SINGER: I think it's best that maybe you can -- I don't want to put pressure on her -- ask Dr. Todd or other people who are involved in the delivery of health care. But it is expensive therapy. Bone marrow and stem cell transplants, depending upon who's providing the service, can cost anywhere from \$40,000 to \$100,000.

ASSEMBLYWOMAN WEINBERG: Well then, why does your company decide to do it?

DR. SINGER: Because it's our belief that if you deliver quality care in an appropriate time, you're going to get better outcomes and it will be cheaper.

ASSEMBLYWOMAN WEINBERG: Just thought I'd give you a chance to give a little commercial there. (laughter)

DR. SINGER: I mean, health care is the type of thing that if people undergo complications of lymphoma or lung cancer or ovarian cancer or breast cancer, they're going to develop pathologic fractures. They're going to have other organ system failures. If you're going to treat someone aggressively, I'd rather treat them early on and appropriately for the primary disease.

ASSEMBLYWOMAN HECK: Thank you, Dr. Singer.

ASSEMBLYMAN KELLY: We'd like your card.

ASSEMBLYWOMAN HECK: He wants your card.

I'm going to announce the next three speakers so that you're aware of who's coming up. We have Dr. Michael Harris, who is the Chief of Pediatric Oncology and the Director of Tomorrows Children's Institute, and then Sally Roberts, a breast cancer survivor from Hackensack Medical University, and Paul Langevin, who's the President of the New Jersey HMO Association. Just to give you an idea, because we do have a number of other speakers.

Doctor.

MICHAEL B. HARRIS, M.D.: Thank you, Assemblywoman Heck.

ASSEMBLYWOMAN HECK: And congratulations on the great program.

DR. HARRIS: Thank you.

Before I begin, I do want to address one question about preventive and prevention in early diagnosis. The Pediatric Oncology Group, which is one of the large multi-institutional cooperatives in pediatrics that treat children with cancer, have something called the Lag-time Study. Lag, as you can imagine, is the lag in diagnosis in children with cancer. It was made mention before that many children are present already with metastatic disease, and that makes our job that much more difficult in treating these children. The study is spearheaded by the statistical office of POG and Beverly Ryan (phonetic spelling) of our institution. We are finding amazing discrepancies in the way we would like children to be diagnosed early and to what are the warnings signs for parents to grab hold of, and even to pediatricians. So that is one way

we are a large national cooperative with careful data collection, which of course does cost money-- Can help in the problems that you've mentioned. Of course, you were more concerned about adults, but obviously in pediatrics, we're very much concerned about that.

The second comment I'd like to make is following Ashley Boone is a very difficult task. So I ask that if I ever do this again, have me speak first and let Ashley speak second, because she certainly I think gave tremendous--

ASSEMBLYWOMAN HECK: She was wonderful.

DR. HARRIS: --testimony. And it's a testimony to her courage and the courage of all the children that we treat in pediatric oncology.

And third, I guess I'm here to tell a fairly happy story in pediatric oncology. For, after all, we cure many more children than we don't. I think that's why it's very important for us to listen carefully to this, so we can gain some insight on how we got to where we are today. Because I believe in listening to this, I hope that our adult colleagues will hear the message on the importance of clinical trials and putting their adults on clinical trials and also for support of both the State, the Federal government, and of course many of the insurers to support these clinical trials. At the present time, the literature doesn't support some of the trials that we're doing, because we are writing the literature as we go along.

Each year approximately 11,000 children, adolescents, and young adults less than 21 years of age are diagnosed with cancer. Twenty-five years ago, 70 percent of these patients with cancer died. Today, 70 percent are cured. Yet despite these gratifying results, cancer remains second to accidents as the leading cause of death in children less than 15 years of age. As an aside,

10 percent of all deaths in childhood are secondary to cancer. One percent for instance is secondary to HIV.

Furthermore, the incidence of cancer in children is increasing. In a report compiled by the Surveillance, Epidemiology, and End Results, the SEER Program, it was noted that between 1973 and 1988 there was a 4.1 percent increase in the overall incidence of childhood cancer among whites. These data needed to be balanced by the fact that by the year 2000, 100,000 school children will be survivors of childhood cancer. It is further estimated that by the year 2000, one out of every 900 and, by the year 2010, one out of every 245 adults between the ages of 24 to 45 will be a survivor of childhood cancer. With these statistics as a background, let us take a quick look at how and why the cure rate for children with cancer increased and then glimpse into the problems and hopes for the future.

As an aside, I apologize. I edited something out in the interest of time, but I would just like to state that the history of modern chemotherapy began in treating acute lymphocytic leukemia and the landmarked studies Sidney Farber (phonetic spelling) in 1950 when he wrote a manuscript -- he and his colleagues in the *New England Journal of Medicine* -- that stated, "The cure of childhood cancer with methotrexate." And acute lymphocytic leukemia was the model, and using methotrexate they were able to "cure 50 percent of children with leukemia" at that time. That 50 percent of children went into remission. Our exultation was short-lived in that all those children within six months to a year succumbed to their disease with a recurrence. But that was a very important study, because it gave us the first inkling that we could clear the bone marrow of leukemia cells. From the 1950s until the present, steady

progress has been made. And now approximately 75 percent of children with acute lymphocytic leukemia will be cured.

The success that has been achieved in acute lymphocytic leukemia is mirrored in the treatment outcomes in non-Hodgkin's lymphoma; Hodgkin's Wilms' tumor, a tumor of the kidney; osteosarcoma; Ewing's sarcoma, which are tumors of the bone; and rhabdomyosarcoma, which is a tumor of the soft tissue.

The improved outcomes of these patients were attained by carefully controlled multi-institutional clinical research trials carried out by the National Cancer Institute-sponsored national research cooperatives that are comprised of centers that treat childhood cancer. The two major research cooperatives are the Pediatric Oncology Group and the Children's Cancer Group. The individual members of these groups include pediatric oncologists, surgeons, radiation oncologists, immunologists, molecular biologists, geneticists, pharmacologists, cardiologists, diagnostic radiologists, psychologists, statisticians, nurses, and clinical research associates.

These individuals banded together when they realized that it would be impossible to discover better treatments for children with cancer in single institutions due to the relative rarity of the diseases being treated. It was recognized that there would be a far better chance in enhancing treatment results by entering large numbers of children onto the research studies. These cooperatives now test various hypotheses, test new drugs and schedules of chemotherapy administration, surgical and radiation therapy techniques on children with cancer in order to cure as many children as possible and unravel

the secrets on the causes and prevention of these devastating childhood illnesses.

This research is vitally important in our efforts to cure all children with cancer and to begin to address the prevention of these diseases. Ninety-four percent of all children diagnosed with cancer in the United States are treated at institutions that belong to one of these two groups. The success that has been attained over the last three decades can be attributed in large measure to the dedication of the personnel at these centers and the courage of the patients and their families. Indeed, there have been several studies that confirmed that children treated on protocols at pediatric cancer centers do far better than children who are treated by physicians who do not participate in these studies. This experience has the impetus for Blue Cross and Blue Shield to join forces with the CCG and POG to develop guidelines for the care of children with cancer. I believe that the pediatric experience should be used as a model for adult oncologists and encourage them to enter more of their patients onto national studies.

Not everything, however, is going well. First, brain tumors which are the most common solid tumor in children, comprising 20.7 percent of all cancers diagnosed in children, and advanced stage neuroblastoma, a tumor of the sympathetic nervous system and the second most common solid tumor in children, remain among the most difficult tumors to treat. The majority of children with these tumors die.

Second, at least one-quarter of the children who are cured of their disease have long-lasting effects from cancer and its management. Among these late effects are cardiac, pulmonary, and renal damage; infertility; growth

disturbances; learning disabilities; physical limitations secondary to mutilating surgery; and an increased risk for second malignancies.

Third, there is an apparent increase in the incidence of childhood cancer, especially in leukemia, brain tumors, and lymphoma. The causes of this increase are not known.

In summary, the progress in childhood cancer over the last three decades has been very gratifying, but still more than 3000 children and young adults die annually. The advances made can be directly attributable to careful clinical research, performed chiefly by POG, CCG, and its predecessors, along with their affiliated institutions. As we enter the next millennium, prevention and treatment need to be our primary goals. Thus, support must be given for carefully planned research studies into the causes of childhood cancer in order to learn how to prevent these illnesses. Finally, we need to be given the wherewithal to continue our research to discover better treatment modalities for children who develop cancer with the goal of curing 100 percent of these precious children while eliminating the long-term effects that color many of these children's lives.

I thank you.

ASSEMBLYWOMAN HECK: Thank you, Doctor.

Assemblywoman Weinberg.

ASSEMBLYWOMAN WEINBERG: Yes.

Doctor, this past week there was a hearing down at the State House in Trenton run by a group of environmental organizations and former Congresswoman Bella Abzug about the possible causes -- links between the environment and the causes of cancer. And I noted in your testimony where

you talk about an apparent increase in the incidence of childhood cancer. Is there funded research going on as to what these causes are, whether or not the environment plays a role, and how are we ever going to try to find out what's behind all of this?

DR. HARRIS: I think up to this point, there has been very little funded research into the epidemiology of pediatric cancer as opposed as to the epidemiology of adult cancer. I believe that the playing field may be changing a bit because of the problem, for instance, that we have in New Jersey and in the Toms River area. But we have to be very careful when we assume that clusters of illnesses, such as occurred in the Toms River area, actually mean that there are environmental causes in that area. There are so many other reasons why one can have an increase in a cancer incidence, be it demographic, be it genetics of the people living there, the trend to live there, etc.

ASSEMBLYWOMAN HECK: Occupation.

DR. HARRIS: Occupation, etc. But there is no doubt that we believe that there are certain environmental hazards that we do not know, things, for instance, like high-tension wires has now been proven not to be correct. And yet if you ask anybody five or six years ago, at least on the studies that we're doing now, it doesn't mean that we eventually won't find that everybody would have sworn that this is a very, very important issue-- One of my patients who lived near a high-tension wire was one of the spearheads in the State, or at least at a local level, to try to get to the bottom of this because she was convinced that her son had developed a rare disease in childhood -- and rare in any rate -- a malignant thymoma, secondary to the area where she

lived. But I honestly believe that there are two areas besides everything else that we need to pay very careful attention to. If I may just--

ASSEMBLYWOMAN HECK: Certainly.

DR. HARRIS: One is to what you're bringing up: I think it's extremely important and imperative that we look into the causes and the epidemiology of childhood cancer just as it is for adult cancer. The second are the late effects that are now occurring. The NIH is now -- finally recognizes the NCI. They do have a late effects program out of Meadows-- Is heading at the NCI, and it is extremely important because, when you cure a child with cancer, you want them to have a happy and productive life. You don't want a child, as I once heard Dan Geo (phonetic spelling) tell a audience -- jeez, I'm getting older -- about 25 years ago when I was a young kid, I guess-- But I remember him getting up and saying that the greatest fear he has -- and this was before we were curing how many children we are curing now -- that a child will come to him who is now a young adult and look at him straight in the eye and say, "You should have let me die."

I believe that we must address the long-term effects that we are causing on these children. Remember, children are growing individuals right through the age of 21 and 22. Some of my adult colleagues will probably stab me and say, "That's our purview." But certainly, we believe through college at least we should take care of these children, but then again, I guess, I'm an aggressive guy.

I think that in all honesty these children are growing individuals, and the things that we do on them on a physiologic level because of their growth and psychological level as they are maturing and they are becoming

adults and autonomous individuals -- the price we pay is enormous. And I said a quarter and some of my colleagues may say a third. I'm always very conservative in anything that I will project. It's probably higher than a quarter, I said at least a quarter. You have to have to come to our long-term follow-up clinic that we hold here or any long-term follow-up clinic in any major pediatric oncology program.

These kids walk in with real problems and there is not enough money that addresses their problems now. The insurance companies are not interested in paying for the services and the developing clinics. You can't treat these children in one office here and one office there and one office there and one office there. You need the body of experts who are interested in this problem getting together and having people say that is a diagnosis that we will support and we will support the treatment that the cardiologist and the pulmonologist and the psychologist and the endocrinologist and everything that you need to get through -- to the urologist for infertility or whatever you -- or the gynecologist for-- Anything that you can think of have to band together. This costs money. But I will tell you that if we spend the money now -- literally now -- we will save hundreds of thousands of dollars in the future. And I guess the problem in the United States is we are always looking at what is the quarter. That's the way we always look.

ASSEMBLYWOMAN HECK: That's not what we're looking at now, Doctor.

DR. HARRIS: The three months, what did we do with the three months?

ASSEMBLYWOMAN HECK: That's not what we're--

DR. HARRIS: Not this assembly, please.

ASSEMBLYWOMAN HECK: Oh, okay.

DR. HARRIS: I'm very happy you're here. No. No. No. No.
Please.

ASSEMBLYWOMAN HECK: That's one of our purposes in
getting together today.

DR. HARRIS: But our purposes are to look-- Believe me, that's
why I'm very happy to state this.

I apologize. This is not any criticism to--

ASSEMBLYWOMAN HECK: No. No. No. I didn't take it as
such.

DR. HARRIS: Okay. But that's--

ASSEMBLYWOMAN HECK: I just wanted to give you a ray of
hope.

DR. HARRIS: That's right. Thank you.

This is something that we need to address for the future. We are
looking for the long run. We're not George Steinbrenners who want to win a
pennant every--

ASSEMBLYWOMAN HECK: No quick fixes.

DR. HARRIS: That's right. There's not a quick fix. This is a very
long fix. I'm sorry to have taken so much time.

ASSEMBLYWOMAN HECK: No. No.

DR. HARRIS: But that is a very good question--

ASSEMBLYWOMAN HECK: Doctor, it's very important.

DR. HARRIS: --and something that is obviously is very dear to my heart.

ASSEMBLYWOMAN HECK: Well, when we held our first meeting at Bergen Pines, we had invited the representative of Bella Abzug who believes that this has an environmental genesis to the hearing. We have since then promoted all of those things.

Charlotte and I are very interested in the total picture. We've received a lot of information since that time. But I did want to add, before you left, that a week and a half, two weeks ago, I had called the Health Department -- and Charlotte knows about this -- because of the report that came out to ask that we have the ASTDR come into the area to discuss. I was notified today that there will be an open house of local counties, State, and I believe Federal officials in our area for the Rochelle Park, Lodi, Maywood people so that all of us can go in -- just a meeting, an open house -- to get information from a variety of people so that we can educate ourselves. It's so important to disseminate legitimate information and not just frighten. We have to look at a positive response to the happenings of the area, of the State, and of the nation.

But what you're doing here in my estimation is phenomenal, because you've come a long way. I mean every day I hear such wonderful things, Charlotte and I. That's one of the reasons we're here, right Charlotte? We've heard that you're the best. This is the best treatment center around. And Ann Marie Hill -- I don't know where you are hiding again -- but Ann Marie Hill has told us so many wonderful reports on how she has bragging rights to all the things you do. But I thank you very much, Doctor.

ASSEMBLYWOMAN WEINBERG: Assemblywoman.

I just want to maybe reiterate what the Doctor said, that there are two areas that really need more funding. Now, I know what you talked about in terms of Maywood, Rochelle Park, and Lodi. That's obviously of big import to those of us who are involved in that area. But what I'm talking about is really kind of bigger. We don't know whether it is an environmental cost.

ASSEMBLYWOMAN HECK: We already understand that. That's why we're having these hearings, Loretta.

ASSEMBLYWOMAN WEINBERG: And there is no research-- There isn't research being done and just -- I don't mean to minimize doing this-- I'm happy to be here. I'm happy that you've called the hearing, and I'm certainly happy to hear from people like Dr. Harris.

What I would like to see us do, though, is come together and maybe get some kind of an action plan. This is about the third or fourth over three or four years that I've attended where we had the Breast Cancer Summit, these kind of hearings to talk about how are we really going to fund research to find out whether the environment -- I'm not saying it does-- I mean, I'm not a professional in this field. I don't know if it does or it doesn't, but we sure should start finding out when we start seeing incidences of this tremendous increase in childhood cancer. It's generally not from smoking, drinking, and driving too fast. We should be finding out why these kids are getting sick, and that's-- We should be putting money there. And you pointed up a subject that I was not aware of certainly -- money into the long-term studies of what happens to these kids after, thank God, you've cured them, but then there could be another whole host of problems as they become adults.

Those are some of the areas, I think, we have to find out. Where do we get the resources, and then if we have them, how do we put those plans into action?

ASSEMBLYWOMAN HECK: Well, possibly a national health care plan.

Doctor, thank you very much, but again, we're focusing on clinical trials which is a very big step in the right direction. This is only, as the Assemblywoman stated, a series of reforms that we're looking for, an action that we've taken. As you know, we've put together the mastectomy bills and the reconstructive surgery bills. So these are not just talking kinds of meetings. We want results, and we do it one step at a time.

But thank you very much.

DR. HARRIS: We thank you for listening to us and thank you for your interest.

ASSEMBLYWOMAN HECK: We're focusing on clinical trials today. Thank you.

We have Sally Roberts. Sally Roberts, breast cancer survivor; then Paul Langevin.

SALLY ROBERTS: Good afternoon. My name is Sally Roberts, and I have inflammatory breast cancer. I was diagnosed October 4, 1996. In previous-- Seven months before that date, my life had been thrown into a turmoil. At the end of February 1996, the gentleman I had been dating disappeared, and police and FBI investigators say that he was kidnaped and murdered. The end of April 1996, I lost my job. The beginning of June 1996,

my brother committed suicide, and I spent the next three months in Maine straightening out his affairs.

During those same three months, I was having problems with my two children in Massachusetts. I was under incredible emotional stress at the time and had been for a number of months. By the end of September, I thought I had gotten my life under control, and the stress seemed to be easing. Then I went to my OB/GYN for a regular visit on October 4, 1996. He discovered the mass in my breast and within half an hour I was in a surgeon's office to be checked. A biopsy was done the following Wednesday with confirmation of cancer by Friday. My life was spinning again. I was told all the treatments I would have to have done: chemo, mastectomy, peripheral blood stem cell transplant, and radiation. And I needed to start treatments right away. As an aside, I also had to cancel a vacation that I had finally planned for myself.

