

Y-ME ShareRing Network
“Clinical Trials: What’s In It for Me?”

Arline Kallick: Hello everyone and welcome to the Y-ME ShareRing Network national teleconference.

Our call will begin with tonight’s speaker, Dr. Hyman Muss. Dr. Muss is currently Professor of Medicine at the University of Vermont College of Medicine. His major research interest is breast cancer with a major focus on the treatment of breast cancer in older women. He also has an interest in adjuvant therapy and the treatment of metastasis. With his colleagues at the Vermont Cancer Center, he is trying to define molecular factors that predict which patients with early stage breast cancer will derive the greatest benefit from chemotherapy or hormone therapy.

In addition, Dr. Muss served for 10 years as the Director of Hematology/Oncology for the Fletcher Allen Health Care and he is currently co-chair of the Cancer in the Elderly Working Group for the Cancer and Leukemia Group B, a National Cancer Institute sponsored cooperative group, and in this endeavor he is trying to increase awareness and clinical trial opportunities for older patients with all types of cancer including breast cancer. Tonight’s topic is “Clinical Trials: What’s In It for Me?” This will be followed by a question and answer session and end with small group discussions.

A reminder, as you all know, we have a new number and you all got through so it was successful. I’m glad about that.

We realize it’s difficult to answer everyone’s questions in a one hour teleconference. So if your question does not get presented during the question and answer or the group discussion, please contact the Y-ME hotline at 800-221-2141. The hotline is answered by

certified peer counselors who are breast cancer survivors and it is available 24/7 or visit our website at www.y-me.org.

When presenting a question to Dr. Muss, please be courteous to other callers by keeping your question brief and realizing that this cannot be a private consultation.

A transcript of each call will be available at our website around a week from now. And beginning this month, we're happy to offer a pod cast and that will be available at our website, which means you will be able to listen to a program at your leisure or read the transcript.

So we're ready to begin tonight's teleconference and we welcome Dr. Muss. You may begin.

DR. HYMAN MUSS: Well, it's a privilege for me to talk to the group and thank you for the wonderful introduction. I'd like to thank Arline Kallick and all the Y-ME people for allowing me to do this presentation on clinical trials. As we will talk about a little later, I've had the opportunity of working with Y-ME on a trial of our own and it's been really very gratifying to work with the group.

"Clinical Trials: What's in it for me?" Well, I provided this really in the four parts. First, we're going to talk about what are clinical trials? And then how do we support clinical trials, especially in the United States? How do you find a clinical trial if you're interested in participating, and then last one why do it, why should I be in a clinical trial?

So to being with, what are clinical trials? What I often find is people think clinical trials are testing of like new drugs that haven't been used before in a group of patients and it's frequently the comment or perception that someone's a guinea pig and that no one

knows whether this drug is safe or not and going to see if it works, let's say, in breast cancer. I would say that that's probably a very, very small portion of all the things that involve clinical trials. For instance, most of the larger trials and trials that have led to major advances have been what we call randomized clinical trials where patients are asked to participate in a trial where essentially a computer does a coin flip and randomizes patients to one treatment or another, a so called Phase III trial. Those trials frequently compare standard treatment, or if there isn't a standard treatment for disease, a placebo with either a new or promising treatment. And in those trials usually the newer treatments have been tested on large numbers of patients but it's uncertain whether the treatments really are beneficial. And if we look at breast cancer, for instance, a lot of the new chemotherapy regimens, these have all been compared in large randomized trials versus older treatments have been shown to be more beneficial. Likewise the use of newer drugs, for instance like aromatase inhibitors as hormonal therapy of breast cancer. These were developed in clinical trials, at least their efficacy in the population, comparing it with drugs like tamoxifen, other drugs in thousands of patients.

So really in these trials people aren't getting a new drug. It's not like someone is walking in the room with a big syringe with red liquid in it and everybody is scared to death that they're going to explode when they're treated. But they're actually getting treatments that have been developed and compared with one another.

