Hormones and Breast Cancer: Through Treatment and Beyond

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Presented By:

Sharsheret

Linking Young Jewish Women in Their Fight Against Breast Cancer

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I. Introduction

Rochelle Shoretz: Welcome, everyone. Thank you for joining Sharsheret as we webcast the national symposium, "Hormones and Breast Cancer: Through Treatment and Beyond." My name is Rochelle Shoretz and I am the Founder and Executive Director of Sharsheret, which is Hebrew for "chain," a national organization supporting young Jewish women facing breast cancer. I'll soon have the pleasure of introducing our distinguished speakers who will share the latest research in a critical area of breast cancer care: the role of hormones in the diagnosis and treatment of breast cancer. I want to welcome those who are joining us here in New York, as well as those who are participating across the country.

I'd like to begin by thanking those who have made this important event possible. A generous grant from the Greater New York City Affiliate of the Susan G. Komen Breast Cancer Foundation enabled Sharsheret to bring us all together this evening through a national webcast, ensuring the broadest access possible. Their support has given this New York event a truly national audience. I'd like to recognize Kavita Das of the Komen Foundation who is with us this evening. Thank you, Kavita. Thank you, too, to Mount Sinai Medical Center, our host this evening. We're grateful for the continued support of Sharsharet's events by Mount Sinai and Komen Greater New York City. Sharsheret's staff and volunteers are the energy behind every Sharsheret event and in particular, I'd like to recognize Elana Silber, our Program Director, and Ellen Kleinhaus, our Program Coordinator, who organized this remarkable event and so many others. Their contributions to the women of Sharsheret cannot be measured.

The subject of hormones and breast cancer is ripe for discussion. Recent studies have demonstrated a connection between hormone replacement therapy (HRT) and increased breast cancer risk. New hormonal therapies to treat breast cancer have been emerging every few years and for younger women, the effects of breast cancer treatment on hormones impacts fertility, the age of the onset of menopause, and the resulting side effects. Having been diagnosed at 28 with an estrogen receptor positive tumor, almost every conversation I have with my oncologist or gynecologist includes a discussion of hormones. In the past four years, many of the women who have called Sharsheret for support have raised the very same subject. Many of you may have hormone-related concerns, including: What is the role of hormones, if any, in the cause of breast cancer? What are the new hormonal therapies being used to treat breast cancer? How can I manage the hormone related side effects of breast cancer treatment and early menopause? What is the current research on HRT and how does this science impact my fertility, my bone health and gynecologic health? Our speakers tonight have generously contributed their time to address these

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important questions and more. We will hear brief presentations from each and then take questions from our audience.

Before we begin, I would like to highlight Sharsheret as an available and valuable resource for those of you participating this evening. Sharsheret was founded in 2001 to support young Jewish women facing breast cancer. We now offer three core programs. Our Link Program connects women across the country in one-to-one conversations with peer supporters who share the same backgrounds and concerns. Sharsheret's Quality of Life programs are designed to enhance the quality of life for younger women living with breast cancer, with initiatives like the Busy Box for parents of younger children, Best Face Forward to address the cosmetic side effects of treatment. We recently launched Embrace, a support program for women living with advanced breast cancer. Finally, our Education and Outreach programs educate women, their families, community and health care professionals about the issues impacting young women and Jewish women facing breast cancer, with symposia like this one.

In just four years, Sharsheret has received more than 7,000 phone calls from women affected by breast cancer, their family members, and health care professionals. During these past four years, the subject of hormones and breast cancer has been a critical topic of news coverage and discussion in the cancer community and in our Sharsheret community.

Our goal tonight is to answer some of the critical questions you've brought to our attention, raise new ones, and generate discussion about the critical interrelationship between hormones and breast cancer. As with each of our medical conferences, this is the first of what is certain to be an ongoing conversation and we encourage you to stay involved as the Sharsheret, the chain, continues to grow in the years ahead.