I had no problems getting any referrals to the different doctors from my insurance company. I went to Drs. Schreibman, Adler, and Reiter as my oncologists on Friday, October 18. They felt I was an excellent candidate for the stem cell transplant and wanted to start the chemo treatments immediately. The insurance company finally authorized the chemo, without authorizing the stem cell transplant, and I started treatment on October 29.

I was a little upset at the time delay since all of the doctors had seemed to be stressing how urgent it was that I get started on the treatment. Shortly after that, I was approved by the insurance company to go to Hackensack Medical to be evaluated for a stem cell transplant. I went for the

evaluation on November 18. I was accepted by Hackensack Medical for the transplant and was given a time schedule of the remainder of my treatment.

At that point, Hackensack notified the insurance company. The insurance company assigned a transplant coordinator case manager to me. She was to help with any problems I might have with insurance or anything else. I started having tests that were required before actually undergoing the transplant. As far as I knew, all the bills were being paid.

At the end of February 1997, I was told by Hackensack Medical that I had been denied coverage for the stem cell transplant. Since I was going in to have chest surgery to correct problems stemming from two collapsed lungs earlier in the month, they told me not to worry. This denial often happens, and they would appeal it, and usually, the insurance company reverses the decision.

The middle of March 1997, Hackensack again informed me that I was turned down for the transplant. By this time, I was getting worried that I wouldn't be approved, and this would drastically cut my survival chances. We discussed the possibility of hiring a lawyer to send a letter to the insurance company, and Hackensack provided me with the name of a lawyer.

I contacted her, and she did write to the insurance company. She gave them a week to reverse the decision before legal action would be taken. The week passed, and I was now into the countdown to the transplant, and certain procedures had to be followed at scheduled times. The insurance company had not replied to the lawyer. The lawyer wanted to give them a couple of more days, but I was feeling very desperate and scared.

The next day, April 10, I happened upon a full-page ad from the CEO of my insurance company stating they “Built The Rock by earning your trust. We’ll do what it takes to keep it.” When I saw that, I decided to call this gentleman. I talked to his secretary who informed me that she would look into it immediately. By 9:00 a.m. the next day, I was approved. The relief that came over me was indescribable. With all the “normal” stress that a cancer patient has to endure -- doctors, tests, needles, treatments that leave you tired, weak, and sometimes sick -- the strain of not knowing if the insurance will pay for what is required to help extend your life is excruciating. With the help of a counseling group I am in and the support of friends and family, I was able to cope with the pressure of not knowing the outcome of a major life decision that is in some business’s hand.

I am now finished with all my treatments and have received a clean bill of health at each checkup. I am working part-time and am looking forward to my long life ahead. I am in day 126 of my transplant.

ASSEMBLYWOMAN HECK: God bless.

Any questions for Sally?

ASSEMBLYMAN IMPREVEDUTO: I just want to say the best of luck and go get ‘em.

MS. ROBERTS: Yeah. I am now fighting them to pay for my lawyer, because they said I didn’t follow proper procedures.

ASSEMBLYMAN KELLY: Typical.

ASSEMBLYWOMAN QUIGLEY: May the rest of your life get good, too.

ASSEMBLYWOMAN HECK: And of course, Paul Langevin. Now after Paul will be Dr. Rosenbluth and Marilyn Lopez, who's an advocate for the African-American community; then Kyle Halpern, an attorney with Halpern Associates, an advocate for oncology and clinical trials. So after Paul, those are the next three speakers.

PAUL R. LANGEVIN JR.: Thank you very much, Chairwoman Vandervalk, Chairwoman Heck, members of the Joint Committee. I want to thank you for the opportunity to appear before you today and to discuss the issue of clinical trials and strategies for improving the public's access to scientifically designed investigations of new therapeutic agents, devices, and treatment and prevention strategies. I appear before you today representing 10 of the largest HMOs in our State which serve over 2 million New Jerseyans by providing high-quality health care coverage to them and their families.

I want to point out also that I've been a member from an HMO for over 20 years. So I know a little bit about from where I speak.

There appears to be consensus among consumers, providers, and insurers that scientific investigation of new diagnostic, treatment, and prevention agents and strategies is both necessary and beneficial. The end result of properly designed and executed research ultimately is the advancement of medical knowledge and an improvement in the quality of care available to the public. Health plans have as an integral part of their responsibility and mission the advancement of their members' health and well-being. To the extent that clinical trials contribute to the goal, health plans are bound to support research.

For a moment, I would like to discuss the erroneous conclusion reached by some that managed care and specifically HMOs are solely responsible for a reduction in the amount of clinical research being conducted in the United States today. Earlier this summer, attendees at an institute of medicine town meeting discussed the status of funding for clinical research at hospitals and academic medical centers. Among the studies discussed was the observation of a possible inverse relationship between the level of managed care penetration in a given market and the level of national institutes of health research awards over the last decade in that market.

The authors of the study did not establish a causal relationship between the two observations and did not provide compelling evidence to support a hypothesis that managed care is responsible for a reduction in the amount of research conducted in the United States. As we are all aware, there are many variables affecting the level of funding -- and several of the previous witnesses have pointed some of those out -- that is available for research and pressure from a variety of entities to restrain the runaway cost of health care nationally. Other factors such as the availability of properly trained clinical investigators and the migration of the point of delivery of health services out of the hospital and into outpatient settings cannot be discounted as insignificant factors.

The problem of conducting clinical trials and securing a venue and funding for this activity is certainly not a new one. Historically, the issue of whether or not to pay for health care delivered within a research setting and whether to pay for all or part of the services delivered has long been debated by researchers and insurers. And let me assure you that there is no bright line

between the cost of routine medical care and the cost associated with advancing medical knowledge through research.

I believe that it would be irresponsible to leave legislative policy makers and the public with the impression that HMOs and their growing membership have somehow created a threat to the viability of research where none previously existed. And I think that we've all heard today from previous witnesses that this isn't a new problem. It's an ongoing one, and hopefully we're going to talk about it and reach a solution.

Under the fee for service health care system of a decade ago, the questions of who should pay and how much they should pay for research were always significant obstacles to be addressed. And as I am sure you are aware, traditional health insurance companies, pursuant to their contracts with their insureds, did not routinely offer coverage for experimental treatments. This issue has been examined by insurers not in the context of societal good, but rather as a matter of compliance with a contract for services.

This summer, the American Association of Health Plans' Board of Directors voted to establish an industry-wide relationship with the National Institutes of Health to increase opportunities for health plans and their members to participate in clinical research. This step, I believe, demonstrates our industry's commitment to participate--

ASSEMBLYWOMAN HECK: May I interrupt?

MR. LANGEVIN: Sure.

ASSEMBLYWOMAN HECK: When this summer? Could you give me a--

MR. LANGEVIN: July.

ASSEMBLYWOMAN HECK: July. Okay.

MR. LANGEVIN: This step, I believe, demonstrates our industry's commitment to participating in a national solution to an important issue.

As a matter of record, many of our Association's members have, as a matter of health plan policy, supported collaborative efforts with academic medical centers in clinical trials. Our Association has participated in preliminary discussions with interested parties, many of which are here today or were here today. We have discussed the best approach to improving public participation in clinical research. As part of these discussions, it has been suggested that a so-called clinical trials clearinghouse would be established here in New Jersey. The group would be comprised of nationally recognized scientific experts. The panel would serve as a reviewer of potential research and ensure that only responsible, scientifically designed clinical trials, endorsed by one of the following bodies, the National Cancer Institute, the Food and Drug Administration, or the Centers for Disease Control, be accepted for consideration and sponsorship. Our Association believes that this is a reasonable approach and an excellent first step in advancing New Jersey's clinical research strategy.

I look forward to working with members of the Committee and representatives of the medical research community to evolve a strategy for supporting and coordinating clinical research which will benefit New Jerseyans and our members.

Thank you. Any questions?

ASSEMBLYWOMAN HECK: Any questions for Paul?

ASSEMBLYWOMAN WEINBERG: Do you -- we heard earlier from the gentleman from First Option--

MR. LANGEVIN: First Option, yes.

ASSEMBLYWOMAN WEINBERG: --so you can speak on behalf of more than the managed care plans.

MR. LANGEVIN: Of more than First Option, yes.

ASSEMBLYWOMAN WEINBERG: Yes. Do you typically approve clinical trials if they have been approved by the NCI or by the FDA?

MR. LANGEVIN: I think that in every single health plan it's a different policy. I would say the one thing that is typical across all health plans is there's no typical approach to clinical trials. And I think, as you heard earlier from the physician from First Option, in many instances, it's done on a case-by-case basis.

I have talked to some of our medical directors. Initially when we were approached actually by -- I don't know what you're calling yourselves -- a consortium of interested parties from the Legislature and researchers in New Jersey--

ASSEMBLYWOMAN HECK: Joint Legislative Committees.

MR. LANGEVIN: And there are other members from -- I know the New Jersey Cancer Institute was there -- several interested groups.

One thing that we believe goes a long way to addressing the problem is having the research that's being proposed and the trials that one would propose our members participate in undergo the scrutiny of a nationally recognized body like NCI or FDA. I think each of the medical directors I had an opportunity to speak with -- and I did not speak with all 10 medical

directors -- thought that that was an excellent approach. I know, for instance, that several of the health plans have actually come out publicly and stated their policy vis-à-vis clinical trials and participation in them. They are certainly fostering that.

As I said earlier, I don't think this is a problem that is new today or new five years ago. And like everything else, including bad weather, HMOs are being blamed as the root of this particular problem.

ASSEMBLYMAN IMPREVEDUTO: In most cases that's true.

ASSEMBLYWOMAN WEINBERG: Well, you're already responsible, but you are responsible for about 80 percent of everything else.

MR. LANGEVIN: I would respectfully disagree with your assessment, and I don't know the statistical validity.

ASSEMBLYWOMAN WEINBERG: Including bad weather. I'll let you off the hook on bad weather.

ASSEMBLYWOMAN HECK: We have some questions for you, Paul.

MR. LANGEVIN: Sure. I would be disappointed if you didn't.

ASSEMBLYWOMAN HECK: Assemblyman Impreveduto.

ASSEMBLYMAN IMPREVEDUTO: Thank you.

Sir, I don't know if you have this in front of you or would someone kindly give this to you, (indicating) the "Health Care Policies Affecting the Treatment of Patients with Cancer and Cancer Research." This is a supplement to and reprinted from *CANCER*, Vol. 74, October 1, 1994, published by the J. B. Lippincott Company. It's in our packet.

Can somebody close up give this to him? Would you be so kind?
Could we give that to him?

MR. LANGEVIN: Do you want to refer me to a section?

ASSEMBLYMAN IMPREVEDUTO: Oh, yes.

MR. LANGEVIN: Okay.

ASSEMBLYMAN IMPREVEDUTO: On Page 2206, third page in, third paragraph down. Well, let's go to the first part, back up to the first part, talking about-- These are oncologists that have interviewed with patients that have been dealing with HMOs. "On average, medical oncologists indicated they spend 2.8 hours per week on appeals. Office managers indicated they spend 5.9 hours per week and other staff spend an additional 14.2 hours per week on appeals." Dropping down to the third paragraph: "Respondents were asked to indicate the number of patients within the last calendar year that they attempted to place in a clinical trial but who had been refused by an insurer. The total number is significant but not outside the boundaries of credibility: These 856 physicians indicated that more than 3000 patients -- 3361 -- were not entered in clinical trials because of insurer denials. Specifically, respondents indicated that Medicare patients were refused in 841 cases, Medicaid patients in 316 cases, Blue Cross and Blue Shield cases in 470 cases, and managed care cases in 1448."

Now if that's not telling me something. Why is it that these numbers are this? Why is it that 10 times the amount that everyone else is denied?

MR. LANGEVIN: Well, I think that it's safe to say, as I said earlier, this isn't a problem that is unique to managed care and HMOs, number

one. And again, I think when you lump in PPOs, self-funded plans, and commercial HMOs onto the same rubric, I think that's inappropriate because they're not operating the same way, number one. Number two, insurance really is a contract between insureds and companies. And historically, the companies have said we've offered to cover the following items. You paid premiums pursuant to that coverage, and if you want to go outside of that coverage, that's fine, but that's not part of our contract. I think that's why you've had historically the problems in accessing clinical trials. That, coupled with the fact that there is no goal standard, if you will, for a yes or no as to whether the clinical trial is properly designed, whether or not it's going to achieve stated ends, and so forth.

ASSEMBLYMAN IMPREVEDUTO: So are you saying to me then I'm buying cheap, I'm going to get cheap? Is that basically what the answer is?

MR. LANGEVIN: No, I think if you want an unlimited coverage for any type of service irrespective of whether it's a proven treatment diagnostic tool, whatever, you can get that but at a cost probably no one can afford.

ASSEMBLYMAN IMPREVEDUTO: And probably not in an HMO?

MR. LANGEVIN: Again, I don't think that HMOs and the research-- This is a '94 article. The research that was done and released during the Institute of Medicine Study -- I believe it was published in the *Journal of the American Medical Association* -- in 1997 found that, in fact, there was an inverse correlation between the awards given by NIH and the level of penetration of HMOs and other managed care products in that market, but

they did not find a cause for that. They didn't say clearly it's because of something that's unique to HMOs that they do or managed care products that they offer that those awards had been reduced.

And again, I think what you're finding is that when you have double-digit inflation, as we had for several years preceding actually this 1994 article, in the medical sector and it's outpacing the cost of inflation in other sectors, it draws scrutiny. It draws scrutiny from several sectors, one of which is from people who pay the bills. And when they start looking at those things, individuals I think look at everything, not only the cost of it, but what kind of treatment it is, is it efficacious, who is getting the treatment. And one of the things that's been historic is the lack of participation of women in clinical trials.

So these are all things, again-- I do not excuse the fact that it is difficult to get placing for a clinical trial, to get sponsorship, and participants, but I don't think it's unique to managed care. I don't think it's a problem that necessarily brought on by managed care. I think it's something that needs a solution.

ASSEMBLYMAN IMPREVEDUTO: If one is insured by a fee for service provider and not a managed care--

MR. LANGEVIN: Yes.

ASSEMBLYMAN IMPREVEDUTO: --do you believe that they suffer these kinds of--

MR. LANGEVIN: I would say that the problems that you've outlined in this article are not unique to managed care and, in fact, have been

talked about for several decades when fee for service was, in fact, the rule not the exception.

ASSEMBLYMAN IMPREVEDUTO: Again though, when I look at it, and I get the numbers that are there that indicate there's 316 Blue Cross cases and 1148 managed care cases denied.

MR. LANGEVIN: I--

ASSEMBLYMAN IMPREVEDUTO: You can't justify those numbers to me.

MR. LANGEVIN: Well, again, with all due respect, I haven't read the article at length, but I would say this--

ASSEMBLYMAN IMPREVEDUTO: Please take it home and do that.

MR. LANGEVIN: Believe me I will, because the next time I appear -- because I'm sure this won't be the last I will see this article-- But I think it's important to note in a fee-for-service system, where there is no case management, where you submit a claim to a company, and they pay a percentage of it, there is no oversight of that. And if it's submitted as some part of routine medical care that would otherwise be paid for, it might in fact sneak through the system. Whereas, in a managed care environment, where you have someone who is case managing and looking at the overall treatment regimen or diagnostic procedure or what the case is, those kinds of things that might be otherwise deemed routine medical costs are going to be flagged if they're associated with some sort of a service that's not being granted pursuant to the contract.

ASSEMBLYMAN IMPREVEDUTO: Can we get into another area, if we can just shift gears for a second.

MR. LANGEVIN: Sure.

ASSEMBLYMAN IMPREVEDUTO: And it's something that I talked about a little earlier, as did Charlotte, is the gag rule. And the fact, and I need to hear this from you, that your doctors have always been and will continue to be free to discuss with their patient any and all options, no matter how expensive they may be.

MR. LANGEVIN: That is absolutely, positively the case. It's part of any physician who is a participant in any plan that our Association represents is free to discuss with their patient any and all options whether or not they are even covered by the plan. That is actually part of the regulations that we've adopted and effective in March of this year. It is part of our philosophy of care, and if the plans don't subscribe to that, they can't be our member.

ASSEMBLYMAN IMPREVEDUTO: Was that the case before March of this year?

MR. LANGEVIN: I would say--

ASSEMBLYMAN IMPREVEDUTO: March of last year?

ASSEMBLYWOMAN HECK: No.

MR. LANGEVIN: Having the Chairwoman shaking her head no, I wouldn't want to contradict her understanding of it. My understanding of it was as follows. There's always been a clause -- a contract clause -- that prevents physicians from discussing other than medical issues with the patient, vis-à-vis, Plan A is better than Plan B and I belong to all three of them, so why

don't you join the other one. That kind of a clause has always been in the contract, but that had nothing to do with whether or not this particular bone marrow transplant, for instance, is something I might recommend, but this company doesn't cover it.

ASSEMBLYMAN IMPREVEDUTO: What in fact-- When you advertise, shouldn't there be a caveat, then, at the bottom that says you may not get all of the options if you belong to my plan?

MR. LANGEVIN: No. Actually, in the member handbooks, there's a complete listing of coverage, and that's available to all members as part of the HMO-member Bill of Rights that's required under the regulations. That's given to all members, actually, during marketing, before they even join.

ASSEMBLYMAN IMPREVEDUTO: My problem is, in all honesty, is that you are concerned more with bottom line. We are concerned with a flat line. And that may be a good thing if the press was here to pick it up, but that's my feeling with managed care. I've got to tell you, and that's up front.

MR. LANGEVIN: I think the bottom-- Good treatment, quite frankly, the right treatment in the right place at the right time, that's good business, too.

ASSEMBLYMAN IMPREVEDUTO: I'm not so sure that the companies that you represent do that.

ASSEMBLYWOMAN HECK: Paul, I want just a little bit of clarification.

MR. LANGEVIN: Sure.