Frequently when we get a new drug we do test it in breast cancer patients, but these drugs are frequently well defined in Phase I trials. And in those clinical trials we treat patients who all have different types of cancers who don't have really good options for treatment and those trials we really look at safety in dose finding and, of course, we're always looking in these trials for treatment efficacy, for improvement, for tumor shrinkage.

So when most of the drugs come into, for instance, a group of breast cancer patients, virtually all of them have had extensive testing in human beings. We know a lot about the side effects. Obviously we all see things can happen late and occasionally we miss side effects in early testing, but the drugs are really as safe as possible for the population.

Now when we think of clinical trials I think a lot of people think it is just drug testing, but clinical trials can look at other things. For instance, we're involved in a very large trial through the Cancer and Leukemia Group B so every time you pay taxes, a small portion goes to the National Cancer Institute, really one of the great governmental bodies we have supporting research, and then that money comes into a group, to a group like ours and we get together groups of hospitals. So we have University of Chicago and Vermont and Sloan-Kettering, Seattle and all types of wonderful hospitals and medical centers all over the country, and we develop clinical trials. And we're just about completing a trial looking at chemotherapy in women over 65 with breast cancer.

As part of this trial, we're really looking, not only at just whether the drugs work, but we're looking at how the drugs affect quality of life. For instance, one drug may be a little bit better than another but if people's lives are really hampered taking that drug - they can't function well, they can't go out and do and work, they can't do activities of daily living - a little bit of improvement in tumor shrinkage or survival by a few months might not be worth all the side effects. As an example of this trial, we have, as part of it, for women who are undecided the opportunity for those patients to talk with a Y-ME volunteer and this is actually built in and supported by the trial. It's a discussion with a patient who's ambivalent about going about the trial as to what would be the risk and benefits.

As part of this trial, we're also looking at quality of life outcomes. We're seeing if people on one of the two treatments, are they functioning better, are they having less side

effects, et cetera. So when we look at a clinical trial, we think of drugs but it can look at other things.

Another example of a clinical trial: we just completed a trial where we took older people with breast cancer that has spread and we randomly assigned them, and I should add all clinical trials in the United States require informed consent and these consent forms are actually scripted and conformed to government guidelines. So actually when you're in a clinical trial, especially one sponsored by the National Cancer Institute or a large pharmaceutical company, you're really being micro, your data are carefully watched by a lot of non-biased, competent people to make sure there aren't undue side effects or if one treatment is really better than another to make sure that we find that out early so we can stop the trial and offer that treatment to all the patients if it was a, what we call, a randomized or comparative trial. But we just completed a trial in these older patients and we randomly assigned the patients to standard follow up or to have a telephone call once a month just to see if they were depressed and see how they were doing.

This is a clinical trial and we found out that this telephone call was very popular with the older people. In fact to some for them it was the only real contact with other people that they had, some of them couldn't get out of the home and we found out that there were less depression and we improved their quality of life with a simple phone call. That's a clinical trial but we don't frequently think of it as such.

The other, and so the outcomes of trials can be what we think of shrinking cancers or, with early cancers, living longer and lowering recurrence rate, but they can also look at other things such as testing can a phone call help someone, can a new IV device result in less pain in giving the treatment than an older device. We have all types of clinical trials.

I just want to point out the diversity of what we mean when we say clinical trial. It can mean many, many things and essentially all of it is researched to learn new things and new information.

Now how are we supporting trials? Well, probably today a little bit more than half the trials are being actually supported by pharmaceutical companies in industry and the remainder by the National Cancer Institute. And there are, in addition, several wonderful foundations that help support trials like the Breast Cancer Research Foundation in New York, the Coleman Foundation, large charitable organization like American Cancer Society, et cetera. The clinical trials that are sponsored by the National Cancer Institute are an especially great source because the National Cancer Institute is willing to invest in new ideas and maybe test things the industry may be not is prone to do because of, industry has to test its own drugs and have other restrictions.