It's now my pleasure to introduce Dr. Ruth Oratz. Dr. Oratz, a member of Sharsheret's Medical Advisory Board, is an associate professor of clinical medicine at the New York University School of Medicine, who recently returned to New York to open the Women's Oncology and Wellness Practice. We're delighted to have her back in New York and grateful for her continued and enthusiastic participation in Sharsheret's medical symposia. Dr. Oratz will begin our discussion this evening with an overview of estrogen and its role in breast cancer. Please join me in welcoming Dr. Ruth Oratz.

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II. The Role of Hormones in the Diagnosis and Treatment of Breast Cancer

Dr. Ruth Oratz: Thank you, Rochelle. It really is my true pleasure to be back and to be home in New York City and as Rochelle said, we're going to begin our conversation this evening with a little bit of history.

More than 100 years ago, Dr. George Beatson made the observation that in young women who had breast cancer - and at that time, they had advanced disease - their tumors sometimes got better if their ovaries were removed, if they had a surgical oophorectomy. It was then realized that the ovaries, which are the source of estrogen production in young women, was this link between estrogen and breast cancer and was very important.

We know that when we look for risk factors for what might cause breast cancer or what might be related to the development of breast cancer in young women and when we take histories we ask questions. What was the time of the first menstrual period? The age of menarche? How many pregnancies were there? How old was the woman at the time of her first pregnancy? And, for older women, what age were they at their menopause? All of those questions get at the of issue of how much estrogen was around. How much estrogen is in the body? What's the hormonal milieu in the body?

It was recognized throughout the 20th century that there was some kind of rough correlation between the kind of global exposure of the breast tissue, particularly for younger women, to the amount of estrogen in the body. As Rochelle said, there's some recent data that HRT given for long periods of time, perhaps, may have a slight, slight increase in the risk of breast cancer for some women. Obesity in post-menopausal women has been linked with breast cancer and we know that adipose tissue, fat tissue, stores estrogen, so there may be an increased amount of estrogen present. Finally, we know that babies in the uterus who are exposed to very high levels of estrogen may, as adults, have diseases or cancers that are related to estrogen exposure.

We've known for a long time that estrogen in very important in the development of breast cancer. So how does that all work? How does estrogen link up with the cancer cell? How does estrogen do anything to any cell?

Estrogen is a hormone and it was first really identified by Dr. Jenson in 1958. The hormone was described earlier and then in 1958 they described the receptor. It's really important for you to get this idea of the hormone and its receptor. I'm going to talk a lot about estrogen and the estrogen receptor and you're going to hear this when we talk about breast cancer or other illnesses, not

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only with respect to hormones and receptors, but other kinds of proteins and their receptors.

The estrogen receptor is a protein on the surface of a normal breast cell or the surface of many breast cancer cells and estrogen plugs in to a spot in the receptor. It goes in like a key going into a lock. What was realized was that breast cancer cells that had many, many of their receptors on their cell surface were very responsive to the signal from estrogen and that signal caused the cancer cells to grow. We now know that at least a third, maybe a half, of breast cancers are very rich in these estrogen receptors. The cancers that do not have the estrogen receptor can't get the signal from the estrogen hormone. It's all about the hormone and the receptor. You need the lock and the key. This is a medieval lock and key and this is exactly what happens. Here's the receptor, the lock and the key is the hormone that plugs in and if you turn the key, you turn on the receptor. That sends a message to the cell and in this case, if it's a cancer cell and the receptor is the estrogen receptor and the key is estrogen, you turn it on, it tells that cancer cell to grow. The hormone is the substance that comes along and fits into the receptor and then that whole process, that whole cascade begins in the cell. You need the receptor and the hormone to get that message.

In breast cancer we know that there are estrogen and progesterone receptors. Progesterone is another hormone that's present in women. It's the hormone that's most prominent during pregnancy and both of these receptors can be stimulated by the hormones that cause the breast cancer cell to grow, but really the estrogen receptor is the one that's most important. Because of the presence of this receptor, we can use it as a target. We can modulate, we can manipulate that receptor to try to turn off the signal and I'm going to show you how we can do that in breast cancer patients. If we can manipulate the signal we can have effective therapy and also, hopefully, prevention – prevention of recurrence of breast cancer, prevention of relapse for metastasis. We can prevent new breast cancers from occurring in the opposite breast in a woman who has already had one breast with cancer and hopefully, we can have what's called de novo prevention. That is primary prevention in people who've never had cancer but who may be at high-risk for the development of breast cancer. These estrogen receptors are very, very important.