ASSEMBLYWOMAN HECK: Are you telling me that the HMOs that you represent -- and let's get rid of all the other things, you know, the PPOs, the other insurance companies, let's not toss it around. Talking to you as a representative of the 10 HMOs, are you saying to us that your HMOs would involve themselves in clinical trials under a certain set of circumstances?

MR. LANGEVIN: I can't speak contractually for 10 plans. I can tell you this. I spoke to the medical directors. They were intrigued by the--

ASSEMBLYWOMAN HECK: Intrigued?

MR. LANGEVIN: Well, they want to follow up on it. They want to have more meetings. As you are aware, I just received the abstract describing what the possibility of the program might be.

ASSEMBLYWOMAN HECK: When was the last time we met?

MR. LANGEVIN: Two weeks ago. We met during the summer.

ASSEMBLYWOMAN VANDERVALK: July 17.

MR. LANGEVIN: We met during the summer--

ASSEMBLYWOMAN HECK: In July.

MR. LANGEVIN: --in July, and I believe I received from Dr. Todd the abstract less than three weeks ago or something like that.

ASSEMBLYWOMAN HECK: But, Paul, the whole basis of what we were doing was at your doorstep in July. I understand you've had other things happen in July. My feeling here is and I would just like to know-- What you're telling me is some of the medical directors with whom you've--

MR. LANGEVIN: I haven't even spoken to all the medical directors.

ASSEMBLYWOMAN HECK: Oh, you haven't spoken to any?

MR. LANGEVIN: No. No. No. I haven't spoken to all of the medical directors.

ASSEMBLYWOMAN HECK: No, I didn't say all.

MR. LANGEVIN: Right.

ASSEMBLYWOMAN HECK: I said some--

MR. LANGEVIN: Yes.

ASSEMBLYWOMAN HECK: --that might be interested in clinical trials.

MR. LANGEVIN: They're definitely interested for some of the plans I know I've spoken to.

ASSEMBLYWOMAN HECK: Okay.

MR. LANGEVIN: That's national policy for their company. So they would definitely like to talk more about the clearinghouse concept.

ASSEMBLYWOMAN HECK: Oh, okay. So when we talk about-- You were talking about NIH, etc., before, the FDA-- Let's say, for instance, New Jersey puts its own group together structuring standards for clinical trials that other groups would meet. Do you believe that that would be recognized as well as a national look? Because don't forget, American Cancer Society, the researchers, and this body changed NIH's mind a few months back because they came out with some information that we didn't accept. So New Jersey has some high standards, too. So what I'd like to know is, would you think that if we put together, through legislation in New Jersey, standard-- Maybe that's what we're going to have to do. Is that what you're telling me?

MR. LANGEVIN: No. In fact to the contrary, I believe-- First off, the abstract I received described three, and only three, nationally

recognized bodies: National Cancer Institute, FDA, and Centers for Disease Control. That's what I've discussed with the medical directors.

ASSEMBLYWOMAN HECK: Okay. Okay.

MR. LANGEVIN: I've discussed it with two. I think one of the biggest mistakes that we can make as a group in New Jersey, or any other state for that matter, is to design unique systems inside the State despite the fact that we're all different 50 states, because companies operate at a national basis.

ASSEMBLYWOMAN HECK: Okay. I'm just concerned. Understand that I'm not a professional or an expert in this area, I just like to pick people's brains. I really feel that what we've seen here in New Jersey is to me a crisis situation. And we have to take some very important steps to resolve the problems that we have here in our State on several levels, including the level that the Assemblywomen on my left and Charlotte -- all of us have discussed over a period of a couple of years, including environmental.

But what we're trying to do is enlist the aid of all of the insurance companies, all of the HMOs, to come to the aid of their fellow and sister people in this State and the children of this State to make a better life for them. And we've heard physicians give us information that if we hit this problem head on and begin to make a difference in research, begin to have early diagnosis, we can see a problem solved at different levels.

What I'm looking for and what I approached -- Charlotte and I spoke to you about months ago was can't you join us in this effort in a more positive way rather than citing all of the other people who aren't doing things. We're not saying that you've done a terrible job. We're saying, are you going to be able to join us in this effort to make a change in the way we do things in

improving the clinical trials that we can make available to people so that we see a change in our health patterns.

MR. LANGEVIN: I think absolutely, and I've stated it today on the record that we are interested. We are ready for the next step.

ASSEMBLYWOMAN HECK: Oh, good.

MR. LANGEVIN: We're ready for the next discussion. I think the one thing that I can tell you is I think it's very positive to have an open discussion. It's bigger than insurance.

ASSEMBLYWOMAN HECK: It is.

MR. LANGEVIN: It's a societal issue. I think we're certainly--

ASSEMBLYWOMAN HECK: It's a life-and-death issue.

MR. LANGEVIN: Absolutely. I think we're certainly willing to pick up our fair share of the load for the members that we cover. There's no question about that. Will I be able at any point in time to tell you that I can commit 10 companies contractually to cover every clinical trial, absolutely not. And I don't think there's anybody that would ever be able to do that. But we're--

ASSEMBLYWOMAN VANDERVALK: But it could be done through legislation.

MR. LANGEVIN: I would--

ASSEMBLYWOMAN VANDERVALK: We're looking at this point-- We're looking at this point for--

ASSEMBLYWOMAN HECK: Cooperation.

ASSEMBLYWOMAN VANDERVALK: Yes. A cooperative--

ASSEMBLYMAN IMPREVEDUTO: Effort.

ASSEMBLYWOMAN HECK: Plan.

ASSEMBLYWOMAN VANDERVALK: --venture that we can all move forward.

MR. LANGEVIN: I believe I used the word cooperation. I'll say it again. I'm waiting to cooperate. You know, if we can have another meeting with the same group that we had the last time, I think we'd look forward to that.

ASSEMBLYWOMAN HECK: We will put the data together, and we will reach out to you--

MR. LANGEVIN: Great.

ASSEMBLYWOMAN HECK: --and hopefully you will have the opportunity to speak to each of the medical directors you represent.

But, Paul, I do know that you, personally, are simpatico with this. If it was within your purview, you would help the children and the people of this world.

MR. LANGEVIN: I would be a most beneficent dictator, believe me.

ASSEMBLYWOMAN HECK: Because I wouldn't want to have to reach out to your family and discuss this with them.

MR. LANGEVIN: My mother wrote my testimony today.

ASSEMBLYMAN IMPREVEDUTO: May I just suggest that maybe in your next meeting that you meet with the gentlemen and the 10 CEOs of the companies he represents and get them to give us the bottom line.

ASSEMBLYWOMAN HECK: If they come--

ASSEMBLYWOMAN VANDERVALK: I must say that they were all invited.

ASSEMBLYMAN IMPREVEDUTO: Well, it's obvious then if they don't, then they're not willing to cooperate.

ASSEMBLYWOMAN VANDERVALK: They were all invited--

ASSEMBLYWOMAN HECK: They were all invited.

ASSEMBLYWOMAN VANDERVALK: --and Paul came. I think there was one other medical director that came to the meeting.

ASSEMBLYWOMAN HECK: Singer. Dr. Singer.

ASSEMBLYWOMAN VANDERVALK: Yes.

MR. LANGEVIN: I believe there was-- I don't recall.

ASSEMBLYMAN KELLY: I've got a question. Paul, isn't it true that there's some self-insured and some others that are insured by-- I mean the Federal government's set up that no matter what we do, they're not covered by anything we say. Is that true?

MR. LANGEVIN: Well, actually, it's not-- We represent 2.3 million HMO in products in New Jersey, but you have folks in that 2.3 even. You have Medicaid enrollees that are in a managed care product in HMO. You have Medicare, and they all have their own policies vis-à-vis coverage of those persons. And yes, you have between 2 million and 2.5 million people in self-funded plans that are exempt pursuant to ERISA.

ASSEMBLYMAN KELLY: And no matter what we do, we can't force them.

MR. LANGEVIN: No matter what you do on the State level.

ASSEMBLYWOMAN WEINBERG: Madam Chairperson.

ASSEMBLYWOMAN HECK: Yes.

ASSEMBLYWOMAN WEINBERG: Assemblyman Kelly, I am glad you brought that up. In fact, I just recently contacted our two U.S. Senator offices because I'm getting more and more complaints from constituents who are in ERISA plans, most recently a breast cancer victim whose doctor sent me-- I actually saw it in black and white from her ERISA plan. She was turned down for breast cancer treatment because they claimed she didn't have a mammogram in 1995, as if somehow having a mammogram -- if she had had one-- But that's irrelevant. But somehow a mammogram was an inoculation against breast cancer, and if she'd had the mammogram, she would still have breast cancer in 1997.

I think that the Federal government is going to have to take a good strong look at these ERISA plans. And I hope that maybe we could get a resolution through our joint Committee and through the joint -- Legislature asking our Federal representatives to take a look at this, because we have so many people that we can't regulate.

ASSEMBLYWOMAN HECK: We'll do that right now. We'll advise everyone here, and, Kate, have that put together for the joint Committees.

ASSEMBLYWOMAN WEINBERG: I did it individually based on the cases I'm hearing, but it would be good to do it jointly.

ASSEMBLYMAN FELICE: One, if I may, Madam Chairperson, one quick fact. About two or three months ago, I met with about 34 other states and nationally on health care issues. It's interesting the figures that were given, even now if you take them and balance them out, right now in the

United States -- you correct me if I'm wrong -- that over 50 percent of the population is on some form of managed care or HMO. So you take those figures, even this in 1994, you add up what the managed care here in '94 and add all the others up, they come up to almost 50 percent, also.

So with that in mind, that over 50 percent of the country already is in some form of managed care, becomes much more important that we look at the overall picture, because that's the way the country is going. I think we have to address those issues that we're talking about now, and everybody's sort of come on board. But in fairness to you, that the figures here do match even years ago that it was coming in that direction. Thank you.

ASSEMBLYWOMAN HECK: Thank you, Paul.

MR. LANGEVIN: Thanks for having me.

ASSEMBLYWOMAN HECK: You'll be hearing from us, probably in the morning.

MR. LANGEVIN: I look forward to it.

ASSEMBLYWOMAN HECK: Thank you.

We have Dr. Richard Rosenbluth, who is now speaking to us as the Chief of Medical Oncology here at Hackensack University Medical Center.

DR. ROSENBLUTH: Thank you very much.

I have some prepared remarks, but with your permission, there are a couple of points I'd like to make at the end before taking any of the questions that you might have.

My name is Richard Rosenbluth, and as you've gathered, I am Chief of Oncology at the Northern New Jersey Cancer Center of Hackensack

University Medical Center. In addition to the past 15 years, I have served as the Principal Investigator of the Northern New Jersey Community Clinical Oncology Program, or CCOP.

My colleagues and I here at the Northern New Jersey Cancer Center have an ongoing commitment to providing the best in cancer care to the population we serve, and we believe that active participation in clinical trials is essential to high-quality cancer treatment. Studies have consistently shown better outcomes, both in survival as well as quality of life, in centers with a strong commitment to such trials. Not only do patients entered on trials themselves benefit from newer and sophisticated treatments, but it has also been shown that participating physicians -- that is, physicians participating in clinical trials -- frequently use treatment regimens similar to those on clinical trials in treating patients who, for reasons of ineligibility or refusal, have to be treated off study.

Because of the excellence of our program, our CCOP has been continually funded since the onset of the CCOP program 15 years ago, and in fact, we were recently ranked at the top of the country in our grant reapplication.

Our interests here include cancer treatment, of course, but in addition, we have a strong commitment to the area of cancer control and prevention. We participated actively in the Breast Cancer Prevention Trial, and we were also among the top 10 accruers in the country to the Prostate Cancer Prevention Trial.

With this background, it is understandable that we are very concerned about the sorry fact that participation in clinical trials in the State

of New Jersey, as you've heard, is approximately half that of the national average and, in fact, that the national average itself is well below the 10 percent to 20 percent participation level that we in the field believe is not only possible, but also desirable. I believe there are several explanations for this deficiency.

First, too many oncologists in the State, and in fact in the nation as well, are currently unconnected to academic centers or the centers offering clinical trials. National organizations such as the American Society of Clinical Oncology, as well as state cancer societies, should do more to encourage networking in the community of practicing oncologists. Patient education programs on the State and national levels can also do much. By demanding treatment on trials, knowledgeable patients can ultimately encourage their oncologists to affiliate with regional centers to a much greater extent.

Recognizing this problem, our CCOP has expanded to include a network of affiliated physicians and hospitals in the northern part of the State. Oncologists at Morristown Memorial, Overlook, Mountainside, and Elizabeth General Hospitals have joined our CCOP over the last few years as active participants. Our physicians have also joined with others in the tristate area to form a private company, the Affiliated Physicians Network, dedicated in part to expanding access to clinical research in the community. We need to encourage even more active involvement by those oncologists who are still unconnected.

The second and major problem, as is so often the case of course, is money, as you've heard. First of all, the development and execution of clinical trials by the Cooperative Cancer Treatment Groups is expensive. And

from the perspective of the private practitioner, the extra time and office personnel required to enroll and follow patients on trial is certainly in excess of what nonstudy patients require. It is, therefore, imperative that additional funding for clinical trials be made available to the National Cancer Institute and passed on to the Cooperative Groups to cover the costs of protocol development and administration.

Most important of all for the private practitioner, the payers, whether governmental or corporate, must recognize the importance of clinical trials and cover treatment costs in their entirety. It is unacceptable for payers to refuse reimbursement for clinical trials on the grounds of their being experimental therapy. It is also shortsighted of them. What better way, as you've heard time and again during this afternoon-- What better way to encourage quality care, superior outcome, and ultimately, most importantly, lower cost than by encouraging clinical trials.

I sincerely hope that our State, which consistently ranks, as you know, among the top in cancer incidence, will take the initiative first to pressure the Federal government to increase its support of clinical trials; two, to advise the State and county medical societies to encourage oncologists to affiliate with regional centers currently involved in clinical trials; three, to educate the citizenry of the importance of clinical trials so that they may, in turn, insist that their own private oncologists network with larger centers; and four, to demand that corporate payers cover the costs of clinical trials so that all patients in our State may benefit from the advances in clinical cancer research.

That's the conclusion of prepared remarks. One or two points that I would like to make with your permission. We here at Hackensack and the Northern New Jersey Cancer Center are certainly far and away the largest accruer to clinical trials in the State of New Jersey. We have been for several years accruers both to cooperative group trials, as well as pharmaceutical industry trials. I think for that reason we are uniquely positioned to get an overview of what's happening in this arena.

I think there are a couple of interesting things that have been developing over the last couple of years. As the Federal government has reduced its support for the National Cancer Institute in general and, as a result, also for clinical trials, we found that pharmaceutical companies have increased their support. What the drug companies have done is they have increased support for trials of their own drugs naturally, but what they've done is they've improved the science of these trials. The science of the trials are now, in many instances, on a level that is totally acceptable to the National Cancer Institute. So much so that the drug companies are not only sponsoring their own clinical trials out in the community, but are networking with the cooperative groups, the half a dozen or so large cooperative groups around the country, and helping them sponsor the trials, picking up some of the slack that the Federal government is responsible for.

Now, I think that's a good development. I think it is important and perfectly reasonable for drug companies who will ultimately benefit from the revenue they receive from new, successful drugs to be actively involved in supporting clinical trials. The trials that they support moreover they support

entirely and in toto. And that's one of the great advantages of drug company trials, patients are not billed nor are their insurance billed.

The problem is that the cooperative groups, and I think the cooperative group mechanism in this country is the single most important way of advancing clinical cancer research-- The cooperative groups need support. And I think it's important, as we've heard witnesses testifying here time and again, that the approach should be that treatment on a clinical trial, if it's a cooperative group trial, is standard of care. It has to be standard of care. It's the best care available.

If you were to call the National Cancer Institute having recently been diagnosed with cancer, as many of my patients have, you call them and tell them, "I've just been diagnosed with breast cancer or prostate cancer, what should I do and where should I go," what they will tell you is find a center that is offering a clinical trial. That's what they will tell you on the phone.

Now, if you're up here in Bergen County and you were to ask them, "Well, where should I go," they'd tell you to come here. They will similarly do that in other parts of the State and other parts of the country. So the National Cancer Institute and the Federal government is already admitting that this is standard of care. So I think-- I don't know if this can be done legislatively, but I think it's important to make the insurers aware of the fact that this is the case. It is not experimental treatment, but standard of care in cancer patients, where in so many instances we don't have the appropriate treatment.

What's more, the drug companies certainly are there to support investigations in the new drugs that they develop. What about drugs that are

generally out there that drug companies are not developing? You may know, of course, that there is a renewed interest in what is now referred to as integrative medicine, or alternative medicine.

One of the reasons there's been no research done in alternative medicine is that there is no major drug company that stands to benefit from St. John's Wort, for example. We and our affiliates at the University of Rochester, for example, are interested in looking at a herbal preparation, such as St. John's Wort, which has antidepressant effects. But there's no drug company that would make a fortune if it becomes successful. So who's going to support that type of research?

So in summary, I think what we need to do is insist that both the Federal government and insurers cover quality clinical research that is peer reviewed, principally that type of research that is generated by the cooperative groups. I certainly hope that we, here in New Jersey, can lend an impetus to this very important principle.

ASSEMBLYMAN KELLY: Do the loonies from the FDA get involved in your plans? I mean, do they interfere or do they--

DR. ROSENBLUTH: You mean in our clinical trials?

ASSEMBLYMAN KELLY: Yes.

DR. ROSENBLUTH: No, we get it after they've had their say.

ASSEMBLYMAN IMPREVEDUTO: Doctor, you alluded to the fact that there were -- in New Jersey there are fewer patients joining the clinical trials. Could it be that how you need location-- I mean, northern New Jersey, if you come down with the disease, the first thing you think about is New York. And if you're in southern New Jersey, the first thing you think about is

Philadelphia. You don't think about Cooper or Hackensack. Immediately you say Sloan, Columbia, Thomas Jefferson, or whoever else is out in Philadelphia. I mean--

DR. ROSENBLUTH: Yes. I think that's true. It's less true than it had been.

ASSEMBLYMAN IMPREVEDUTO: Yes.