However, that being said, over the last several years, several of the major drugs that have advanced the treatment of breast cancer had actually been developed by industry and there's wonderful basic and laboratory research in industry as well. So to do these trials and collect the data and maintain all the safety features requires a lot of support and the government industry foundations have really been critical.

And I want to point out that we really collect a lot of information. When you go on a trial we collect much more than your outcome, you know, whether your tumor shrank or whether you had, whether you took a longer time to relapse, let's say, if you had cancer spread or if you were treated with so called adjuvant therapy for breast cancer, whether your relapse was delayed or you never did relapse or hopefully were cured. We also collect an extreme amount of toxicity information.

And I want to point out that at least with the newer regulations and even before the new HIPAA regulations, the federal regulations, these data are really kept in great confidence. I think if the credit card companies did as well as we did in protecting patient data, we wouldn't have issues with losing people's social security numbers and having their documents lost in some large database.

So a lot of good support, but I want to add support has been rather modest for the government supported groups and I'm a big advocate and member of these groups. So we really need your push with Congress to fund the National Cancer Institute and keep the high level of support for the groups that are doing such wonderful research.

In the last few years there's been a relatively cut in funds because of shortfalls in government funding and obviously issues related to our war in Iraq and to Hurricane Katrina. But nevertheless, cancer is a disease that's pervasive in this country so when you see these issues in Congress, write your Congressman and that'll be very helpful. We need to continue the funding.

Now what if you're interested in a clinical trial, how do you find it? Well, you know, I spend my whole life doing trials but it's impossible for me to know all the trials available for patients. And I'm an academic based physician even though I have a large academic practice and some of my colleagues in the community are much busier seeing patients. So how can we possibly find a trial for everybody or see if someone is eligible for a specific trial or new drug?

Well, I would say that if you go to a major cancer centre or large community practice or even a small private practice that does trials and they're interested, they'll probably have a good idea of what's going on. But I can't help but underscore the fact that many of you, in

fact all of you on this call who are interested, can really be beneficial by you yourself looking to see what's available.

And so what I tell all my patients, and anybody that I talk to in the public, is you should all have a copy of your pathology report, you know, it's yours. All the medical record information now in the United States by law is yours. But you should have a copy of the pathology report. You should all, you know, by being involved with groups like Y-ME know a little bit about the treatments and staging. There's a lot of excellent websites and you should know your cancer stage. And then you can go on websites like the National Cancer Institute and there's something called PDQ. And in that database you can put in that you have breast cancer and you can put in what stage and you can look at different trials for hormonal therapy, chemotherapy. There are literally hundreds of trials in this database. And why I think you should become familiar with this is no doctor, I don't care how involved he or she is involved with research, can possible know all the trials that are going on. So by doing a little research yourself, by I'm sure the Y-ME counselors and group can help direct you to websites and help you find trials, you can do a lot for yourself. And I encourage my patients when they find something or things to bring it in and show it to me.

First of all, when you go to your physician it's not a charitable event. You're paying he or she so don't be embarrassed or bashful to say, you know, I was interested in a clinical trial, I heard about this new drug and here's what I learned. Any good physician will probably be appreciative because a lot of us are working long hours and if you can bring something to my attention from a legitimate source that I didn't know about, really, you're helping me be a better doctor and you're helping yourself find perhaps better treatment. So I would urge you to play a really assertive role in looking for opportunities and you can do this today by, you know, help from groups like Y-ME and other local groups, American

Cancer Society, even maybe your local librarian to help find out what clinical trials are available.

And in addition, if you happen to live in a large community where there's a cancer center, especially a National Cancer Institute sponsored cancer centre and you can find lists of them on the web, those cancer centers usually have a good idea of clinical trials available as well as maybe specific trials that they are doing within their cancer centre that may just be restricted to the community or patients in the area. So you can do that and I think that really helps you in taking the best care of yourself and finding a trial that may be helpful to you.