Even in premenopausal women, almost half of them will have cancers that are both estrogen and progesterone receptor-positive and another 12% will have ER-positive and another 15% PR-positive. Overall, even in premenopausal women, almost two-thirds will have some presence of one or both of these hormone receptors. In postmenopausal women, the number is even greater. This is a very, very important component for younger women and older women. Until recently, it wasn't recognized that the estrogen receptor was so important in premenopausal women.

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What does this mean biologically? What I'm going to show you here is in the premenopausal patients and in the postmenopausal patients the cascade for how estrogen is produced in the body and this will explain how we then derive the treatments.

In young women, in premenopausal women, the story begins in the brain and the hypothalamus (which is part of the brain) sends a message to the pituitary gland. The pituitary gland sends a message with a hormone called prolactin and that message goes to the breast tissue and allows for lactation after pregnancy. Also coming from the brain is a message to the ovary through these hormones called gonadotropins and that ovary then gets a message that says, "Make estrogen and progesterone." In young women, this access from the brain to the ovary is where hormone production takes place. In older women, after menopause, the ovary sort of shuts down and that pathway is not so active. Where does the estrogen come from? Mostly from the adrenal gland, the little gland that sits on top of the kidney, and there's a message again that comes from the brain that says to the adrenal gland, "Make hormones." The adrenal gland makes lots of hormones that are very important in our bodies, amongst them are the estrogens. The precursors to estrogen are all of these other hormones, the corticosteroids and the androgens. There are two different places in our body where estrogen is made. In young women, the ovary is the primary focus for estrogen production, in postmenopausal women, the adrenal gland.

How can we take advantage of that biology? One thing we can do is block the activity of estrogen on the receptor. Remember I said you need the lock and the key. We can fiddle around with the lock a little bit. We can block the receptor and that's going to be medicines like Tamoxifen. We'll spend some time talking about that in a few moments. We can block the synthesis or the production of estrogen and we can do that in a few ways. In younger women we can ablate the ovarian function. That means we can erase the function of the ovaries and we can accomplish that by a number of different methods. Or, in older women, we can block the activity of the adrenal gland, block the production of estrogen here and we do that by blocking the enzyme that allows estrogen to be produced. That enzyme is called aromatase and we use medicines called aromatase inhibitors. We're blocking the production of estrogen.

There are some other things we can do to override the activity of estrogen on the estrogen receptor and then we have some new treatments that actually affect the receptor itself directly, that decreases the amount of the receptor that's present. What does that mean for treatment? If we're talking about young women with breast cancer and if the estrogen receptor is present, we now know that if we take advantage of that and block the estrogen receptor, then we will prolong survival and reduce recurrence, and also, prevent a second breast cancer from developing in the opposite breast. Even in premenopausal women, we now know that hormonal therapy, whether it's in addition to chemotherapy or even

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other targeted biologic therapies like Herceptin, plays a very, very important role in systemic treatment.

Now, how do we know if someone's going to respond to hormonal therapy? We first want to know if the estrogen and progesterone receptors are present. If the estrogen and progesterone receptor is present on the cancer cell, there is a very high likelihood that treatment targeting those receptors would be of benefit. If there are no receptors of estrogen or if it's only the progesterone receptor, we still might have a small benefit. If no receptor is present at all, you're probably not going to benefit from hormonal therapy and we would probably not recommend it.

Coming back to our message of how we can take advantage of this lock and key, the first type of drug option we can use are medicines like Tamoxifen, the anti-estrogens that block estrogen activity on the receptor. The second big category for premenopausal women is to stop the production of estrogen from the ovaries. That can be accomplished surgically by removing the ovaries, chemically by blocking the message from the brain to the ovary, or by radiating the ovaries using low-dose radiation therapy to cease the function of the ovaries.