DR. ROSENBLUTH: Twenty years ago when I first went into practice here at Hackensack, I think we're still seeing a significant number of patients going into the cities, New York and Philadelphia. We're seeing another large group of patients go into the cities for second opinions or conservatory opinions and then come right back. But I think your point is well taken. If we wanted to get an accurate reflection of the number of patients going on clinical trials, we would need to poll the hospitals in New York and Philadelphia and find out how many of their New Jersey-based patients are on clinical trials. I don't think that number is captured in the 1 percent to 3 percent that we normally hear.

ASSEMBLYMAN IMPREVEDUTO: It's probably substantial.

DR. ROSENBLUTH: I would think so. We here, in general-- We have between 10 percent and 20 percent of our patients on some form of clinical trial, either cooperative group, pharmaceutical company or in-house generated trial. I think that is a percentage that is achievable. It should be achievable around the country at a minimum.

ASSEMBLYWOMAN HECK: Any other questions?

ASSEMBLYMAN IMPREVEDUTO: No.

ASSEMBLYWOMAN HECK: Loretta?

ASSEMBLYWOMAN WEINBERG: No.

ASSEMBLYWOMAN HECK: Okay. Thank you very much, Doctor, appreciate it.

Dr. Leitner, I know you have to leave, but if you could just come up for a few minutes. Dr. Leitner is the medical oncologist representing the Saint Barnabas Health Care System.

STUART LEITNER, M.D.: Thank you very much. I appreciate it. I have been asked to present the position of the Saint Barnabas Health Care System to the panel. I'd like to read a few notes, and I think we submitted something to Ann Marie and, hopefully, people on the panel will get a copy.

The war against cancer is progressing in a positive direction but, unfortunately, at a pace that's too slow for all of us who have friends and family members facing these dread diseases. Recent mortality figures are showing a decrease in cancer-related deaths by 6 percent. The factors that are responsible for this small, but highly significant, improvement are many. Advances have been made in prevention, screening, treatment, and basic science understanding of the malignant state.

All of these successes reflect enormous efforts in the area of research. Successful research requires educated and inquisitive minds, a societal commitment, and appropriate funding for the necessary resources. We of the Saint Barnabas Health Care System are convinced that the New Jersey professional community has the intellectual and the strong desire to drive forward this fight against cancer. What we need is strong support for obtaining the necessary financial resources and for public education.

Who can provide these resources? Government, as well as industry, money helps to provide these resources but are becoming increasingly more difficult to obtain. That is why we're here today.

Basic science research, the groundwork upon which most advances depend, must continue to receive adequate support from all sources. We of the Saint Barnabas Health Care System are mostly involved in the clinical side of research, and this is the area I wish now to address.

Clinical research should not be stifled by economic forces. A quote from a recent background paper of the Association of Community Cancer Centers emphasizes the important role of clinical research: "Currently, with available cancer treatments, approximately 50 percent of patients with cancer can be cured of their disease, but 50 percent also still die of their disease. No cancer can be said to be so well treated that an improvement in the approach or outcome cannot be readily imagined and desired. Advances in medicine and in cancer can come only from the application of new knowledge from clinical research."

Payers recognize that people enrolled in clinical trials may sometimes require more office visits and testing to verify both the efficacy and safety of a new treatment. The American Association of Community Cancer Centers continues in the background paper by saying: "Medical beneficiaries should not be discouraged from participation in clinical research by the threat of reimbursement denials. They receive the best available care when enrolled in high-quality clinical trials. In oncology, 'standard care' often involves treatment in the context of a clinical trial, where patients can receive access to new agents that promise even greater benefits than conventional therapy."

Both government and private payers must be encouraged to cover such trials if progress in oncology is to continue.

But there is distressing evidence that research opportunities are being missed. Nationally recognized comprehensive cancer centers, once the bastion of clinical research, are acknowledging that their increasing emphasis on “standard care” at the expense of testing innovative programs is a result of financial constraints. Applications for National Cancer Institute-sponsored Community Clinical Oncology Programs, or CCOPs, which Dr. Rosenbluth just spoke about-- CCOP grants designed to foster community clinical research appear to be falling are also apparently due to financial factors.

The problem with the standard care, if I can digress a little bit from the paper, is that, as everybody has acknowledged at this meeting, standard care for many cancer patients is still woefully inadequate. And that’s why standard care is really just a backbone on which to build, and clinical research hopefully can improve upon the successes that we’ve already achieved in clinical cancer treatment.

We challenge the New Jersey Legislature to support and to demonstrate its support for a continuing major effort in oncology research and to take every opportunity to educate our citizens regarding the importance of research funding and research participation. I might add that it also should include educating physicians about research funding and research participation. We challenge our colleagues in the health care insurance industry both in private and public sectors to work with us to develop modalities by which research can continue to be funded. We, as health care professionals, challenge ourselves to be unwavering in bringing forward our

time, energy, and expertise to continuing to pursue every appropriate research opportunity on behalf of New Jerseyans.

Cancer mortality can be reduced in the State of New Jersey. These are some givens. The public must be educated as to appropriate steps in prevention and early detection. Health care providers must be committed, as we are in Saint Barnabas Health Care System, to providing state-of-the-art treatment with careful monitoring of quality and outcomes. All citizens should have access to appropriate medical care in the areas of prevention, screening, and treatment. And of paramount importance, the research effort must be nurtured, expanded, and supported and made available to all. Without continuation of our research efforts, progress against cancer will stop, and one out of six Americans will continue, perhaps unnecessarily, to die from this disease.

Thank you.

ASSEMBLYWOMAN HECK: Thank you, Doctor.

Any questions for the Doctor? (no response)

You have another colleague with you?

DR. LEITNER: No. Not that I know of.

ASSEMBLYWOMAN HECK: Thank you very much.

DR. LEITNER: Thank you.

ASSEMBLYWOMAN HECK: Thank you again, and Ann Marie has your testimony?

DR. LEITNER: Yes.

ASSEMBLYWOMAN HECK: Yes. Good. Thank you.

We have Marilyn Lopez, who is from the Latin American community. Are you here? Yes.

Is Kyle Halpern here, or did he arrive? (no response)

I don't think so. Okay.

After Ms. Lopez, we will have to call upon Dr. Arnold Rubin.

M A R I L Y N L O P E Z: Good afternoon.

ASSEMBLYWOMAN HECK: Good afternoon.

MS. LOPEZ: My name is Marilyn Lopez. I'm the Financial Counselor at the--

ASSEMBLYMAN IMPREVEDUTO: Could you just move that other microphone? That's it, move it closer.

MS. LOPEZ: This one doesn't work?

ASSEMBLYWOMAN HECK: Yes, the one in the center is the one that amplifies the sound.

MS. LOPEZ: This one.

Good afternoon. I'm the Financial Counselor at the Cancer Institute of New Jersey. My primary responsibilities at the Cancer Institute are to obtain prior authorization for all chemotherapies, surgeries, and radiological procedures among other things.

I cannot tell you the frustration that I, not to mention the patients, go through on a daily basis when the many different insurance companies repeatedly deny services to patients of clinical trials. I spend a lot of time, sometimes hours, talking to insurance companies and being, so to speak, liaison between patients, doctors, and insurance representatives. Some

times I happen to be the only advocate or voice that the patient has to speak to these insurance companies.

I think that the last thing an ill cancer patient needs is to be told that their insurance company is telling them that perhaps their last possible hope of care has been denied. This is very devastating to the patients, and it adds to their stress more than anyone can imagine.

I truly believe that the insurance companies should be the ones who are managed, as opposed to the health of the patients. Anyone who has been touched by cancer, as I am daily in my work or as many people are by family members, knows how important a cure is for this dreadful disease. The only way to achieve a cure is through clinical trials.

Thank you.

ASSEMBLYWOMAN HECK: Thank you very much.

MS. LOPEZ: Any questions?

ASSEMBLYWOMAN HECK: I think you've emphasized what we have been working towards.

ASSEMBLYMAN KELLY: So they've been giving us a lot of hot air?

MS. LOPEZ: Yes.

ASSEMBLYMAN IMPREVEDUTO: I mean, you're the person who deals with this.

MS. LOPEZ: Basically, I've been sitting back there just nodding my head because a lot of what these directors--

ASSEMBLYMAN IMPREVEDUTO: The managed care people are saying.

MS. LOPEZ: --are saying, right, managed care people are saying are totally untrue. I experience it every day. I sit on the phone with these people every day. I mean, I go through denials and denials. I think Dr. Mary Todd can back me up by saying-- I mean, we get tons of denials, and, you know, our doctors who are constantly doing other things have to sit down and do all this clerical work and write letters of denial because the insurance companies just don't want to pay.

ASSEMBLYMAN IMPREVEDUTO: Can I ask you a question?

MS. LOPEZ: Sure.

ASSEMBLYMAN IMPREVEDUTO: We've heard them here today say that they would deny treatment for some radical, clinical whatever and certainly, if it were state-of-the-art, current treatment that everybody's getting, of course we'll be out there paying for it.

MS. LOPEZ: Sure.

ASSEMBLYMAN IMPREVEDUTO: Is that what your experience is?

MS. LOPEZ: Well, I think what the bottom line is that basically it's a big game out there. It's all about-- It's between the insurance company and the doctor, and the only people who are suffering from all of this are our patients.

ASSEMBLYWOMAN HECK: Is it a question of who gives in first in many instances? The time that you have consumed?

MS. LOPEZ: Yes.

ASSEMBLYWOMAN HECK: It's kind of frustrating.

MS. LOPEZ: Basically, yes. Yes it is.

ASSEMBLYWOMAN HECK: Some people will give up and others won't.

MS. LOPEZ: After fighting and the letters and yelling, I mean, sometimes screaming, I get into screaming matches. I mean--

ASSEMBLYMAN IMPREVEDUTO: But why-- When you call the insurance company and say, "Are you going to pay for this?" and they say, "No"--

MS. LOPEZ: It's-- They'll just say--

ASSEMBLYMAN IMPREVEDUTO: --what is their reasoning?

MS. LOPEZ: --it's not a covered expense. The drug is not FDA approved.

ASSEMBLYMAN IMPREVEDUTO: Okay. The drug is not FDA approved. So that would be a clinical--

MS. LOPEZ: Right. Or the drug is not FDA approved for that particular diagnosis. So they'll say, "No, we won't cover it." I mean, we have literally thousands of dollars on hold from Medicare because of this -- because of the clinical trials-- Because just Medicare and the insurance companies just really don't want to pay.

ASSEMBLYMAN IMPREVEDUTO: Now, is it Medicare, or is it the part of Medicare that someone has chosen to take the managed care part?

MS. LOPEZ: No. It's Medicare. It's Medicare.

ASSEMBLYMAN KELLY: It's Medicare.

ASSEMBLYWOMAN HECK: It's Medicare.

ASSEMBLYMAN IMPREVEDUTO: Was it Part A and Part B?
I'm not there yet.

MS. LOPEZ: Part A. Part A and Part B. I mean it's just-- What's one number? And we bill the medical part. The hospital has thousands of dollars just sitting on hold because these are drugs that are not FDA approved. Whatever the reasoning is they're just not paying. They're just not paying.

ASSEMBLYWOMAN HECK: I'm going to ask you and Dr. Todd just to give us a couple of examples of that in writing so that we can use that as a base.

MS. LOPEZ: Sure. I think--

ASSEMBLYWOMAN HECK: I think--

MS. LOPEZ: Definitely.

ASSEMBLYWOMAN HECK: --that's important.

MS. LOPEZ: Absolutely.

ASSEMBLYWOMAN HECK: Thank you very much.

MS. LOPEZ: Sure.

ASSEMBLYWOMAN WEINBERG: Can I just ask a quick question?

ASSEMBLYWOMAN HECK: Yes, certainly.

ASSEMBLYWOMAN WEINBERG: Do you find-- I mean, we heard it earlier from a doctor who talked, you know, if you're very aggressive and sometimes--

MS. LOPEZ: But why should we be aggressive?

ASSEMBLYWOMAN WEINBERG: Yes. I agree with you. But I'm-- We've heard from--

MS. LOPEZ: There's absolutely no reason.

ASSEMBLYWOMAN WEINBERG: --a cancer -- the woman who has cancer who finally got the Rock to approve her treatment once she happened to see an ad and called the CEO even though she had been turned down all along the way.

MS. LOPEZ: Can I just say something about that?

ASSEMBLYWOMAN WEINBERG: Yes.

MS. LOPEZ: Sometimes people are not as well versed on their insurance--

ASSEMBLYWOMAN WEINBERG: Right.

MS. LOPEZ: --companies. A lot of times, for example, in the Latino community where, you know, somebody is working in a factory, and they get this insurance company, and they're like, well, this is the only insurance company that we're offering, they have absolutely no clue what this insurance company -- what their policy and procedures are. So they'll go to a specialist without knowing that they need to bring a referral or without knowing that they need to get prior authorization. And when they do go-- I mean, I have this woman who speaks absolutely no English at the Cancer Institute, and she had no idea about what her insurance company covered and what they didn't cover. So I think that-- You know, I think this woman was very fortunate, and I think-- But there's not as many fortunate people out there. I mean, there's a lot of people who don't know where to go, who don't have family members, who don't have anyone, and they don't know how to get on the phone and call the insurance companies and talk to the insurance

companies and talk to their Senators and their Assemblypeople. They don't have anyone to turn to--

ASSEMBLYWOMAN HECK: They don't have that protection.

MS. LOPEZ: --you know, especially in the minority community. You know, it's really devastating to the patient, because they receive thousands and thousands of dollars in bills and they're just like, "What will I do?" It really does add a lot of stress to these poor patients.

ASSEMBLYWOMAN WEINBERG: And I think what you said a little bit earlier or alluded to a few minutes earlier, Rose, is that I get the feeling when we act as advocates for constituents who call that they just sometimes say, "No, no, no," just to wear everybody out.

MS. LOPEZ: Of course.

ASSEMBLYWOMAN WEINBERG: And it's only those who have the discipline, the stick-to-itiveness, the ability, whatever--

MS. LOPEZ: Right.

ASSEMBLYWOMAN WEINBERG: --to get through it all that finally get the "Yes."

MS. LOPEZ: Right.

ASSEMBLYWOMAN WEINBERG: I find that even when we're calling on--

ASSEMBLYWOMAN HECK: Absolutely.

MS. LOPEZ: Right. I think it's--

ASSEMBLYWOMAN HECK: Absolutely.

MS. LOPEZ: I think it's very rewarding. Yes. I mean, just to stick on these insurance companies and just, you know, run around to them.

ASSEMBLYWOMAN HECK: Yes.

MS. LOPEZ: A lot of the running around with the doctor and whatever it is. Right.

ASSEMBLYWOMAN HECK: It's an important point.

MS. LOPEZ: Right.

ASSEMBLYMAN KELLY: Do you think we should publicize the companies that give you a hard time?

MS. LOPEZ: Absolutely.

ASSEMBLYMAN KELLY: I really mean it.

MS. LOPEZ: Good. Absolutely.

ASSEMBLYMAN KELLY: Should be a public record.

ASSEMBLYWOMAN HECK: Give us a list.

ASSEMBLYMAN KELLY: Put it in the papers. These are the companies that give you a hard time.

MS. LOPEZ: I think First Option is a pretty good insurance company.

ASSEMBLYMAN KELLY: Okay.

MS. LOPEZ: First Option, I think, with -- in terms of like getting--

ASSEMBLYWOMAN HECK: Response.

MS. LOPEZ: --approval and response, I think--

ASSEMBLYMAN KELLY: Can you furnish us with the companies that give you a hard time? (no response)

ASSEMBLYWOMAN HECK: Well, she's going to talk to Dr. Mary Todd.

ASSEMBLYWOMAN QUIGLEY: Assemblyman Kelly always manages to get right down to the bottom line.

MS. LOPEZ: Are there any insurance companies in the house right now?

ASSEMBLYWOMAN HECK: There are.

MS. LOPEZ: Okay, then I won't say.

ASSEMBLYWOMAN HECK: They can hear this.

MS. LOPEZ: Yes. Okay.

ASSEMBLYWOMAN HECK: But thank you very much.

MS. LOPEZ: Okay. You're welcome.

ASSEMBLYWOMAN HECK: I appreciate that.

Dr. Arnold Rubin from St. Joseph's Hospital and Medical Center.

ARNOLD D. RUBIN, M.D.: Ladies and gentlemen, thank you for the privilege of being here. My name is Arnold D. Rubin. I am Director of the Cancer Institute at St. Joseph's Hospital and Medical Center, in Paterson, New Jersey. We have an intense interest in clinical trials and, of course, their proper support.

I might just digress for a minute, apropos of the foregoing remarks, that I can give you an interesting example. St. Joseph's may be a little unique. While we're very much involved in national clinical trials that we've been discussing today, we're involved in some interesting original work, which doesn't represent the state of the art as what the state of the art may be next year. And again, it doesn't necessarily involve particularly elaborate or expensive treatment.

This is a situation that came up last year where a lady who had a bone marrow transplantation for acute leukemia -- she relapsed. So the acute leukemia came back. But through our work, we discovered that she still had a little bit of the graft left, that there were still some donor cells. By use of a technique which we call adoptive immunity, or donor leukocyte infusion, we put immune cells from the donor in an effort to drive away the leukemia, which was quite successful.

We felt that an important thing was to stimulate these cells with a substance called interleukin-2, which is on the market. Unfortunately, it is only approved for the convenience of the drug company for kidney cancer. It has really not much affect on kidney cancer, but it has been approved for that. So it can be used for anything on a legal basis, and we were using it for this situation, and we're not unique. People use interleukin-2 to stimulate lymphocytes for several years now. Well, it's a fairly expensive agent, and when we tried to use it, the insurance company found out about it and they refused. And their only reason was "We're not arguing that you should use this or not, we're saying that this is not covered because it is not FDA for that condition."

ASSEMBLYWOMAN HECK: Isn't that awful.