Now the last thing is perhaps sometimes the most difficult. Why should I participate in a clinical trial? Well first, if you look at the advances in breast cancer in the last, let's say, 30 years. And in fact now since the early 1990s we have had a 2 to 3% reduction in the mortality rates from breast cancer each year. So it's probably about 25 to 30% decrease in a woman's risk of dying of breast cancer if she has it over the last 10 years. If you look at the reasons for that, there have been two major reasons.

One is the increased use of mammography in finding small cancers. Now how do we know that mammography really saves lives? Well, we did clinical trials and years ago there was a big trial by the health insurance plan in New York City in '60s, '50s and '60s that compared mammography with no mammography. And there were other trials all over the world, and those trials showed that women who had mammograms had smaller breast cancers found and live longer. The curability was higher. That was a clinical trial. It didn't involve drugs. And so now knowing that and having mammography accessible to most women on, unfortunately not all women, we've made a really dent in the mortality rate of breast cancer.

And the other thing is the use of what we call adjuvant therapy, using chemotherapy and hormonal therapy after your diagnosis to lower your risk of recurrence. And I'm sure many people on this call have had chemotherapy after their diagnosis, many people have had tamoxifen or aromatase inhibitors after their diagnosis or a lot of people have had chemotherapy and hormonal therapy. What we've learned is these treatments over the years have really lowered the risk of breast cancer recurrence. There have been no home runs in these trials. There hasn't been a magic bullet and there probably won't be in a disease like breast cancer. There are too many differences among patients and their genes and in the cancer cells. But what we've learned is by getting a lot of bunts and singles, we've won a lot of ball games.

And so over the last 10 to 20 years, these improvements of a few percent with treatment B compared to treatment A and then a few percent improvements with the next treatment, have really, really improved outcome. As someone once said, you know, in the government \$1 million here, \$1 million dollar there and pretty soon you're talking about real money. Well it's the same thing. By having small but positive results and continually building on your good results and adding to it, over time we've made good headways.

So clinical trials have added a lot and so what the answer would be, what's in it for me??, is when you go on a clinical trial that's sponsored by the National Cancer Institute such as these cooperative groups that all get grant funds such as we talked about earlier, or you go in an industry sponsored trial that's trying to find a new drug and compare it with an old drug, especially if it's a company that wants to find a new drug that improves outcome and bring it into the market place, you will be getting the best treatment available because when we do a clinical trial the ethics of it dictate that we're not going to compare a new chemotherapy regimen with a placebo. We're going to compare a new chemotherapy with

something of proven value that should be at least the best around that we know of. And so that if the new treatment is better, it's not that we compared it to something that wasn't very good or to no treatment at all but that we compared it with the best. So if you agree to that coin flip, you either get the best available therapy or the new therapy which may or may not be better.

Now we're Americans, we always want the new therapy, the most aggressive therapy. But the truth is the newest and most aggressive isn't always the best. And so by on a clinical trial you're either going to get the best known or the newest and not every trial we do is positive and shows one treatment is better than another, so when you go on a trial, you're always getting the best of therapy and if the trial is approved by a cancer centre or a pharmaceutical company, it's been reviewed by an ethics board and science board. So you can have some certainty that a lot of smart, ethical, decent people have looked into this trial and said we think that this is good and it's in the interest of the public and our patients. So that's a reason. When you go in a trial, you're going to get, at least for you, you should be getting among the best treatments or the best know treatment or a new treatment that has great promise.

The second reason for many patients to be in a clinical trial is altruism and, you know, I think all of us, and especially in many of our religious traditions, were taught that there's more than you and I alone. We all probably like to feel that we're doing something for our neighbors, for our families, for our daughters, granddaughters, et cetera, specifically let's say for breast cancer. And so when you go on a clinical trial, you are going doing the good thing for the people that come after you.