Tamoxifen blocks the estrogen receptor. The estrogen comes in and attaches to the receptor and that sends the message into the nucleus and tells the cell to grow. Tamoxifen comes into the receptor and it locks it up so that the natural estrogen cannot get into the receptor. It's the key that goes into the lock and gets stuck. It doesn't turn the lock open and then it cannot send the cell the message to not get sent to the receptor. That's how Tamoxifen works. We use it in hormone-positive breast cancer and it's very effective in women of all ages, pre- and postmenopausal, and with all stages of breast cancer. It is, in fact, the first hormonal therapy that we have had experience with and it's been on the market for more than 30 years and many millions of women have taken this medicine for many years. We have lots of experience with it and although it does have side effects, it is a very, very effective treatment for breast cancer. In premenopausal women, it still remains the mainstay of treatment for hormone-positive breast cancer in combination with chemotherapy and/or other biologic treatments. We also know that it helps reduce the risk of new breast cancers and may be effective as well in preventing recurrence from in situ breast cancer. Tamoxifen is a pill. It's taken once or twice a day. There's a standard dosage and the current recommendation in premenopausal women is to take Tamoxifen for up the five years. For women who have advanced breast cancer, if they're responding to Tamoxifen, we would continue the medicine for as long as it is helpful. The advantage to Tamoxifen is that it helps prevent breast cancer recurrence and therefore improves survival. It reduces the risk of a second breast cancer in the opposite breast.

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The good news is that in binding to the receptor, some parts of the body think that it's actually getting a little bit of estrogen, so it helps to prevent osteoporosis and may help with the lipid profiles. Here's the bad news, and for any of you who've taken Tamoxifen or know anyone who's taken Tamoxifen, these side effects are very real and very troubling -- hot flashes, hot flashes, hot flashes. Did I mention hot flashes? That's a really big problem with Tamoxifen. The problems that I have to worry about for patients are blood clots and a very small risk of uterine problems, uterine cancer, mostly in older women. Some women complain of vaginal discharge. We don't usually see dryness with Tamoxifen. Hot flashes are really the biggest problem with Tamoxifen. But there are some other side effects also and a lot of young women who take Tamoxifen are taking it on the heels of chemotherapy and after just having been diagnosed with breast cancer. There is so much going on that it's hard to sort out what's the chemotherapy, what's the Tamoxifen, what's just this whole overall huge issue for a young woman facing a diagnosis of breast cancer. We certainly see depression and a lot of other emotional and psychological side effects related to this. Can Tamoxifen contribute to these? Yes, absolutely. We see depression. We see sexual dysfunction. Weight gain is a real problem for women undergoing treatment. I think chemotherapy contributes to this almost as much as the Tamoxifen does. Although these side effects aren't life threatening, they're serious and they're important and they really affect our quality of life. We need to talk about them and address ways that we can take advantage of the benefits of this treatment and hopefully lessen some of these very serious and life-affecting side effects.

What about fertility and what about pregnancy? This is a really big issue for young women who've had a breast cancer diagnosis. Let me just say at the beginning that pregnancy in and of itself is not dangerous for a woman who has had a history of breast cancer. The issue, though, is when is it safe for her to have that pregnancy and how soon after breast cancer diagnosis and the completion of treatment can we think about having a pregnancy? Fertility is a major issue for young women. We know that in most premenopausal women, they're going to get chemotherapy and/or Tamoxifen. If they're on Tamoxifen, they may continue to have normal periods, but they may get irregular. Being irregular doesn't mean that you're infertile and in fact, Tamoxifen actually acts like a fertility drug in young women. It is chemically, in its structure, very similar to a medicine called Clomid, which we use to induce ovulation. Women who are taking Tamoxifen are ovulating a lot, even though they may be skipping periods or they may not feel that they're regular. Young women on Tamoxifen definitely can get pregnant, so it's very important for young women on Tamoxifen to be careful, to use other forms of contraception to make sure that they don't get pregnant, because that exposure to a fetus would be dangerous.