DR. RUBIN: And that's in the fine print and this poor lady didn't know anything about this. I can tell you by the time-- We even tried to admit her to the hospital so we could give it through the hospital to get it swallowed up that way, but they caught on to that one quickly. The drug was stopped because she couldn't afford to pay for it. By the time we got the drug company to donate it -- they were a little bit tight-- They finally agreed to donate it. By

the time they agreed, she had relapsed into the central nervous system and died.

Now this is a dramatic example of what goes on in a parallel fashion or similar fashion every day. This is the type of thing, not just this, but this is the type of thing that I think we do have to address.

ASSEMBLYMAN IMPREVEDUTO: Doctor, could I just interrupt?

DR. RUBIN: Sure.

ASSEMBLYMAN IMPREVEDUTO: What would the cost of that drug have been?

DR. RUBIN: Well, I can't tell you offhand. I wasn't really prepared because--

ASSEMBLYMAN IMPREVEDUTO: No, that's--

DR. RUBIN: I would say several hundred dollars a day. It's not astronomic, but it is considerable.

ASSEMBLYMAN IMPREVEDUTO: So it would have cost her \$10,000--

DR. RUBIN: It might have, yes.

ASSEMBLYMAN IMPREVEDUTO: --to get the treatment?

DR. RUBIN: It's somewhere in that range. I could give you exactly, but somewhere in that range.

ASSEMBLYMAN IMPREVEDUTO: No, I used a ballpark.

DR. RUBIN: Yes.

ASSEMBLYMAN IMPREVEDUTO: So it might have cost that woman \$10,000--

DR. RUBIN: Yes.

ASSEMBLYMAN IMPREVEDUTO: --or the insurance company \$10,000?

DR. RUBIN: Right.

ASSEMBLYMAN IMPREVEDUTO: The possibility would exist that that woman would be alive today?

DR. RUBIN: Yes.

ASSEMBLYMAN IMPREVEDUTO: So they literally bought a life for \$10,000.

DR. RUBIN: Because the other patients we've treated that way, we've kept on this agent, and they are still alive today. This is sort of almost a miraculous and one of the most exciting aspects of cancer today using immune cells. There aren't too many other people in this country that are doing that, and we have an opportunity here in New Jersey to show what we can do and help these people. I think it's a shame.

ASSEMBLYWOMAN HECK: I think it's a shame when a physician decides to use a drug that's already been approved as a safe drug, because it wasn't specified for one particular area of the body or cancer or certain type of cancer, you can't prescribe it.

DR. RUBIN: Yes.

ASSEMBLYWOMAN HECK: Because it should be ultimately your choice.

DR. RUBIN: Well, you understand the reason that it isn't approved is because it's such a difficult and expensive process for a drug company to get approval for a specific disease. So they'll go in for a disease.

ASSEMBLYWOMAN HECK: Yes.

DR. RUBIN: And that might turn out not to be the disease you could have used that drug for, but that's what it's approved for.

ASSEMBLYMAN KELLY: Does the FDA really know what it's doing?

ASSEMBLYWOMAN HECK: To put these little-- The FDA--

DR. RUBIN: Yes. I have a lot of experience. We have-- As part of our immune program, we're involved with the Garden State Cancer Center where we use radioactive antibodies. Again, this is an original. This is not on a national clinical trial; although, it's approved by the NCI. Each one-- This agent is approved by the FDA on what's called an IND. We're able to use the drug, which we make through the Garden State Cancer Center, and it's-- We're able to use the agent on our clinical trials and our protocols.

The FDA controls this very, very carefully. I'm very impressed with the degree of attention that they give us when we want to veer in any way from our protocol. They're right down on us. Do you understand-- Some of these cases that we're referred are desperate, and they don't fit the protocol. And they don't fit the protocol because we wrote the protocol, so it's our fault that this variant we didn't look into first.

ASSEMBLYMAN KELLY: But how can you be knowledgeable of all the variances?

DR. RUBIN: We can't. So we applied to the FDA, and they consider it. And if it's reasonable, they will give us a variance. So the system does work. It's not very efficient, but it does work. I think the FDA should be supported. I think there is some liberalization going on now, from what I read

in the newspapers, that it will be easier to approve drugs. But beware, the FDA is protecting us. Let's not jump on them.

ASSEMBLYMAN KELLY: No. No. No.

DR. RUBIN: The insurance companies are against us.

ASSEMBLYMAN IMPREVEDUTO: I like the way you think.

DR. RUBIN: I hope that fellow left.

ASSEMBLYMAN IMPREVEDUTO: I like the way you think.

ASSEMBLYWOMAN WEINBERG: How would-- The case you talked about in terms of the interleukin. That wouldn't be covered by anything we would do on clinical trials, would it?

DR. RUBIN: Well, you see-- What do you mean by covering it?

ASSEMBLYWOMAN WEINBERG: Well, you talked about that if we were to somehow mandate that all clinical trials had to be covered by insurance--

DR. RUBIN: Well, see, you would have to specify. What I heard preceding -- and you really haven't gone into my own testimony because I was upset by this restricting this to the large-group national clinical trials. I think some Federal legislation's probably in order for that, and I don't really think it should be up to every state to have their own unique solution to this.

However, there are other aspects of clinical research, and we call them clinical trials, but it's clinical research where, as soon as the insurance company sees the word experimental, that's the buzzword. It doesn't matter what it is. They're going to stick on that to try to prevent you from doing that. If you simply write some legislation which affects only the national groups, that's not going to help us very much because there are other people, I think,

that are looking into this. And while you may be able to even do a better job, I think you really should be more general in your approach to clinical research that they can't cut us out because it's experimental.

In our work with our radioactive antibodies, people are coming from all over the world to get this. They're coming to New Jersey from Australia, from Germany, from all over the country to get an antibody which we can give here. So not to mention the fact that they're bringing people in-- That money is coming into New Jersey from these people from outside, so it's not costing-- Insurance companies outside are paying for this. But of course, there are many people in New Jersey that are getting this treatment, and they will bark when we tell them that this is an experimental form of treatment. Although what we're doing is simply injecting an agent for which they don't have to pay because that is experimental. We can't charge for that. But they won't pay for the clinical care, the regular care that these patients receive. They won't pay for that.

ASSEMBLYWOMAN HECK: Examinations, etc.?

DR. RUBIN: Yes. Test, CAT scans, whatever, they won't pay for that because it's an "experiment." If we brought the same patient in and we said the patient has pancreatic cancer, we use a standard drug for pancreatic cancer, which incidentally doesn't work, they'll pay for that. But they want to ratchet down on these experiments.

ASSEMBLYWOMAN WEINBERG: So you're saying--

DR. RUBIN: That's what they want to get a hold of.

ASSEMBLYWOMAN WEINBERG: --in order to cover things like that--

DR. RUBIN: Yes.

ASSEMBLYWOMAN WEINBERG: --we would have to be much more general.

DR. RUBIN: Much more general, yes.

ASSEMBLYWOMAN HECK: And one of the physicians mentioned peer review--

DR. RUBIN: Yes.

ASSEMBLYWOMAN HECK: --rather than just national-based trials.

DR. RUBIN: All hospitals in New Jersey doing clinical research should have their institutional review board, which has to be fully constituted according to the National Cancer Institute or the National Institute of Health-- They have a specified membership and the meetings and the minutes, and so forth. Everything has to be just so.

ASSEMBLYWOMAN HECK: So you believe--

DR. RUBIN: That's peer review. That's what we all have.

ASSEMBLYWOMAN HECK: So I'm looking at-- You have a detailed report and I know we're all going to read it, but I would like you to synopsise.

DR. RUBIN: Sure.

ASSEMBLYWOMAN HECK: But I would also like you to answer the broad question that we're asking today. Do you believe that clinical trials will expedite new cures?

DR. RUBIN: Yes, absolutely. There are several types of clinical trials, and it's outlined here, one, which we were talking about in the earlier

testimony, are the national cooperative groups. They're Cancer with acute Leukemia B, or CALGB; Southwestern, or SWOG; Eastern Cooperative, or ECOG. And then there are a few specialty groups like Gynecology Oncology Group, or GOG, then there are some pediatric groups. These are national and often international groups which often do collaborate with one another to establish clinical protocols. These are usually ones that are very close to the state of the art at the present time. They are not very innovative usually. They don't involve something that's very new. They're simply asking a question, but-- The information that comes out is not terribly exciting. It's going to measure a little bit, say a coffee spoon improvement rather than a quantum improvement.

What's important about that is that it does represent the very highest quality of care not only in what's in the protocol, but the machinations you have to go through to stay on that protocol. And you're investigated on a regular basis by the protocol group or by the NCI. And they make sure you dot every *I* and cross every *T*. So that this is one of the best forms of QA that I've ever seen. And it has stimulated us to simply, in the hospital, to treat people who are not on protocol the same way. So, if you're using clinical trials in your institution, you can say pretty safely that that institution is doing high-quality work.

ASSEMBLYWOMAN HECK: Good. So the move towards asking HMOs, insurance companies--

DR. RUBIN: Yes.

ASSEMBLYWOMAN HECK: --ERISA plan, etc.--

DR. RUBIN: Yes.

ASSEMBLYWOMAN HECK: --federally and statewide to cover clinical trials is an important factor. What we are addressing today.

DR. RUBIN: This is extremely important.

ASSEMBLYWOMAN HECK: Otherwise you wouldn't be here.

DR. RUBIN: That's right. But I wanted to add to that something that you haven't heard too much about--

ASSEMBLYWOMAN HECK: Okay.

DR. RUBIN: --was the innovative types of treatment should be supported as well, because that's what's going to cure cancer. We have our hands on a couple of things I think that no one else is doing. You know, if we're going to have trouble putting patients on these studies because we're not on -- because of their insurance companies, then we're not going to cure cancer so quickly.

ASSEMBLYWOMAN VANDERVALK: Doctor, there's a fear out there-- I hear what you're saying and it makes a lot of sense. But we also have to live with the insurance companies who say, "Well, you can't expect me to pay for everyone who wants to put a trial on. You know, we-- It's impossible. We won't do it," whether they can. But they won't do it. Now-- So we're trying to come to certain--

ASSEMBLYWOMAN HECK: Conclusions.

ASSEMBLYWOMAN VANDERVALK: --yes, conclusions. I don't want to use the word standards, but when you look at the NCI, the FDA, and the NIH, and when you look at those three bodies and they approve clinical trials, it's sort of a recognized group. What you're suggesting is perhaps maybe we'll get more breakthroughs from what you're suggesting in

the way of trials. But how do we turn around and say to the insurance companies, which is what we're trying to do, to say, "You have a particular interest or should have a particular interest to cover the basics"? How do we separate what you're suggesting from just any old trial? A trial that-- I can't think of an example, but--

ASSEMBLYMAN IMPREVEDUTO: Shark cartilage.

ASSEMBLYWOMAN VANDERVALK: --a trial that some people might say, "Well, it's too selective, it's too radical, it's too whatever, and we just don't want to be part of it."

DR. RUBIN: Well, you mentioned shark cartilage. If someone wanted to use shark cartilage, I don't think that the insurance company should pay for the shark cartilage. That's an experimental agent.

ASSEMBLYWOMAN VANDERVALK: But what you're saying--

DR. RUBIN: But if your patient has to come in to get treatment, they should pay for the treatment.

ASSEMBLYWOMAN VANDERVALK: Right. But what you're saying is-- How do we set something-- It's not a standard. Parameters, something to say that this shall be covered or should be covered, but you don't have to go this far. I mean, how do we make that distinction?

ASSEMBLYWOMAN HECK: When you're saying treatment, what does that encompass from your point of view?

DR. RUBIN: Well, if the patient is coming in to get a conventional treatment, they have to have a history and physical, an X-ray, a CAT scan, lab tests. Then, they're going to get a treatment. Well, if they are going to get a standard treatment, fine. If they are going to get an

experimental treatment, they shouldn't have to pay for the extra experimental part of it. They should pay for the basic treatment. And what they're doing is saying, "No, you cannot come into this hospital for this treatment because it's experimental. If you want to come in to give this patient something that doesn't work, even though it's standard, then that's fine. We'll pay for that."

So I think if you can establish to pay for the basic hospitalization for a treatment-- Now, if the treatment is in some way so out of the way and expensive, fine, or if it involves a drug which is not yet on the market, I shouldn't have to pay for that.

ASSEMBLYWOMAN HECK: Okay.

ASSEMBLYMAN IMPREVEDUTO: The drug?

DR. RUBIN: They shouldn't have to pay for the drug.

ASSEMBLYMAN IMPREVEDUTO: I agree, but everything else, the X-ray, the CAT scan--

DR. RUBIN: Yes. Yes.

ASSEMBLYWOMAN HECK: But the treatment leading up to that.

DR. RUBIN: Yes.

ASSEMBLYMAN IMPREVEDUTO: They should pay for that?

DR. RUBIN: Absolutely. I think that's what we're really looking for because that's what costs-- If you bring a patient in for a bone marrow transplantation-- Now we're doing transplantation with cord blood. Well, it's a transplantation. Pay for the transplantation, it's standard, but don't say because it's a cord blood we can't do it. We haven't been turned down yet, but I'm waiting--

ASSEMBLYWOMAN HECK: Yes.

DR. RUBIN: --“Oh, with cord blood, we don’t cover.”

ASSEMBLYMAN IMPREVEDUTO: Call it something else.

DR. RUBIN: Yes. Well, actually--

ASSEMBLYWOMAN HECK: But that’s what they try to do.

DR. RUBIN: --there are ways of getting around this.

ASSEMBLYWOMAN HECK: But they shouldn’t have to do that.

DR. RUBIN: You can do it step by step often, and they don’t catch you until it’s too late.

ASSEMBLYWOMAN HECK: See, that’s the terrible part, and that word has been used a number of times today “if they catch you.” And you’re treating a patient.

ASSEMBLYMAN IMPREVEDUTO: It’s almost as if you’re doing something wrong.

DR. RUBIN: Yes. Right. Yes.

UNIDENTIFIED SPEAKER FROM AUDIENCE: Rose, I think you’ve really struck on a very, very important issue because the set of circumstances under which we operate is under State regulation and almost forces physicians to be behaving in a way which, one, violates their own ethical standards, two, outsiders might say it’s fraudulent behavior, and that’s going to get us into a little trouble. That’s a slippery slope we don’t want to go into, and I think the issue is we can’t wait for the Federal government. The Federal government has taken over 200 years to have one national insurance act passed. Insurance-- Health insurance is a State-controlled, State-regulated industry, and we have to regulate our--

ASSEMBLYWOMAN HECK: What have to look at the semantics involved--

UNIDENTIFIED SPEAKER FROM AUDIENCE: That's right.

ASSEMBLYWOMAN HECK: --as well as the procedure and the standards they use to make a determination of treatment to that point.

UNIDENTIFIED SPEAKER FROM AUDIENCE: Exactly.

ASSEMBLYWOMAN HECK: So that's one-- Is anybody listening? Okay.

ASSEMBLYMAN IMPREVEDUTO: At what point-- You've taken an oath, which is to do the best that you can to help to maintain life.

ASSEMBLYWOMAN HECK: That's right.

UNIDENTIFIED SPEAKER FROM AUDIENCE: Right.

ASSEMBLYMAN IMPREVEDUTO: And if you know that you can do that or that you're being stopped from doing that because of the capital that isn't being supplied, but there's another way to do that, and if it means that you may have to do it step by step and not get "caught," you're living up to your oath. And nobody can fault you ever for that. And I disagree with the word fraudulent, because I don't think you are being fraudulent. And quite honestly if you were, I think that's a situation in which it's excusable.

ASSEMBLYWOMAN HECK: Well, I think, I think we have--

ASSEMBLYMAN IMPREVEDUTO: The shame of it all is that you have to go to that point.

UNIDENTIFIED SPEAKER FROM AUDIENCE: That's right. That's the issue.

ASSEMBLYWOMAN HECK: I think we have to look at the regulations and the rules whereby they operate and the insurance companies judge the--

ASSEMBLYMAN KELLY: We're getting off the subject. He was testifying and we got into space somehow.

ASSEMBLYMAN IMPREVEDUTO: Rose, I think the time for looking is over.

ASSEMBLYWOMAN HECK: No, but that's what his purpose is.

UNIDENTIFIED SPEAKER FROM AUDIENCE: That's all right.

ASSEMBLYWOMAN HECK: That's what his purpose is.

UNIDENTIFIED SPEAKER FROM AUDIENCE: And I'm supporting that-- And I'm simply saying focus on the insurance industry, focus in New Jersey, don't worry about the Federal government--

ASSEMBLYWOMAN HECK: That's what we said before.

UNIDENTIFIED SPEAKER FROM AUDIENCE: Those people can't make it happen.

ASSEMBLYWOMAN HECK: Focus on New Jersey, focus on the insurance industry and the way they deliver the payment to the physician, the consumer as well.

UNIDENTIFIED SPEAKER FROM AUDIENCE: And force them to pay for the procedure.

ASSEMBLYWOMAN HECK: And force them to pay for the procedure.

UNIDENTIFIED SPEAKER FROM AUDIENCE: That's right.

ASSEMBLYWOMAN HECK: I'm saying that again, because they say they're not picking you up on the tape. That's why I'm repeating what you are saying.

UNIDENTIFIED SPEAKER FROM AUDIENCE: Right.

ASSEMBLYWOMAN HECK: It's not that I don't understand. I just want it to go on the tape.

ASSEMBLYMAN KELLY: Speak louder like I do. (laughter)

UNIDENTIFIED SPEAKER FROM AUDIENCE: I should, John. I'm Irish you know. (laughter)

ASSEMBLYWOMAN HECK: But, Doctor, that's a very important point.

DR. RUBIN: Yes. I think--

ASSEMBLYWOMAN HECK: Because it must be terribly frustrating for physicians. It must be very frustrating for health care providers and Ms. Lopez who said that she's got to spend days on the phone.

DR. RUBIN: Well, you see, what she told you is-- It goes on every day in all of the institutions.

ASSEMBLYWOMAN HECK: In every hospital and every office.