For instance, I suspect many of the women on this call had a lumpectomy and breast radiation and were able to preserve their breast. Well, you may be surprised to hear that

one of the old clinical trials randomized women to mastectomy, removing their breast, or having the lump removed and radiation. Women actually agreed to that, and so we learned, in an unbiased fashion that the lumpectomy and radiation to the breast was as effective as the mastectomy. That's a clinical trial. Those women who agreed and had a mastectomy certainly were altruistic but what they did was they now today made it so that we don't even think about that. We offer everybody, where it's technically feasible, a lumpectomy. For many people it's not appropriate but most women with breast cancer today can have a lumpectomy and breast radiation and that was done on the base of a clinical trials and really you have to say altruism because a lot of the women may have said geez I'll wait for that trial and I'm afraid to have a lumpectomy. Maybe it's really bad and my breast cancer will spread. So the altruistic motive as well as getting the best treatment is really, I think, two of the most compelling reasons that we can participate in clinical trials and is something we all need to take in consideration.

So to wrap this up and have time for questions, I think clinical trials as we've talked about are not just testing a new drug, something unheard of that comes out a big laboratory but include everything, like looking at lumpectomy and radiation, can telephone calls help patients, can adding a new drug or trying a new drug do better than an old drug? That they're supported now by many excellent organization including the National Cancer Institute, pharmaceutical companies, many of the larger ones which, in spite of some issues are generally highly reputable, by some wonderful foundations, that you can find clinical trial information on the web. There is published information but here I think the web is better because it can be so current and the National Cancer Institute website, cancer.gov, is really a wonderful resource.

And then lastly, why me? And my answer would be because you're going to get the best of therapy even if there's a coin flip. Those therapies have all been carefully considered. And secondly, and perhaps most importantly, you're going to be doing something for your fellow man/woman and perhaps your family in time to come.

So I appreciate the opportunity of speaking with the group and I'm happy to take any questions.

Our first question comes from Patricia

PATRICIA: Yes. I was diagnosed last year at 65, aggressive tumors, (inaudible) positive three plus and estrogen positive. So he put me on Arimidex for five years and I've been almost a year of IV Herceptin weekly. I have about 10 left to go for the year. I opted out of chemotherapy because they told me at two different places that the percentage, I wouldn't gain that much in terms of recurrence and that the Arimidex was the best way to go. It would knock my recurrent rate in half.

So my question is, I guess, on the Herceptin. Since I didn't have the chemotherapy, of course I'm worried now that maybe I should have had it because I run across people who had recurrent disease after, say, several years, five years plus. And do you know anything about Herceptin? I haven't been able to find, this oncologist used it as a single agent. He just does not use it in combination.

DR. HYMAN MUSS: Yes. There's been a lot of clinical trials on Herceptin and there are, we've learned that adding Herceptin to chemotherapy has really improved outcomes for patients with breast cancer that are HER2 positive. There are no clinical trials available in

people with breast cancer that's early, even if it involves lymph nodes, but breast cancer that hasn't spread using Herceptin alone. So I can't tell you anything concerning that.

PATRICIA: I had bilateral mastectomies and clear margins and sentinel node was clear. So I guess my staging was I but I had pretty aggressive tumors.

DR. HYMAN MUSS: So from a clinical, from this point of view of this discussion, you'll have to talk with him about the specific issues or how he would estimate how it would help you. But Herceptin alone really has not been tested there and the drug, you know, the hormonal therapy you're taking, the Arimidex, you know, has been compared with drugs like tamoxifen and most studies have been found to be a little bit better and those were very large clinical trials. So those are all appropriate for you.

PATRICIA: You can't go into chemotherapy now after a year of Herceptin.

DR. HYMAN MUSS: Most physicians would probably not do it.

PATRICIA: Okay, all right. Thank you very much.

DR. HYMAN MUSS: Sure. Good luck on this.

OPERATOR: Thank you. Our next question comes from Joanne.

JOANNE: I just got diagnosed with metastatic breast cancer. My original cancer was diagnosed November of 2005 and I was not on any hormone therapy. I'm just wondering how difficult it is to find trials for metastatic breast cancer. I'm a tad overwhelmed. I started treatment already of Xeloda, avastin and zometa. I actually have no symptoms. I was the one that said I needed to go for a scan at 18 months because I wanted to be a little bit more proactive than waiting for a tumor marker to show in my blood work. My blood work was always perfect. So it was quite a surprise that I do have this at the moment.