In some protocols that we're looking at now experimentally, in trying to induce ovulation in women who've had a history of breast cancer, either immediately

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before they're getting treatment or once they're done with treatment, we are now actually using Tamoxifen instead of Clomid to induce ovulation. But Tamoxifen does not cause infertility. Chemotherapy can contribute to infertility. The biggest issue in infertility is age. The older you are, the less likely you are to conceive naturally. That's true whether or not you've had breast cancer. That's true whether or not you've had chemotherapy. We know that. The older you are the harder it is to conceive naturally.

If you're already in your 30's and you've had chemotherapy, you've already knocked your fertility down significantly. Then, if you're taking Tamoxifen, if you're on treatment for two years, three years, four years, five years and we don't want you to get pregnant during that time, we may, then, be looking at someone who is now five, six, or seven years older after her diagnosis. She's had chemotherapy, so they're looking at a significant impact on fertility, which is certainly age-related. And the combination of chemotherapy and Tamoxifen is what's going on here. The older we get, the more follicles, the more eggs we lose from the ovary and that's what's really impacting fertility. Fertility is really a time-related issue and chemotherapy is the bigger offender, not so much Tamoxifen. Sharsheret did have a symposium last year that really addressed this in great detail and you could go back to that information if you want more details on that.

What about other ways, in young women, in premenopausal women, of taking advantage of the estrogen receptor for treatment? As I mentioned, we can do what's called ovarian ablation. This is still a little bit controversial. In Europe, there's data that if we completely eliminate estrogen in premenopausal women by a combination of Tamoxifen, which is blocking the estrogen receptor, and using a medicine like Zoladex, which blocks the signal from the brain to the ovary, completely shuts down estrogen production, so that it's the same as giving chemotherapy, the results are the same.

The big question here in the States, where most women get chemotherapy, is do we have to add hormonal therapy after chemotherapy in order to get the best possible result? We don't know the answer to that question, but I'll show you a clinical trial that's suggesting it. Surgically we can remove the ovaries. The advantage to that is, yes, you remove the ovaries you completely get rid of estrogen production. But of course the disadvantage is that that's irreversible. Once we remove the ovaries, until we get really new technology, we're going to have irreversible infertility and irreversible and very abrupt onset of menopausal symptoms. Surgical removal of the ovaries, although we sometimes do it, has very profound consequences for young women. I would say, though, that in people who are at very high risk of ovarian cancer, particularly if they have a defined mutation in BRCA1 or BRCA2, we do sometimes remove the ovaries to prevent ovarian cancer. That's both therapeutic for their breast cancer,

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preventive for ovarian cancer. But we really have to cope, then, with this very abrupt surgical removal of the ovaries.

The other way that we can interrupt ovarian function is to use medicines like Zoladex, which switches off the message from the brain to the ovaries. This drug is given by injection under the skin. It can be given once a month or even once every three months once the body adjusts to the side effects. You have a longer-term action. This is an option for young women. The question about this is: can we use this ovarian ablation to protect against the effects of chemotherapy and maybe preserve fertility? Very controversial, not a lot of data about that. And should we add Zoladex to Tamoxifen when we're using this treatment? We don't really know the answer to this question and therefore we're running clinical trials like this one. This is called the SOFT trial. There are a number of studies now where we're looking at young women who've had surgeries for their breast cancer, either they get chemotherapy or not. Then they're being randomized if their tumor is hormone receptor-positive, either to the standard treatment of Tamoxifen for five years, ovarian suppression plus Tamoxifen for five years. This can be accomplished either by removing the ovaries or giving the kinds of medicine I was describing or giving low-dose radiation treatment to the ovaries. We don't do that so much in the U.S., but in Europe they sometimes do it. Or, instead of Tamoxifen, they use one of those newer drugs, the aromatase inhibitor plus one of those methods of blocking the ovaries. What we're looking at in this clinical trial is what's the best way of taking advantage of the estrogen receptor to get the best results in young women with breast cancer. This is just a slide that gives information about this low-dose radiation to the ovary, which was shown to be very effective and very safe and this again, is data from Europe. We don't usually do this too much in the United States.