DR. RUBIN: But there are many techniques how they can whipsaw you. On my way, I was a little late today, because I had a hurried call from my office. We're doing a transplant on a gentleman with a disease I think we can treat him definitively. I think we can probably take care of his disease with a transplant. He was set to go tomorrow. Now, if there's a sudden phone call that says, "The insurance company just called. They'll only

pay 70 percent if it's done in our institution. They'll pay 100 percent if it's done somewhere else"--

ASSEMBLYWOMAN HECK: Isn't that awful?

DR. RUBIN: So what they are doing is they are whipsawing. Obviously, I don't know what's happening, but I suspect this is the old-fashioned lowball.

ASSEMBLYWOMAN VANDERVALK: Is that because you weren't in their network?

DR. RUBIN: No. We're all in the network, but the rules keep changing. They make deals with different hospitals. I won't mention it because you may be in one.

ASSEMBLYWOMAN HECK: No, that's fine. That's fine.

DR. RUBIN: They'll make a deal with the hospital to--

ASSEMBLYWOMAN HECK: But the fact of it is--

DR. RUBIN: --undercut.

ASSEMBLYWOMAN HECK: --on record, and we will look into that.

DR. RUBIN: Yes.

ASSEMBLYMAN IMPREVEDUTO: But see they got you by the potatoes, because you signed--

ASSEMBLYWOMAN HECK: Tony, we have to do this in a very strong bipartisan way and stay focused on this issue--

ASSEMBLYMAN IMPREVEDUTO: Well, Rose, let me tell you this--

ASSEMBLYWOMAN HECK: --because you are a good fighter. We're all good fighters.

ASSEMBLYMAN IMPREVEDUTO: Let me say this to you. I think that time for looking into it is over.

ASSEMBLYWOMAN HECK: No, I mean direct--

ASSEMBLYMAN IMPREVEDUTO: I think you've had a number of hearings and they've all been wonderful.

ASSEMBLYWOMAN HECK: Yes.

ASSEMBLYMAN IMPREVEDUTO: We've learned an awful lot. Looking now is ended. Now it's legislation.

ASSEMBLYWOMAN HECK: No. No. No. We've done legislation at each phase.

ASSEMBLYMAN IMPREVEDUTO: Well, no, I think--

ASSEMBLYWOMAN HECK: But this is why we're here.

ASSEMBLYMAN IMPREVEDUTO: --we need now to do a bigger piece.

ASSEMBLYWOMAN HECK: No. No. This is the big piece. But the point is I thought, and we believed, that our work outside of this room would have brought forth some fruit. It didn't. We heard that today, "Oh, we're not sure," and "We don't know." But now we're finding things that we can focus on immediately besides the clinical trials. What's wrong now has to be changed.

ASSEMBLYMAN IMPREVEDUTO: Well, first of all, I think you can't use the word experiment. We got to ban that from medicine.

ASSEMBLYWOMAN HECK: That's right.

DR. RUBIN: That's right.

ASSEMBLYMAN IMPREVEDUTO: The second thing we have to do is get rid of the word clinical trials, and they should be done in secrecy.

DR. RUBIN: You should take out the word transplantation because that's another buzzword.

ASSEMBLYMAN IMPREVEDUTO: There you go. Can't use that one either.

DR. RUBIN: They go into a panic.

ASSEMBLYWOMAN HECK: Yes.

DR. RUBIN: We have a unique type of transplantation. How was the insurance company -- what right do they have to say you should have it done in other institutions? It's going to do it differently. What we're doing is specifically designed for this patient, in this situation, and it happens in many of the cases. And in this case, we're unique with it. They couldn't be done somewhere else.

ASSEMBLYMAN KELLY: They want you to throw your hands up and not do it. That's what they're doing.

DR. RUBIN: Well, yes. And if you stall long enough, it becomes moot.

ASSEMBLYWOMAN HECK: The patient dies.

DR. RUBIN: Yes.

ASSEMBLYWOMAN HECK: That is sad.

ASSEMBLYMAN IMPREVEDUTO: Well, Jack, you've got the right idea. I'm going with you.

ASSEMBLYWOMAN HECK: Where are we going?

ASSEMBLYMAN IMPREVEDUTO: I can't tell you, Jack's got it planned. Jack's got plans, he and I.

ASSEMBLYWOMAN HECK: Doctor, I really appreciate your being here. We will make sure that we act on this.

DR. RUBIN: Okay.

ASSEMBLYWOMAN HECK: As quickly as we possibly can. Because the time for waiting for them to come forward is over now. It's over. Because we hear this "Maybe, no, you didn't give me the transcript, the paperwork early enough." Well, we met with you in July. If you didn't know what we were saying then, you're not going to know it because you saw it in writing.

DR. RUBIN: One other thing that I wanted to add--

ASSEMBLYWOMAN HECK: Please.

DR. RUBIN: --just in case you don't read this carefully--
(referring to statement)

ASSEMBLYWOMAN HECK: Oh, I'm reading it. We're reading it.

DR. RUBIN: Well, anyway--

ASSEMBLYMAN IMPREVEDUTO: And you can bet it's going to be read.

ASSEMBLYWOMAN HECK: You've got some good points there.

DR. RUBIN: There is a technique where the insurance companies get into the research business themselves. And I think this is wrong. I think this is a conflict of interest. They actually get involved. And I am very upset with my own colleagues in the cooperative groups that have made alliances

with insurance companies to get their protocols supported. What this does is gets their protocol supported but not someone else's, because they've made a deal with the insurance company. And I can see the insurance company-- I don't know, what I'm thinking is that if they can get a hold of that protocol and say I'm going to support that one, they have now narrowed it down considerably from the people who will be--

ASSEMBLYWOMAN HECK: And limit it.

DR. RUBIN: --the number of people--

ASSEMBLYWOMAN HECK: Yes.

DR. RUBIN: --who would be--

ASSEMBLYWOMAN HECK: Have access.

DR. RUBIN: --able to have that treatment.

ASSEMBLYMAN KELLY: Well, Doctor, I'm concerned like Blue Cross is an insurance company, but they also set up clinics.

DR. RUBIN: Yes.

ASSEMBLYMAN KELLY: I wonder how the hell they do that.

DR. RUBIN: Well, they do that. I don't know much have an impact--

ASSEMBLYMAN KELLY: I know they do it. It's sort of annoying, either you write insurance or you cure. You can't do both.

ASSEMBLYWOMAN HECK: Through Policy and Regulatory Oversight, we're calling them in.

ASSEMBLYMAN KELLY: Okay.

DR. RUBIN: They have these companies like a HIP plan that will both insure and treat. But you really have to have a complete care from cradle

to grave if you're going to do that properly. It usually doesn't work out very well, but I'm not an expert on the economics of medical care.

ASSEMBLYMAN KELLY: Well, it would seem to me that they're either going to be in insurance or be in care. You can't--

DR. RUBIN: You can't do both.

ASSEMBLYMAN KELLY: --be worried about the bottom line on both of them, because one of them has to give, one has to be heard.

DR. RUBIN: They should stay the hell out of research.

ASSEMBLYMAN KELLY: Correct. They should stay in insurance, but they won't.

DR. RUBIN: Yes. Yes.

ASSEMBLYMAN KELLY: Good. I didn't vote for that merger anyhow.

ASSEMBLYWOMAN HECK: Doctor, thank you very much.

DR. RUBIN: Okay.

ASSEMBLYMAN IMPREVEDUTO: You made me vote with you.

ASSEMBLYWOMAN HECK: We appreciate the time. We know how important-- And your time is very valuable.

DR. RUBIN: Thank you.

ASSEMBLYWOMAN HECK: But I will promise you that Charlotte and I will get on this immediately.

DR. RUBIN: Well, if I can be any further help--

ASSEMBLYWOMAN HECK: We'll call on you.

DR. RUBIN: Okay.

ASSEMBLYWOMAN HECK: No doubt.

ASSEMBLYWOMAN VANDERVALK: Thank you, Doctor.

ASSEMBLYWOMAN HECK: Thank you.

We have Peter Doherty, a prostate cancer survivor, Morristown Memorial Hospital. And then, is Denyse Adler here? (affirmative response)

ASSEMBLYWOMAN HECK: Good. Then Donna, Ann Marie, and Mary Todd can come up in one fell swoop at the same table. That will conclude our meeting.

Peter.

P E T E R D O H E R T Y: I'd like to thank the Committee for being so patient today. You've had a long day, and I'm sure--

ASSEMBLYWOMAN HECK: Very informative though.

MR. DOHERTY: It is. And I admire your tenacity.

I'm 70 years old, and I've been suffering from prostate cancer for 7 years. I'm a three-time reoccurrence man. I'm now on what we call chemical castration. I'm sorry the Assemblyman left who has the father with prostate cancer because he'd probably understand this. My next step will be clinical trials.

But I want to come to you today to talk about Medicare. As you all are well aware, how the Medicare system works is the provider in our State is different. And I don't know what you've done about that, but I know for a fact that Medicare, in many instances, will not pay for clinical trials.

I passed this sheet up because I was in Washington on Tuesday where we had a big conference and I had a chance to go in and see Senator Torricelli and Senator Lautenberg, and we talked about what we can do for cancer. In some regards, they said to me, and I think it's true, the squeaky

wheel gets the action. People that come in and bang on the table and say, "We need this," they're the ones that get the action.

I'm afraid in too many times cancer has become a political situation where we proselytize one cancer against another. If you'll look at this there's 5200 people with lung cancer -- 4700 are going to die. That means that, you know-- It's fatal. And I don't hear anybody talking about lung cancer.

As I said, Assemblymen, I have prostate cancer. I'm in chemical castration. My next step will be to go into clinical trials as a Medicare patient. That's something I hope you'll be able to look into. I don't know how it works, but I do know-- And there's one other thing that the previous doctor spoke about. It's not so much the medicine. It's all the work that has to go into it, the blood testing and all the other-- And the doctors don't give all their services free. And we talk about these trials, and I doubt that these doctors can afford to give all the free time to do the trials. They have to be paid also. And it's important.

I noticed there are some receding hairlines in your group earlier today, and prostate cancer is talked about as an old man's disease. But it is not really true. I was fortunate to lead a prostate cancer support group at Morristown Memorial Hospital. It now has 443 men in it. And we're one of twenty-five prostate cancer support groups in New Jersey. We lead the nation in prostate support groups. They're very active. Almost 2500 men meet monthly in this thing. And we feel, unfortunately, the PSA testing and the other things that are going on, which luckily you folks saw well enough to pass

legislation last year mandating the insurance companies with 50 or more enrollees would pay for the testing--

The last two months in our group we brought 18 new men in, and 10 of them have been under 45. So it's no longer, you know, the old man's disease. I think we're seeing, because of the testing, more and more people.

So my message is: Don't forget the Medicare people. I hear all about the HMOs and all the other initials that we work with, but there's a lot of people today that have a problem. I wanted to just take another minute. Some of you may or may not have seen the article in *The Star-Ledger* of September 24 about the young man, age 32, who has inoperable bile duct cancer and has had 27 trips to Johns Hopkins. His bills so far are more than \$200,000 in medical bills has accumulated. Much of it is being denied by his health insurance plan. They have two young children. I couldn't help thinking about this and saying there goes their education, there goes their families. I mean, they're going to have to pay for this.

And also on the bottom line it says, "Bills have been sent to a collection agency." Hospitals can't wait. They've got bills to pay, too, and everything else that goes along. So I think this is more involved for those of us that are cancer fighters, it's very important that these things, you know, have--

I want to conclude by sharing with you and you being the first people, I think, in the State of New Jersey to see this. I have a friend of 35--

UNIDENTIFIED SPEAKER FROM AUDIENCE: No. Carol Murphy was the first.

MR. DOHERTY: Okay.

ASSEMBLYWOMAN HECK: Who?

MR. DOHERTY: I have a friend of 35 years named Carol Murphy, Assemblywoman up in Morris County.

ASSEMBLYMAN IMPREVEDUTO: Familiar with her.
(laughter)

MR. DOHERTY: And of course Carol has a particular interest in cancer research--

ASSEMBLYWOMAN HECK: Yes.

MR. DOHERTY: --and everything that goes along with it. Our prostate-- I want to enforce this. The Prostate Cancer Support Group at Morristown Memorial Hospital designed this license plate (indicating), Conquer Cancer. This is not-- We didn't make it prostate cancer. You know, we don't politicize. We say this is for all cancer. And all the money raised by this will go to Ann Marie Hill's New Jersey State Commission on Cancer Research.

UNIDENTIFIED SPEAKER FROM AUDIENCE: Peter, clarify that for the record.

ASSEMBLYMAN KELLY: Has that been approved?

MR. DOHERTY: I'm sorry.

ASSEMBLYMAN KELLY: Is it approved?

MR. DOHERTY: Yes, this is going to be available very shortly to buy it. As you know all vanity plates -- it's the same deal -- \$50 the first year about \$43 will go toward cancer research. And of course, as you well know, the Commission-- They will put 100 percent of that money to research. And in the \$15 a year, about \$12 will go toward research on cancer.

You probably see my button -- I hope you have -- Research Cures Cancer. I mean, that's the answer folks. I mean, we're not going to cure cancer unless we have all these trials and all the other things. I can't say-- This is the first time I've seen the plate.

Schering-Plough donated \$50,000 for this so that Dick Kamin's Motor Vehicle Bureau would not have any expense money taken out of this plate. They have certain expenses. So 100 percent of all the money derived from this plate will go to cancer research. And you got to know folks that everybody that buys this is going to say, "I'm helping to conquer cancer." That's my--

ASSEMBLYWOMAN HECK: Well, may I also suggest to you that you also use the breast cancer checkoff on your tax forms each year.

MR. DOHERTY: Well, why don't we make that a uniform cancer-- I'm serious, Assemblywoman. New York State, by the way--

ASSEMBLYWOMAN HECK: That's why we use that one.

MR. DOHERTY: --just took their breast cancer and changed it to both breast cancer and prostate cancer. I was going to mention that to you, but as long as you brought it up, why can't we just make it a cancer research fund checkoff?

ASSEMBLYWOMAN HECK: Well, we were told when we started the breast cancer research that all of that goes to all cures.

MR. DOHERTY: I realize that.

ASSEMBLYWOMAN HECK: Okay.

MR. DOHERTY: I realize that. But as a prostate cancer survivor that doesn't really--

ASSEMBLYWOMAN HECK: Well, it should.

MR. DOHERTY: Anyway, but this plate, I hope, will do something -- that all cancer -- can say, "We're helping to do it."

ASSEMBLYWOMAN HECK: Yes.

MR. DOHERTY: If there's any questions, I'd be happy to-- But just bear in mind there's a lot of us old guys that really need to have you look into that Medicare thing.

ASSEMBLYWOMAN HECK: You're not that old. You're only five years older than I am.

MR. DOHERTY: And you're a young woman.

ASSEMBLYWOMAN HECK: That's why I consider you young.

ASSEMBLYMAN IMPREVEDUTO: You're 32?

ASSEMBLYWOMAN HECK: Sixty-five.

ASSEMBLYMAN KELLY: How old are you?

MR. DOHERTY: Seventy.

ASSEMBLYMAN KELLY: Well, I'm older than you are.

MR. DOHERTY: But we're Irish and it doesn't really show.

ASSEMBLYMAN IMPREVEDUTO: And you're on palmetto weed or whatever the hell that stuff is.

ASSEMBLYMAN KELLY: Saw palmetto.

ASSEMBLYWOMAN HECK: You're right. I'm Italian so--

MR. DOHERTY: You've had a long day. And if there are no questions, I'll excuse myself--

ASSEMBLYWOMAN HECK: No, I appreciate that.

MR. DOHERTY: --and I thank you.

ASSEMBLYWOMAN HECK: All of it. And thank you for the testimony.

MR. DOHERTY: Okay.

ASSEMBLYWOMAN HECK: And we will look into the Medicare coverage.

MR. DOHERTY: Very good. Thank you very much.

ASSEMBLYWOMAN HECK: Thank you.

This young lady, and then the three members will be up -- people who helped us with this.

It's Denyse Adler, Chairperson, Nursing Psychosocial Advisory Group to the New Jersey Commission on Cancer Research.

D E N Y S E A D L E R: It really is a mouthful, isn't it?

ASSEMBLYWOMAN HECK: It is.

MS. ADLER: It's a very long title, but thank you very much. I'm delighted to have this opportunity and privilege to speak to you as I have--

ASSEMBLYWOMAN HECK: In the past.

MS. ADLER: --on occasion at some of your other hearings.

I am representing the Psychosocial Advisory Group to the Commission. And one of the things that concerned me listening here all day long was that one of the critical issues around clinical trials that has not been talked about today, but is very essential, is quality of life.

Increasingly, clinical trials are including components relative to quality of life. And I think that our role here is to not only encourage and support, but insist that clinical trials include this component, which is to say that it is fine to have a trial to identify whether some drug or some treatment

extends life by three months or five months or six months, but unless you're looking at whether that's a six months that's worth living, then the trial really isn't advancing what we know. If the three months or six months are in intractable pain, if they're required to be in an institution without communication from family members or unable to benefit in any way, we really need that kind of information as well.

So clinical trials that don't include this component really should be discouraged. We need to look at what are the outcomes, what are the symptoms, what are the issues that make a trial worth doing and make a new treatment worth adopting. Increasingly, we do see clinical trials adopting this approach, but I think that we need to strongly encourage whatever costs there might be associated with that or independent trials that look at what are symptoms that make those treatments worthwhile to have.

So I would like to encourage you, when you look at clinical trials, to be sure that any legislation or any action that we take strongly encourages or even requires outcomes relative to psychosocial issues: what is the quality of life that we're offering along with the treatment.

ASSEMBLYWOMAN HECK: Well, I think we heard from the Tomorrows Children -- the Director of Tomorrows Children, saying that we have to look at a long range because some of the children whose lives are saved said, "Why didn't you let me die?" when they got older.

MS. ADLER: Well, and in fact, you know, I can mention also that next October, a year from now, we're going to have a major international conference here in New Jersey supported by the Commission and Tomorrows Children--

ASSEMBLYWOMAN HECK: Good.

MS. ADLER: --looking at survivorship and quality of life issues.

ASSEMBLYWOMAN HECK: That's an important point.