DR. HYMAN MUSS: There's lots of clinical trials for patients with breast cancer that spreads, metastatic breast cancer.

DR. HYMAN MUSS: And here's my: "did you ask your doctor?"

JOANNE: Yes. He said he doesn't really participate in any and the issue is I'm located in New Jersey and I have a very good insurance policy but yet Sloan-Kettering doesn't accept it.

JOANNE: So, you know, I'm at a loss and I'm going to try Fox Chase to see if they accept it because I want to be associated with a large major institution so that if these current drugs that I'm taking doesn't, isn't successful that I'll have access to a trial. I'm just very overwhelmed how to even start the research.

DR. HYMAN MUSS: You know that's another major issue in the United States about payment for clinical trials, but most insurers do pay for this. Some states have laws. I'm not

sure about New Jersey but New Jersey has a lot of wonderful cancer centers and I think you bring out that unfortunately a lot of our doctors don't participate in trials. And that's not a criticism because I can tell you that clinical trials are under funded many times and they require lots of work and support staff. You have to collect all the data. It has to be available and so it's frequently very hard, especially for someone in a smaller practice. But Fox Chase is a wonderful place. You have other cancer centers in New Jersey.

JOANNE: What would be in New Jersey

DR. HYMAN MUSS: Well when you go on the NCI PDQ, you can go on the website.

DR. HYMAN MUSS: And they actually tell you by state and location where some of these trials are going. So you could look up metastatic breast cancer and they actually have like a checkbox by region.

DR. HYMAN MUSS: So you can put it in and they will tell you centers in your area. And they usually provide the phone numbers, because we're all looking for patients for clinical trials and so you might touch base with them. And a lot of those centers will help you screen your insurance, you know, to see if it's accepted but that's where this can be very helpful because there is a geographic box on the web that you can put in, like New Jersey. Or even sometimes your, where you live, your city and it'll tell you areas around you that are doing the trials.

JOANNE: Okay. All right, well thank you. I appreciate it.

OPERATOR: Thank you. Our next question comes from Shirley.

SHIRLEY: Hi. As I understand your presentation, we can go to the website that you mentioned and I guess what I'm confused is clinical trials are done by the NCI you said, some major cancer centers, universities say that have research, and then you said pharmaceuticals. My question would be is this website that you mentioned going to have all of those there?

DR. HYMAN MUSS: That's a good question.

SHIRLEY: I know University of Washington does a lot of excellent studies for women with metastatic breast cancer or the Indiana University does that. Would those be on there or do you go to those websites specifically to look?

DR. HYMAN MUSS: Yes that's a great question. The NCI is going to have a lot of the trials including the pharmaceutical sponsored trials, and the reason now is that there is the medical journals, like the New England Journal made a rule that unless you have a registered clinical trial, and the National Cancer Institute database in the United States is one of the registrations, that they're not going to allow you to publish your trial when the results come in unless you registered it. And the reason for that is because a lot of people, or and it hasn't been the government as much but even doctors if they get a negative trial like treatment A isn't better than B, they don't tend to publish it that quickly. And so you can have a very big trial that asks a very important question clinically and because it wasn't positive it may be that a big pharmaceutical company isn't too excited about publishing it.

Not because they're dishonest but because they'd rather waste their, you know, put their efforts on the positive trials. So when you register it gives an opportunity of you, me, anybody to look and see what trials are ongoing. And if we see one and say, hey, how come that was never published, we could go back and look into it. So it's really a safety valve, so most of the trials are on that site, on the website, even if they're done locally but not all of them. So if I lived in Seattle, I would call the University of Washington, they have a wonderful cancer center. And I would ask, and I would, they all, these are federally funded cancer centers and you could call there. Most of them have websites with their local trials and you could look up their individual website. I would look at both.