The other medicine that I mentioned earlier is a medicine called Faslodex, or Fulvestrant, which actually reduces the amount or estrogen receptor that's present. It blocks the receptor and by blocking it, the receptor itself degrades. It falls apart. This treatment is only effective in postmenopausal women. It is not a treatment that we would use in young women, but I wanted to include it in case you come across it in some of your research.

What does a young woman do who has estrogen receptor-positive breast cancer? How does she make a decision about whether or not hormonal therapy is appropriate for her and what kind of hormonal therapy should she get? These are very, very individualized decisions and shouldn't just be made based on some cookie cutter recipe. I think each woman needs to sit down with her doctor, with whoever else is important in her life, to help understand what her values are, what her dreams are, what her life is about, how this treatment is going to impact her life, and how we can find a way to put all of that together in a synthetic process that makes sense.

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We know that there are benefits to hormonal therapy and we know that there are disadvantages. How that balance is going to weigh for each individual patient is going to vary and is going to be different. In women who have a very, very high-risk of recurrence where we have to do everything possible to make sure we're treating that breast cancer, the scale is going to tip largely in favor of giving that hormonal therapy. Perhaps, for some young women who have a prognosis where there's less of a chance of recurrence, where things look like they're under very good control, maybe where fertility is a very important issue, she's never had children, she's very young, maybe we'll hold off. Maybe the scale tips in the other way a little bit. This also changes over time and this is an ongoing conversation between each woman and the doctors and the whole health care team that is taking care of her. Treatment should be individualized.

What we did 50 or 80 or 90 years ago is different than what we're doing today and particularly for our younger patients. I think that when we started to treat cancer and when we made our first strides earlier in the 20th Century, we went for the best effect at whatever cost. I think we're really examining that and saying now, "You know, there are disadvantages to some of these treatments." We need to see what's really required, what isn't required for everyone, and what was acceptable in the past to some women that may no longer be acceptable. We can look at surgery. In the past, when a woman had breast cancer, everybody had radical mastectomies. That is no longer the case. Many women can have breast conservation therapy today, with lumpectomy and radiation and not have to have mastectomies. In some circumstances it is still medically advisable to do mastectomies. That decision has to be made on an individual basis. I believe that decisions for systemic therapies, including hormonal therapy, also have to be made on an individual basis, where our goal is maintaining the wellness of the individual. Yes, we want to make sure we cure your cancer, but we want to keep you healthy for the rest of your life, too, and for a long time.

Breast cancer treatment planning for early-stage breast cancer is based on the traditional prognostic factors and now we have some new tools available to us. As you know, this is a multi-modality approach - surgeons, plastic surgeons, medical oncologists, radiation oncologists, gynecologists, and your psychosocial health care deliverer. There is nutrition, exercise, and genetic counseling. A young woman diagnosed with breast cancer probably has 10 specialists she needs to see. She needs to see all of them. She needs to make sure that she chooses the right treatment and she needs to also make sure that she has the right support and the right team behind her. Sharsheret certainly has contributed, in the years that I've been associated with Sharsheret, not only in providing information to patients, but in providing that kind of support, especially for women who are not in major medical centers or in big cities. So that like this kind of a webcast, you can link up with each other individually and also as a

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community to make sure that that information gets out there. Therapy needs to be targeted to the individual.

In addition to all the work we've done on the estrogen receptors, research is continuing in trying to understand the molecular biology of breast cancer. Genomic is the buzzword of the 21st Century and where we're doing with genomics is trying to take a molecular portrait of the cancer cells. There are lots of different technologies out there. There's one particular technology, which has already been approved and which has been shown to be very useful to us, using the Oncotype DX test, in young women -- in all women and women with early-stage breast cancer that's estrogen receptor-positive. We're looking at a whole set of genes in the cancer cells, some related to the estrogen receptor, some related to HER 2 nu and other genes that tell us about the biologic behavior of the cancer cells: how likely that cell is to proliferate or grow and how likely it is to metastasize or invade. When we get that information from this test, it gives us a recurrence score. That's very helpful to the medical oncologist in predicting not only the risk of recurrence but what kind of treatment would be useful for that patient. This test helps us to predict whether the patient will benefit from hormonal therapy like Tamoxifen or if chemotherapy is also required. This test has been validated for estrogen receptor node-negative patients.