MS. ADLER: That's a very important issue for our--

ASSEMBLYWOMAN HECK: You see that in elder care.

MS. ADLER: Well, I think what we're finding across a life span is the children become young adults and young adults become older adults and become geriatrics populations. We need to really understand the implications of the treatment.

The other thing I'd like to mention quickly, because I know this has been a very long day for everyone, is that the hearing really was focused on the issue of why do we have such a low accrual in clinical trials. And I think some of the issues that we have to address-- And I think this is a legislative issue, because it may require some funds to do our own research looking at it. There are a lot of barriers to clinical trials. Some of them have been mentioned today.

Outside of insurance reimbursement, which is clearly a very major barrier, we are also talking about physician attitudes. I think a few of the speakers mentioned earlier physicians need to be educated more clearly on the benefits and the drawbacks and assisted with it. But I think we also need to understand, what does a trial mean to an individual? What does that word mean? One of the things that we know in psychosocial oncology is that words carry very different meanings for different people. So when you say something, you know what you mean. You don't know if it's being received in the same way. So we need to look at what does a trial mean.

In some populations, this is considered, you know, something like akin to an attempt to eradicate a particular racial or religious group. And some of that builds on our unfortunate history in this country when in fact that happened. So we need to understand where people are coming from.

The costs associated with clinical trials are not just the cost of health care. It's parking, and it's driving to the place where you need to go once a week to be checked. And perhaps, it's child care or care of a spouse who's not able to care for themselves, respite care for the family member that the cancer patient themselves is looking for. So there are a lot of associated costs in clinical trials that can become a barrier -- taking time off from work if the person's able to be working. There's, you know, a whole host of other costs associated with clinical trials. And I think that everyone here has commented on the fact that people who are getting clinical trials get better care.

ASSEMBLYWOMAN HECK: Those same costs, though, are apropos of anyone with an illness.

MS. ADLER: Not necessarily.

ASSEMBLYWOMAN HECK: Oh, I don't know.

MS. ADLER: They could be increased by trials. Because if you're on a trial, for example, some trials require a weekly blood test or a more frequent examination in order to comply with the requirements. So yes, it is true with everyone in an illness, which is why if you're asking to be part of a trial, you may be asking--

ASSEMBLYWOMAN HECK: Have to look-- They may incur other expenses.

MS. ADLER: --them to even increase additional expenses.

ASSEMBLYWOMAN HECK: Yes.

MS. ADLER: Because in order-

ASSEMBLYWOMAN HECK: But it's a good point.

MS. ADLER: --to comply you do have to-- You may have to come more often. You may have to stay there longer. You may have to take more time off of work. So these are things that we need to also be looking at as barriers.

The informed consent process is sometimes very overwhelming in clinical trials. Each individual has a different need for how much information they want or should get. It's a very thorny, ethical issue, but we need to look at how that's interpreted.

But most important what I do want to raise is the issue of a multicultural approach. I think nationally what we do know is that fewer minorities participate in clinical trials.

ASSEMBLYWOMAN HECK: True.

MS. ADLER: Now part of that is just a result of minorities, as the whole in our country, generally speaking, getting a less aggressive level of care, and, consequently, it's not surprising that we see fewer minorities on clinical trials. But, if we do want to take a very progressive approach in this State, which we have up to now and have demonstrated, we need to invest time, money, and resources in looking at how do we reach out to these populations. It isn't enough to translate the informed consent form into Spanish or into Russian or into any other language. Simply changing the way a word is said is not going to approach a multicultural group. We need to understand what are the issues in that cultural group, what are the decision-making processes,

who's involved, how does that group feel about clinical trials, and what are the issues that might be barriers for that specific group of people. And until we do that, we're not ever going to increase the minority population. I mean, obviously, we have to look not only at HMOs and Medicare, but the uninsured. Bringing in people into trials and enabling them to participate in trials if there's no insurance company that's taking care of their care and whether they're absorbed into a hospital's general uninsured care. So there's many issues, but I think that until we address multicultural issues--

ASSEMBLYWOMAN HECK: But we have to focus on one thing at a time, Denyse.

MS. ADLER: Oh, I do understand.

ASSEMBLYWOMAN HECK: I understand the whole spectrum, and it's not as if we haven't addressed that, you know, in the whole picture, in the general picture. But you have to focus on one step at a time and then accomplish it and then move on to the next one. The major step here as was conveyed to us is the fact that if we had more people covering-- And as doctors and the individuals have told us, they believed they're covered, they're not covered, they have to fight for the money. All of that is, you know, devastating as we move along.

MS. ADLER: It is.

ASSEMBLYWOMAN HECK: The next-- And we have to solve that first and then we can go on to the rest, but it's all legitimate.

MS. ADLER: I would agree. I would agree--

ASSEMBLYWOMAN HECK: Absolutely.

MS. ADLER: --that that's very critical. I would venture to say that solving that problem would not astronomically increase the participants in clinical trials by itself. I think they're a number of other major barriers. I agree that's what we need to do first. And I'm wholeheartedly in support of that. I would encourage you as you look at that process, once that happens, to begin to look at some of the other issues that create these barriers so that we cannot only assure that once we've reached to people, then they can get those.

ASSEMBLYWOMAN HECK: Solutions in those areas also mean education.

MS. ADLER: Education resources. Right.

ASSEMBLYWOMAN HECK: Has to incorporate education and communication.

MS. ADLER: Absolutely.

ASSEMBLYWOMAN HECK: And that's a barrier not only for clinical trials. It's in so many areas. So I think in terms of that we have to look towards again not just the Health Department, but the Education Department has to do more outreach in so many areas for the multicultural community. But again, it's a point well taken. And if you have any information you'd like to pass onto us--

MS. ADLER: Okay, I don't have this in written form, but I'd be happy to write something I'm sure.

ASSEMBLYWOMAN HECK: --we'd appreciate it. But if you do, please.

Thank you, Denyse. Thank you for coming out.

Dr. Mary Todd, Donna, and Ann Marie.

American Cancer Society Research--

D O N N A B O C C O: Donna Bocco with the American Cancer Society.

ASSEMBLYWOMAN HECK: Yes.

MS. BOCCO: I'd be pleased to leave the last words to Ann Marie Hill, my colleague from the Commission, and Dr. Mary Todd from the Cancer Institute.

Ditto. Ditto. Ditto. What more can I say. You heard one of my doctors who chairs our service committee earlier on in today's testimony. I think they're tired of being gorilla warriors spending time that should be devoted to the research, devoted to the patients, to get coverage for medical care while a person is in clinical trials, or encouraging the person to go into clinical trials knowing that that medical care will be covered.

You have the American Cancer Society fact sheet. We did it in a page and a half, but the one line that I would like to draw your attention to and, Assemblywoman Heck, you said it: The time is now.

The American Cancer Society advocates for laws to make sure that health insurance plans, public employee plans, Medicaid, and Medicare cover all patient costs associated with participating in any phase of a high-quality, peer-reviewed clinical treatment trial. That is critical. And as to what those trials are, we have it delineated here. I don't want to get into those details. I think my doctors would love to maybe give up one hour of the time they play gorilla commando fighting with that to maybe even take a little respite and come out and raise more money for research--

ASSEMBLYWOMAN HECK: Good.

MS. BOCCO: --as opposed to having to do that.

ASSEMBLYWOMAN HECK: I don't blame them.

MS. BOCCO: Thank you for the effort--

ASSEMBLYWOMAN HECK: Thank you, Donna.

MS. BOCCO: --of keeping us all connected so that we are marching toward the goal--

ASSEMBLYWOMAN HECK: We have to.

MS. BOCCO: --which is handling our mutual consistency in the best possible way we can.

ASSEMBLYWOMAN HECK: Yes.

MS. BOCCO: Thank you.

ASSEMBLYWOMAN HECK: Thank you, Donna.

ANN MARIE HILL: I'm not going to read--

ASSEMBLYWOMAN HECK: No, I know you're not.

MS. HILL: --much of my testimony. I am submitting on the part of Robert Spiegel, who is Director of Worldwide Clinical Research for Schering-Plough Research Institute, testimony from the pharmaceutical industry with his apologies that he couldn't be there. If we had more time, I would read a portion of it. I think you see very clearly the type of commitment to clinical trials that New Jersey's pharmaceutical industry does provide.

ASSEMBLYWOMAN HECK: Absolutely.

MS. HILL: And I think that they are willing partners in the process of increasing access to clinical trials. So I ask you to have that included in the record.

ASSEMBLYWOMAN HECK: Okay.

MS. HILL: I have been working on this problem with the Commission on Cancer Research for over 10 years. We've tried to do models, we've tried to bring doctors together, we've tried to deal with all the barriers. We don't know the answers. So I am going to very briefly say that I thank you all for bringing together all of the players to try to help -- and help we need-- We need your help, we need researchers' help, we need the pharmaceutical industry's help, we need advocates' help, patients' help, and we need health insurances' support.

ASSEMBLYWOMAN HECK: Absolutely.

MS. HILL: Now, the Chairpersons of the Committees did charge me a little while ago with trying to find out a little information. I'm going to try not to bore you with too many statistics, but-- Because-- Actually there's very little information on cost benefit for clinical trials. We have none nationally, and we certainly don't have data available in New Jersey. We don't know what reimbursement rates exist for our insurance industry in New Jersey, and we don't know what denial rates we have. And that's a gap that clearly that we would like to find out. I have been able to glean a little information, although it's not exactly all of New Jersey, and that was in 1995 from the Association of Community Cancer Centers who did a national survey of physicians. And I happen to have the Mid-Atlantic region results. So it actually includes New Jersey, New York, and Pennsylvania. But I think that is an area that we can look at.

ASSEMBLYWOMAN HECK: I just have to comment. A couple of years ago, I had tried to do a study and get some information through the Office of Legislative Services on HMOs and insurance companies. I want you

to know, there were no responses. They referred us to information that they send to the insurance committee, which did not include any of the questions that were in our questionnaire.

MS. HILL: Very hard to get data.

ASSEMBLYWOMAN HECK: And OLS sent it out once, twice, three times. They will not respond. They will not give you facts, and they will not give you data.

MS. HILL: I agree.

ASSEMBLYWOMAN HECK: They just ignore you en masse. It's not one or another. They do it as an industry.

MS. HILL: Oh, well.

Again, I'm talking about physician responses right now. I'm not going to read every statistic, but the way the Association did average out what their concerns were for denials was on a patient-per-position response. While for capitated contracts, the Mid-Atlantic region had an average of 1.8 patients denied per physician. For managed care contracts, it was 3.7 patient denials per physician. And for indemnity contracts and for commercial, it was 2.9 patients per physician. In every case--

ASSEMBLYWOMAN HECK: That's terrible.

MS. HILL: In every case, the Mid-Atlantic region was well above the national average. And these statistics are in my testimony, so I ask you to take a look at it.

ASSEMBLYWOMAN HECK: We will.

MS. HILL: On top of that, the survey included questions, again from the Mid-Atlantic region, about concerns that physicians have where they

might not recommend or pursue a clinical trial for a patient because of coverage for health care. And 42 percent in capitated contracts said they felt concerns and would, therefore, not recommend a clinical trial to a patient; 91.7 percent for managed care contracts responded that they would not -- they had concerns so much so that they would not recommend a clinical trial; and 25 percent for indemnity and commercial plans.

I would also-- And it is a different state. And I stand here and say I wish I could say it's New Jersey, but in Arizona where managed care is 50 percent of the market -- and we were talking about the national average now of 52 percent -- clinical trials were down 10 percent to 15 percent for last year.

That is all the data that I could find. I did work very closely with Pennsylvania. I will tell you there is some good news, and I think maybe we should have some good news on the record.

ASSEMBLYWOMAN HECK: Okay.

MS. HILL: In 1995, Rhode Island passed legislation that covered the cost of phase III and IV trials. They saw no additional costs to their insurance coverage. They are now considering including phase II trials in their legislation. We have a number of other states considering similar legislation including New York, and I have been talking very closely to Pennsylvania. And I will get a-- I just got yesterday--

ASSEMBLYWOMAN HECK: Get a copy of the Rhode Island draft and give it to us and we'll start working on it.

MS. HILL: Yes, well, and I also have a great deal of information from Pennsylvania--

ASSEMBLYWOMAN HECK: Oh, good.

MS. HILL: --although I just got it yesterday, so I can't -- I don't have a copy of it yet.

ASSEMBLYWOMAN HECK: Ann Marie, don't work by yourself on that one. Incorporate the OLS department--

MS. HILL: Absolutely.

ASSEMBLYWOMAN HECK: --so that we move it along very quickly. So that when we come back into session, we introduce it as a group.

MS. HILL: Okay.

ASSEMBLYWOMAN HECK: As a Joint Committee.

MS. HILL: Let's be aware that CHAMPUS, the Armed Forces insurance, does have an agreement with the NCI and the Department of Defense. They will now agree to cover clinical trials. The Veterans Administration has expanded opportunities for their patients to enroll in investigation studies. The Blue Cross/Blue Shield Association has an agreement now formed with pediatric cancer networks to cover the cost of cooperative trials. General Motors, self-insured ERISA, has agreed to do a pilot study to look at reimbursement for breast cancer studies. And earlier this week -- and I faxed this to you, Rose -- the major HMOs of Wisconsin and Minnesota formed an agreement with national cooperative groups to cover all NCI-approved trials.

Standard treatment costs that's all we're asking for. And I don't think that's too much. I think that New Jersey can continue its groundbreaking leadership, and this Committee or Committees has certainly played major roles in that. I hope researchers--

ASSEMBLYWOMAN HECK: I just thought that today would be a day when they'd just come in and say okay.

MS. HILL: Yes.

ASSEMBLYWOMAN HECK: But apparently, I was too optimistic in the humanity area of the HMO groups and disappointed. I will talk to Paul again tomorrow and tell him that we had hoped that this would be done without legislation. But Charlotte and I agreed prior to this hearing that if nothing were forthcoming, we will put in legislation immediately on behalf of the Joint Committees.

MS. HILL: Okay.

ASSEMBLYMAN KELLY: Betty White does a good job of giving everybody a snow job on those big, two-page ads. How wonderful they are.

MS. HILL: Yes, well, it's very true. But--

ASSEMBLYWOMAN HECK: But it's too important to all of us. It may not be-- Most people I know, cancer has affected their lives within the immediate family. But thinking in terms of cousins, aunts, and uncles, there are numbers of people who have been affected by cancer. So I think that this is overdue now. We can't waste any more time.

MS. HILL: Right.

ASSEMBLYWOMAN HECK: We've gone too far here.

MS. HILL: I'm going to let Mary finish.

MARY TODD, D.O.: Thank you for your patience, and I'll try not to-

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ASSEMBLYWOMAN HECK: Thank you. And the children--

ASSEMBLYMAN KELLY: Mary who?

ASSEMBLYWOMAN HECK: Dr. Mary Todd.

ASSEMBLYMAN KELLY: Okay.

ASSEMBLYWOMAN HECK: And the children coming in -- being carried in-- Paul was there that day. A young boy with his mother, another toddler at her side, being carried in limp-bodied, skin as white as a piece of paper, no hair, attached to an oxygen unit, and you cannot feel that we should be doing something here. This is beyond belief. But go ahead.

ASSEMBLYMAN IMPREVEDUTO: Well, they'll tell you that those are the extremes.

ASSEMBLYWOMAN HECK: Yeah, right.

DR. TODD: I want to thank all of you for your patience. When a patient is diagnosed with cancer, there's an overwhelming fear, and the fear is they are going to die. Unfortunately, frequently that is the outcome. It's not the outcome that we want. You've heard today about the increased incidence and mortality rate of cancer in this State. I would say it's a crisis and that things do need to be done and need to be done rapidly. Everyone is affected either directly or indirectly by cancer. So there's good reasons for us to want to continue to improve care, and actually what we really want to do is to be able to cure this disease.

How we go about doing that is by better treatment of the disease and by prevention of the disease. And how we go about finding out what is the best treatment and how to prevent the disease is through the use of the conduct of clinical trials. They're absolutely crucial, and you've heard that today to how we practice medical and surgical oncology.

Those of us in New Jersey who are health care providers, the insurers, those involved with policy setting, and the patients -- we all have a vested interest in wanting to move this along so that we can find an answer to this dreaded disease. There are many barriers. And you've heard some of them today to why patients are not enrolled into clinical trials. There's a barrier from the perception of the patients. They don't want to be treated as guinea pigs. They would like for us to come and say we know what to do, we have an answer. Unfortunately, that's just not always the case in cancer. Patients need to be educated to that fact.

You have heard, too, though, that patients enrolled in clinical trials, regardless of the outcome of the clinical trial, do better than patients not treated on a clinical trial. And you've heard the wonderful story of how many childhood cancers we can now cure through the conduct of scientifically valid clinical trials. So it's a wonderful story. We need to educate patients to that.

Physicians need to be educated to that fact as well. They-- One of the barriers for physicians is the amount of time that it takes, not only the time dealing with reimbursement, but the time of enrolling patients under trials. We now have an NCI-designated cancer center here in this State. We have formed a network of partner and affiliated institutions.

ASSEMBLYWOMAN HECK: We do have in this State?

DR. TODD: The Cancer Institute of New Jersey is a NCI-designated cancer center.

ASSEMBLYWOMAN HECK: It is in NCI?

DR. TODD: Yes.

ASSEMBLYWOMAN HECK: So this is good.

DR. TODD: We received our accreditation in March of this year.

ASSEMBLYWOMAN HECK: Wonderful.

DR. TODD: Yes. So we're the only one in this State. We have formed a network of partner and affiliated institutions where we assist those physicians, who are staff members there, with an infrastructure to help them be able to enroll patients under clinical trials.

ASSEMBLYWOMAN HECK: I think that the amount of people who came out to testify today is a testament to the need of cancer research in the State of New Jersey. And the caliber of the people who volunteered to come and give their information tells us that we are definitely in a crisis situation. Physicians of the highest caliber came here today to plead the case for their patients.

DR. TODD: Right.

ASSEMBLYWOMAN HECK: So to me there's no more -- no better demonstration of the need. And they're coming out in those number today.