DR. HYMAN MUSS: Frequently smaller trials with new drugs or new treatments are only done in an individual place and they're not likely to be on the website. That doesn't mean that if I live in New York and I saw something good in Seattle I couldn't be treated out there, but those trials are mainly done to attract patients locally especially if their treatments are going to be given daily or over weeks. It's not usually practical for someone to move to the city to be treated although it happens. So I would look on both of the websites.

SHIRLEY: Okay and then just a part B real quick. If you ask your doctor about a clinical trial and he or she says well why don't you do some homework and let me know, you're trying to say that that's a normal thing for the doctors to suggest? That doesn't mean the doctor is disinterested or doesn't care? I mean I guess I was expecting the doctor to say well I'll have a nurse help you look for them...

DR. HYMAN MUSS: Sure. I think it's very variable. I think that you know people like me, I work in a major cancer center. We have all our trials on the web and I have a card of them all I put in my pocket and I have data people that come to help me. So I'm in a unique situation but most cancer care in the United States is not given in a major cancer center. It's given in the community and some community docs are really so overwhelmed with work and patients that they can't go to the computer screen at night, you know, for the patients they've seen and look up all the trials.

So I would say: well do you have a nurse or someone that could help me? Some doctors will try to spend the time to look some up but they can be very busy and it might take a day, you know, several days or a week or two until they can get that time to go on the web because it does take time to search this out. So my feeling is to do both. To ask your doctor what he or she knows about the trials, to ask if there's anybody in the office or that they work with that could help you. But I also feel it's very good for people to be their own advocates and to go on the web themselves and find things.

SHIRLEY: Thank you very much.

OPERATOR: Our next question comes from Nancy.

NANCY: Dr. Muss, I am very familiar with your situation. My daughter went to (inaudible) so I know the Burlington area. But I am in the Boston area with (inaudible) Dana-Farber. I would believe there are trials there at Dana-Farber.

DR. HYMAN MUSS: Oh yes, there's some wonderful trials...

DR. HYMAN MUSS: Well I actually was a fellow at the Dana-Farber Cancer Centre in Boston and actually the Dana-Farber is a member of one of the national groups called Cancer and Leukemia Group B that we're in here at Vermont and also includes the Sloan-Kettering doctors in breast cancer and many others and fine doctors in the United States. So you have some fine cancer centers in Boston, Dana-Farber is excellent. There are some other, the Mass General and Dana-Farber actually (inaudible).

NANCY: Well my lumpectomy was done by Dr. Smith at Mass General.

DR. HYMAN MUSS: Absolutely so there, they have lots of great trials for you to ask about.

NANCY: I was (inaudible) in November of 2006 and I was horrified the way it was presented. I went to (inaudible) for radiation and I thought it was horrible. And you know the oncologist (inaudible).

DR. HYMAN MUSS: Well I think you'll be in excellent hands

Arline Kallick: Nancy, do you have a question?

NANCY: Yes, my question is how do I keep emotionally proceeding with this?

DR. HYMAN MUSS: Well, I think that, you know, places like Dana-Farber and other cancer centers, they frequently have really good support groups. They have psycho-social

oncology groups, psycho-social oncology people that can do one-on-one care with patients. It's a little bit different than our discussion tonight but I would call your oncologist there...

NANCY: I'm going to see a new oncologist at Newton Wellesley.

DR. HYMAN MUSS: Well I would definitely ask about all the support services because there are a lot of support services available for people to deal and cope with their illness.

NANCY: Thank you.

OPERATOR: Thank you. Our next question is from Kathleen.

KATHLEEN: Hi. Three years ago when I was on chemotherapy I took part in a clinical trial for, I think it was either neupogin or neulasta...

KATHLEEN: Okay. Three years ago when I was on chemotherapy I participated in a trial for, I can't remember if it was neulasta or neupogin, but it's the shot that they give you to boost your white blood cell count.

KATHLEEN: But, in any case, I didn't have to actually pay for those shots because I took part in a clinical trial.