In conclusion, hormonal therapy is a very, very important component of breast cancer treatment for premenopausal women. There are many advantages to this therapy. There are lots of side effects. Some of the side effects are short-term, some of them are long-term, but we need to focus on all of these as we make our treatment decisions.

I spent the last few years out in Boulder, Colorado, where it was very beautiful. These are the Flat Irons and I have hiked all of those mountains. But I'm very, very happy to be back in New York City and to be part of this symposium this evening. Thank you.

Rochelle Shoretz: Thank you, Dr. Oratz. It's a pleasure to have you back in New York and your remarks helped set the stage for the remainder of our discussion tonight. Dr. Gila Leiter has been a member of Sharsharet's Medical Advisory Board since the organization's founding. She's an Assistant Professor at the Mount Sinai School of Medicine and an attending at the Mount Sinai Hospital. Dr. Leiter maintains a private practice in New York City in OB/GYN. Tonight she will discuss strategies for addressing the impact of breast cancer treatment on hormones and, in particular, symptoms of menopause in breast cancer survivors. Please join me in welcoming Dr. Gila Leiter.

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III. Gynecological Issues Related to Estrogen Deprivation in Breast Cancer Patients

Dr. Gila Leiter: Thank you for the introduction. I'm really delighted to be here tonight. Sharsheret has been an incredible resource for my patients and in fact, for the entire community.

I'm going to be talking a little bit about declining hormone levels in breast cancer patients, its evaluation, and treatment. I'm also going to talk a little bit about exogenous hormones, HRT, and oral contraception in breast cancer and its relationship to breast cancer and I'll also talk about the hormones of pregnancy and its impact on breast cancer.

Increasing numbers of women have menopausal symptoms after breast cancer treatment and Dr. Oratz discussed some of the treatments that might be causing these symptoms and this affects quality of life. The definition of menopause is loss of ovarian function. These menopausal symptoms can be caused by cancer treatments such as the surgery that Dr. Oratz referred to, to remove ovaries, chemotherapy-induced ovarian failure, and the various anti-estrogen therapies that we hear about. This may be temporary. It may be permanent. It depends on the age of the patient, the doses, and the agents used for treatment. In premenopausal women, chemotherapy combined with endocrine treatment causes premature menopause in over 80% of patients during the first year after diagnosis, so it's a huge problem. The other cause of menopausal symptoms is cessation of HRT. When breast cancer is diagnosed, patients who are on HRT usually stop their HRT and this will commonly produce the kinds of the symptoms that caused them to take the HRT in the first place. One Western Australian study explained that 40% of patients who were diagnosed with breast cancer were on HRT, so this is actually quite a large clinical problem. When a patient is being treated and diagnosed with breast cancer and then stops HRT, obviously this exacerbates some of the psychosocial issues. Two-thirds of postmenopausal women who have had breast cancer report hot flashes, so it may not be caused by treatment at all.

Symptoms of menopause relate to falling estrogen levels. Estrogen affects many organs. It affects the brain, the skin, blood vessels, the heart, bones, and breasts. There are major clinical issues resulting from estrogen deficiency. Most commonly, everybody knows about hot flashes. This is called vasomotor symptoms, night sweats. Central symptoms are much more difficult to quantify. These are sleep disturbances, changes in memory, concentration, and moods. People talk about irritability, urogenital symptoms, vaginal dryness, painful intercourse and possibly an increase in vaginal infections, and urinary symptoms such as urinary urgency, urinary tract infections. Long-term, estrogen deficiency can cause osteoporosis and increased risk of fracture. We know about

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vasomotor symptoms. They have been described for millenniums. But interestingly enough, why they occur is not very well understood at all. Most people, most scientists believe that it is due to the instability of the brain center that regulates temperature, which is induced by estrogen withdrawal. Low levels of estrogen itself don't cause hot flashes. It is estrogen withdrawal and this is probably mediated by serotonin receptors. Hot flashes are what most commonly lead to treatment requests and as a gynecologist that is, in fact, what drives patients to the office. They can occur day or night, so night sweats is a misnomer, and a flash usually last four minutes. It could be associated not just with sweating, but with anxiety, palpitations and irritability and these tend to be the most troublesome for patients. And no one knows if the symptoms are different after cancer treatment as compared to natural menopause.