DR. TODD: You've heard about the barriers in terms of the reimbursement issues, and those are real.

ASSEMBLYWOMAN HECK: Yes.

DR. TODD: And you've heard that today very clearly. There's the issue of the research costs. We're not suggesting that the insurers, payers pay for the research costs. The sponsors, meaning the NCI, us, the pharmaceutical companies, should pay for that. We are requesting that they pay for routine care.

ASSEMBLYWOMAN HECK: Routine care.

DR. TODD: Patients, regardless of whether they were treated in the context of a clinical trial-- Cancer patients do need a certain amount of routine medical care that can be sometimes difficult to determine which is which -- not really, not really. That's pretty-- It's pretty straightforward as to which is which. Certainly in our model, we think we can address that issue that the routine care is what we would like to have reimbursed. There's also the cost that arises from the time that it takes for both the physicians and the staff of physicians to deal with the insurance companies.

ASSEMBLYWOMAN HECK: Cover the cost.

DR. TODD: And it's a cost to the insurance companies as well.

ASSEMBLYWOMAN HECK: Absolutely.

DR. TODD: And I think that--

ASSEMBLYWOMAN HECK: But more a cost to the patient.

DR. TODD: And a cost to the patient.

ASSEMBLYWOMAN HECK: Who's endangered.

DR. TODD: Right.

ASSEMBLYWOMAN HECK: And how many times have we heard today that patients have died?

DR. TODD: Right.

ASSEMBLYWOMAN HECK: That's something unacceptable.

DR. TODD: There's also a cost of not doing adequate, scientific valid research. And I think that this is a very important point. Many times things get approved as standard, when they've not really gone through the kind of clinical trial research that they need to go through, particularly when something is approved for one thing, it can be used for another thing.

Sometimes that's appropriate and sometimes, quite frankly, it's not. We need to make certain. It's not fair to the patients. And quite frankly, it's not fair to us as citizens or to the insurers. Because then they are paying for something that's very costly and that is not efficacious. So that it's important that we make sure that these are scientifically valid trials.

ASSEMBLYMAN IMPREVEDUTO: Dr. Todd, how do you advise us to do that? You've heard a little while ago that they're using interleukin for--

DR. TODD: Yes. What he was really talking about, and I'm glad you raised it, is a separate issue. It's off-label drug use, we call that. That's, once it's been approved for one issue, then it can be used for something else. There are compassionate uses for that. The bottom line is that he felt strongly for doing that. It wasn't that they weren't going to-- I guess his issue was they would not have reimbursed both for the interleukin-2 and for admitting the patient perhaps. But there are ways of getting a clinical trial approved by one of the Federal groups that we've suggested that they all be approved for.

ASSEMBLYMAN IMPREVEDUTO: But if you have a drug that's proven to be successful -- not successful on another tumor and now--

DR. TODD: It may or may not be successful on the tumor you want to use it on.

ASSEMBLYMAN IMPREVEDUTO: And now--

DR. TODD: And the only way to find that out is through a clinical trial.

ASSEMBLYMAN IMPREVEDUTO: Right.

DR. TODD: And to do ad hoc design for one patient is-- You run into issues of whether it is scientifically valid. He said that every hospital does have its own review mechanism. The review mechanism that they have is what's called an IRB, which is to review them to make sure that the informed consent process is adequate. They do not review them for scientific validity.

ASSEMBLYWOMAN HECK: Oh.

DR. TODD: There are mechanisms by which clinical trials can be submitted to a body at a Federal level and get approval.

ASSEMBLYMAN IMPREVEDUTO: Or you might have a drug that's been successful. For instance, in colon cancer, now you want to use it in -- or you want to try to use it in esophagus cancer because it's similar or whatever the situation may be.

DR. TODD: Right. We would suggest that be done in the context of a clinical trial so that we find out is it really useful. Just finding it out on one person isn't going to tell you the answer.

ASSEMBLYMAN IMPREVEDUTO: Doesn't show anything.

DR. TODD: It's not going to really help with the long-term goals.

Finally, there's the cost of not doing the clinical trials. And that is, we're not going to move forward in this important area of research. We are not going to improve the outcomes. There's a loss of life and loss of productivity. The loss of life is just not fair to the patients, and we certainly have to move that forward.

What we are proposing then is a model. We think that now with an NCI-designated cancer center we have a unique opportunity. New Jersey has so many of the pharmaceutical companies here, and I think some of the

managed care companies, as you've heard from Dr. Singer today, are willing to work with us. And certainly you people have been incredibly helpful. I think we can form a model that would be extremely useful to address these issues.

There's one more barrier that I should mention that -- I mention briefly, that's in terms of policy setting. Some of those barriers can't really be addressed, because they need to be addressed at a Federal level. I was glad Assemblywoman Weinberg mentioned some earlier, but also the HCFA wording regarding reimbursement for clinical trials is very gray at best. Given the increased audits that are being done on HCFA's behalf regarding reimbursement for graduate medical education of house staff, it's raised a lot of concerns from hospitals regarding reimbursement of clinical trials. While HCFA has said that they do not plan--

ASSEMBLYWOMAN HECK: I'd like to ask staff to access Ann Marie and Dr. Mary Todd and Donna Bocco on the wording of the resolution so that it incorporates the proper intent.

MR. PRICE (Committee Aide): I'm sorry, Assemblywoman, which resolution?

ASSEMBLYWOMAN HECK: The one we discussed before on -- to address the national concern.

MR. PRICE: You mean the ERISA?

DR. TODD: And HCFA.

ASSEMBLYWOMAN HECK: That and this.

DR. TODD: We need to address the Medicare--

ASSEMBLYWOMAN HECK: The Medicare element.

DR. TODD: --element as well.

ASSEMBLYWOMAN HECK: When you're drafting material, the resolution--

ASSEMBLYMAN IMPREVEDUTO: Dr. Todd--

ASSEMBLYWOMAN HECK: --try to do it in one; if not, then we'll do two.

ASSEMBLYMAN IMPREVEDUTO: --what are you finding with Medicaid? Is Medicaid paying for this kind of stuff?

DR. TODD: No. They fall into the same as HCFA. I mean, yes and no. It's very gray. It's very gray.

ASSEMBLYMAN IMPREVEDUTO: So that this--

DR. TODD: We've always interpreted they should pay for the routine costs, not for the experimental agent. If you read the regulations, it's very, very gray. They have indicated to the director of the National Cancer Institute that they do not intend to audit, but that's only a promissory note. That's this week exactly.

ASSEMBLYMAN IMPREVEDUTO: So including Medicaid in that also.

DR. TODD: Yes.

ASSEMBLYMAN IMPREVEDUTO: It's Medicare and Medicaid.

DR. TODD: Needs to be both.

And now something that I think you can help us to address. The New Jersey State Benefits Handbook states very clearly in there that they will not pay for patients on clinical trials.

ASSEMBLYWOMAN VANDERVALK: Well, I think what we have to do, personal opinion-- I think what we have to do is address the overall issue and pull that into it and use that as an example, but I don't think we could single them out--

DR. TODD: Right. Right.

ASSEMBLYWOMAN VANDERVALK: --on the front end. I think we have to do that on the back end.

ASSEMBLYMAN KELLY: That's a perfect example of the self-insured, they'll play games.

ASSEMBLYMAN IMPREVEDUTO: Exactly right.

ASSEMBLYWOMAN VANDERVALK: Well, I'm not saying to give up on it. I'm just saying--

ASSEMBLYMAN KELLY: No. No. No. I'm just making my point. All the self-insured play games.

ASSEMBLYMAN IMPREVEDUTO: Do they define-- I mean and I don't know this, I've never read the book, but do they define what clinical trial is in the handbook?

MS. HILL: (speaking from audience) They-- I believe they define it-- They used the terms experimental--

DR. TODD: Any unproven experimental--

MS. HILL: (speaking from audience) --study or experimental procedure. But there's a clause in that handbook that's very clear.

ASSEMBLYMAN IMPREVEDUTO: Who makes the determination whether or not it's experimental?

MS. HILL: (speaking from audience) That's a good question.

UNIDENTIFIED SPEAKER FROM AUDIENCE: The insurance company where the employee signed up with.

ASSEMBLYMAN IMPREVEDUTO: So the insurance company, not the physician, makes the determination this is experimental?

DR. TODD: Certainly, it really comes down frequently to the medical directors of the individual insurance carriers. So even though that's in the handbook, that may or may not be reality, but still it gives--

ASSEMBLYMAN IMPREVEDUTO: Well, if the medical--

DR. TODD: It sends a very bad message.

ASSEMBLYMAN IMPREVEDUTO: May I ask this and if I can be so presumptuous -- forgive me, for although all doctors are general practitioners -- if the medical director happens to be a podiatrist, he's going to rule as to whether or not a chemotherapy or specific kind of chemotherapy is experimental?

DR. TODD: Yes. Certainly if they--

ASSEMBLYMAN IMPREVEDUTO: I have trouble with that. I need to tell you.

DR. TODD: Well, and it puts us in a position of-- If we use the term clinical trial or experimental, they frequently will try to deny that, so yes.

ASSEMBLYWOMAN VANDERVALK: Am I right in saying that if we're looking at-- Maybe we can avoid the whole phrase experimental. Avoid that by just saying to cover the standard treatment care of the patient. The routine care of the patient as opposed to, you know, the doctor--

ASSEMBLYWOMAN HECK: Going beyond--

DR. TODD: Right.

ASSEMBLYWOMAN VANDERVALK: Right. I mean can we--

ASSEMBLYWOMAN HECK: --that point which was stressed before.

ASSEMBLYWOMAN VANDERVALK: Can we avoid the experimental--

DR. TODD: Use of that drug, sure.

ASSEMBLYWOMAN VANDERVALK: --or nonexperimental, if we--

ASSEMBLYWOMAN HECK: To that point.

ASSEMBLYMAN IMPREVEDUTO: Well, I guess you always run into the problem then is, if you do the treatment, which is fortunate for the patient, and later on they find out, "Hey, wait a minute, you tricked us. This was experimental, we're not paying it." Well, now the doctor and the hospital take it on the chin.

ASSEMBLYWOMAN HECK: Well, that shouldn't-- The experimental part should not be part of the treatment.

ASSEMBLYMAN IMPREVEDUTO: No. No. But what I'm saying is no matter how she or he writes it up--

ASSEMBLYWOMAN HECK: Yes. Yes.

ASSEMBLYMAN IMPREVEDUTO: --the word-- Leave the word experimental out.

ASSEMBLYWOMAN VANDERVALK: They will-- They will throw it--

ASSEMBLYMAN IMPREVEDUTO: Leave the word clinical trial out. In some point in time, somebody may look at this thing and say, “hmmm.”

ASSEMBLYWOMAN VANDERVALK: They will say that, but--

ASSEMBLYMAN IMPREVEDUTO: Yes.

ASSEMBLYWOMAN HECK: We’re going to get some advice.

UNIDENTIFIED SPEAKER FROM AUDIENCE: There’s very clear definition for phase I, phase II, phase III, phase IV, phase V.

ASSEMBLYWOMAN VANDERVALK: Okay. Okay.

UNIDENTIFIED SPEAKER FROM AUDIENCE: You may want to have-- (indiscernible)

ASSEMBLYWOMAN VANDERVALK: Okay. We may see that in Rhode Island’s example, too, if they were covering III and IV.

MS. HILL: If-- We may need to look beyond Rhode Island. It does exclude-- It--

ASSEMBLYWOMAN HECK: Right.

MS. HILL: --wasn’t--

ASSEMBLYWOMAN HECK: But that’s why you have to be addressed when we’re putting this together.

MS. HILL: Right. Absolutely.

ASSEMBLYWOMAN HECK: It’s too complicated.

DR. TODD: It’s very complicated. And I don’t know the best wording. We will be glad to work with you and help but just so you’re aware.

ASSEMBLYWOMAN HECK: But give it some thought.

DR. TODD: I certainly will.

ASSEMBLYWOMAN HECK: All of you. And then you'll come up with it. I know you will.

ASSEMBLYMAN KELLY: Explain something. Maybe I'm confused. One doctor said that a certain drug was refused for use by the insurance company because it wasn't approved for the use. It was approved for kidneys rather than whatever they--

MS. HILL: That's off label.

DR. TODD: That's called off-label drug use.

ASSEMBLYMAN KELLY: That's what?

ASSEMBLYMAN IMPREVEDUTO: Off label.

DR. TODD: Off-label drug use. And it's really-- We can address that, but it's not really a clinical trial that he was talking about.

ASSEMBLYWOMAN HECK: We know that, but in the resolution could do one thing, and then let's look at the other in the context of law.

DR. TODD: The other-- We want to be careful about that though because one of the things that as a clinician and as a medical oncologist and as a researcher that I would want -- is that we make certain that things really are useful.

ASSEMBLYWOMAN HECK: No. I agree.

DR. TODD: We don't want to permit people to use--

ASSEMBLYWOMAN HECK: No. I agree.

ASSEMBLYMAN IMPREVEDUTO: You don't want to become a radical.

DR. TODD: Yes. We don't want to use them if they're not useful and at treating--

ASSEMBLYWOMAN HECK: But wait a minute now. I know that there are times when certain experimental drugs in a clinical research context happen to be used to save lives.

DR. TODD: Yes, absolutely.

ASSEMBLYWOMAN HECK: "If you don't take this, you're going to die. We don't know if you're going to live if you take this, but there's a possibility--"

DR. TODD: Right.

ASSEMBLYWOMAN HECK: I think that should be--

DR. TODD: Approved.

ASSEMBLYWOMAN HECK: --an option.

DR. TODD: Right. And I would say, I absolutely agree. And that's one way to deal with off-label drug use. To say if it's done within the context of a clinical trial--

ASSEMBLYWOMAN HECK: That's right.

DR. TODD: --we mean that we know it has scientific validity, absolutely.

ASSEMBLYWOMAN HECK: Right.

ASSEMBLYMAN IMPREVEDUTO: I think what the doctor is saying, if someone comes down and said, "Well, I want to try hydrogen sulfate because I think that's going to work"--

ASSEMBLYWOMAN HECK: Yes. Yes.

ASSEMBLYMAN IMPREVEDUTO: --should that be covered?
And the answer, the oncologist that I've--

UNIDENTIFIED SPEAKER FROM AUDIENCE: (indiscernible)

ASSEMBLYWOMAN HECK: Yes. A shot in the dark--
Difference.

DR. TODD: Exactly. Exactly.

ASSEMBLYWOMAN HECK: But please-- But please draft
those--

DR. TODD: Suggestions. We will.

ASSEMBLYWOMAN HECK: Please. Because we have to move.
I am just-- I am delighted at the information that we've gotten today. I didn't
think that we were going to get that much. But by the same token--

ASSEMBLYMAN IMPREVEDUTO: My wife is not delighted,
however.

ASSEMBLYWOMAN HECK: --I was disappointed in--

ASSEMBLYWOMAN VANDERVALK: In one person.

ASSEMBLYWOMAN HECK: Yes.

DR. TODD: I think we can reach out one more time. I think we
can reach consensus here in terms of our goals, which is to continue to really
try to cure this disease which I think we can do.

ASSEMBLYWOMAN HECK: Absolutely.

DR. TODD: I really think we can do.

ASSEMBLYWOMAN HECK: And I think that's our major goal.

DR. TODD: Yes.

ASSEMBLYWOMAN HECK: But again, we have to move very rapidly towards getting rid of the unnecessary minefields that are out there.

DR. TODD: Absolutely. Absolutely. What we are proposing then is a model that is a synergistic model. A panel could be convened to make certain that we can determine what is standard--

ASSEMBLYWOMAN HECK: Right.

DR. TODD: --cost of standard care versus experimental cost, mainly to make certain that--

ASSEMBLYWOMAN HECK: And that has to be done by professionals.

DR. TODD: Yes.

ASSEMBLYWOMAN HECK: So when you pull it together, we can now move it along through legislation. But whatever it is, we have to do it now, because there are things you already know. So what we already know to be a fact-- Let's use that in its simplest form in one bill and then go on to another that might be a little bit more complicated. Let's take the baby steps--

DR. TODD: Right.

ASSEMBLYWOMAN HECK: --and then go on to the major -- major league.

ASSEMBLYMAN IMPREVEDUTO: I think you're looking at a package of bills here.

ASSEMBLYWOMAN VANDERVALK: Yes. I see any number--

ASSEMBLYWOMAN HECK: Yes. There's a package.

ASSEMBLYWOMAN VANDERVALK: This testimony today has been very broad reaching.

ASSEMBLYWOMAN HECK: Let's do it a piece -- in separate bills so that we can start moving them in, along and in and out. Right?

ASSEMBLYMAN IMPREVEDUTO: Absolutely.

DR. TODD: We'll be glad to.

ASSEMBLYWOMAN HECK: Okay. I'm ready.

Anything else?

DR. TODD: Thank you. Again, thank everyone.

ASSEMBLYMAN IMPREVEDUTO: And certainly on a bipartisan basis.

ASSEMBLYWOMAN HECK: That's right.

ASSEMBLYWOMAN VANDERVALK: I just want to thank everyone who had a role in structuring this.

ASSEMBLYWOMAN HECK: Fantastic. Thank you. (applause)

Thank you, again.

ASSEMBLYMAN IMPREVEDUTO: Most importantly, I just want to say thank you to the oncologists, because you guys have a job-- You ladies and gentlemen do a job that I couldn't ever, ever do--

ASSEMBLYWOMAN HECK: Right.

ASSEMBLYMAN IMPREVEDUTO: --no matter how intelligent I may have been. I couldn't deal with what you're--

ASSEMBLYWOMAN HECK: What do you mean, "May have been?"

ASSEMBLYMAN IMPREVEDUTO: Well, no, no. To deal with the situation where you know that a good chance that 60 percent of the people

you are working with may not be here is, gosh-- Don't know how you do it, but thank you.

ASSEMBLYWOMAN HECK: Thank you so much.

ASSEMBLYMAN IMPREVEDUTO: Thank you, Rose.

ASSEMBLYWOMAN HECK: Thank you, everyone. Thank you.

(HEARING CONCLUDED)