KATHLEEN: I was wondering is that pretty much standard that when you're in a trial you don't have to pay for the medicines that they're doing the trial on?

DR. HYMAN MUSS: That's a great question. So it really depends on what the medicines are. If the medicines you get are standards like a lot of the chemotherapy in the trial, you will probably get billed for the chemotherapy.

DR. HYMAN MUSS: But if the trial is, let's say, in those trials they were trials to see if they could give the chemotherapy closer together and they used drugs like neulasta and neupogin. If that's the key portion of the trial, those drugs are usually paid for as part of the trial. They're given free from the National Cancer Institute.

KATHLEEN: Is there any way of knowing that ahead of time because I...

DR. HYMAN MUSS: Absolutely. In fact it is part of the consent process for the consent form to tell you whether there's going to be any extra costs added to the trial. And if there's any concern I would ask the trial directly, the people directly about the medication and they will tell you that. But when you do a trial, and if it's any reputable center, and most are, in the consent form that you sign it's going to have to tell you whether there's added costs in participating in the trial. So drugs like neupogin and neulasta, if they weren't part of that standard chemotherapy regimen, they would have to tell you if that would be added costs and I would point out that those are very expensive drugs. And virtually no one could afford to pay for them outside of a trial. And now those drugs are commercially available and FDA approved on the basis of some the trials, perhaps the one you participated in. But it is

mandatory to tell people if they're going to incur extra out of pockets cost of participating in the trials, whether its drugs or x-rays or scans or extra blood tests.

KATHLEEN: Thank you very much.

Arline Kallick: And we'll go to our last question now.

OPERATOR: Our last question comes from Pamela

PAMELA: Oh, I wanted to know if you could explain a little bit more about informed consent.

DR. HYMAN MUSS: Yes so informed consent in clinical trials, I hope that, I may be getting, informed consent in clinical trials is a, actually the elements of informed consent are set out in the federal record. And informed consent requires us to, in writing, to tell you what's the purpose of the trial, why are we doing it? And then if there, the treatments in the trial it's to give really details about the side effects. All the side effects of the drugs and then we tell you in informed consent about how many patients there are going to be in the trials. So you can get an idea of how big it's going to be. You know, is this going to be a small trial of 100 people? A lot of the breast cancer trials today comparing new drugs have several thousand patients in them. It also tells you that you know it tells you something about if you're injured in the trial, who you call or if there are any concerns. It should tell you about any extra costs that you might have. It's also mandated in there, let's say you come to a place like our cancer center and we tell you a clinical trial and you say I don't really want to do it. It actually we put in writing now that if you say you don't want to do it, it's not going to

compromise your care in any way. Now I don't think that happened before but that's actually written in the document. And in addition, it puts, you know, it gives you numbers and people to call involved with the trial directly for any specific questions.

So it's a very comprehensive document and some of these documents, especially for complicated treatments or very toxic treatments, can be 10 pages, 15 pages long. So it's a very well defined process. Now the document is in addition to people like me, nurses, clinical research people explaining the trial in detail and answering all your questions to your satisfaction. So it's a very well defined, actually federally defined methodology for participating in clinical trials.

PAMELA: Thank you.

Arline Kallick: At this time everyone , we have to end this portion of our call and I'd like to thank you Dr. Muss for your extremely knowledgeable, insightful and excellent presentation this evening on clinical trials.

Really, because of the generosity of medical professionals like yourself it's possible for Y-ME to provide all this information and assistance through the breast cancer journey and we thank you again very much. Thank you Dr. Muss.

DR. HYMAN MUSS: Y-ME is a great group. You do great things and thanks for having me.

Arline Kallick: Have a good evening.

Everyone please stay on the line for our discussion group and I'd like to remind everyone that Y-ME has again 24/7 hotline with certified peer counselors that are always available to

answer questions and concerns. And the hotline number is 800-221-2141. Thank you for attending tonight's sharing network teleconference and we hope that you will participate in our discussion group. All you have to do is stay on the line.