HRT is the most effective treatment for menopausal symptoms in healthy women. Most women are reluctant to take HRT after breast cancer and many believe that its use caused their disease. What is the data and are there any circumstances in which this therapy can be recommended after breast cancer? Interestingly enough, observational data or epidemiological data, meaning studying groups without randomized trials, suggested that there was no increase in recurrence rate in those women who took HRT. This is, again, HRT after breast cancer. This led to two randomized, controlled trials of HRT after breast cancer. One was called the HABITS trial, which stands for HRT After Breast Cancer Is It Safe and the Stockholm trial. In the HABITS trial, they studied 432 women with controls and they found a relative risk of recurrence, which was very high, 3.3, and that led to the study being terminated after two years. The Stockholm trial, which had problems of both recruitment of patients because some of the data about HABITS was coming out, as well as compliance, so it had lower numbers but actually showed a lower risk of recurrence of breast cancer with the use of HRT. The combined relative risk of recurrences reported is 1.8 and as a result, it was suggested that HRT is not first-line management for menopausal symptoms after breast cancer. It's interesting to review the data, though, because indeed in the Stockholm trial, which again, didn't show as high a rate of recurrence of breast cancer with HRT, they actually used very different doses of estrogen and progesterone. The progesterone doses were lower. They were intermittent instead of continuous and the patient populations of the two studies were not the same. Nonetheless, these were two trials when combined showed there was an increased risk of recurrence of breast cancer after HRT.

Another problem with hormone use after breast cancer is that we know, as clinicians and the WHI (Women's Health Initiative) study showed, that HRT use makes breast tissue more dense and abnormal mammograms are more common. If a woman who has had breast cancer is on HRT then, in fact, it's more difficult to screen her for recurrence. It's not first-line management for menopausal symptoms after breast cancer, even though it is the most effective treatment for such symptoms.

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What about treatment without estrogen? One thing that's very important to remember, and it is really quite fascinating when you think about it, is that there is a placebo affect of 30 to 40%, which is a huge number, in reduction of symptoms with any treatment. That makes significant efficacy difficult to demonstrate. In the United States, in order to demonstrate efficacy, you have to prove that the treatment actually lasts. It cannot be just short-term treatment but it lasts for at last 12 weeks. Many of the studies, unfortunately, don't see this with breast cancer patients, but amidst a group of patients. It's hard to make generalizations about the use of these treatments for breast cancer patients, but we all do the best we can.

Let's talk a little bit about hormonal treatments without estrogen. Progesterones actually, progesterones in of themselves are the best studied agent after breast cancer. Megace, in doses of 40 mg a day, which was used as anti-breast cancer treatment in the past, actually reduced hot flashes significantly, by 85%, but had a lot of side effects, especially weight gain. In light of the progestins adding to breast cancer risk in healthy women and can't be assumed to be safer than combined HRT, its use is not recommended for menopausal symptoms in breast cancer patients. Tibalone is a fascinating molecule. It is a hormone, which has been used in Europe for decades. It's not United States FDA-approved and it's a mixed hormone. It has weak estrogenic progesterone and male hormones or androgen properties. It's effective in hot flashes. It decreases it by 63% and has the bonus of helping vaginal dryness and increased libido, which many women who are suffering from menopausal symptoms suffer from. There is no increase in the breast tenderness of mammographic changes that one sees with HRT. However, the UK million-woman study, which is a very large, well done, observational study (it's not a randomized clinical trial), did show an increased risk of breast cancer with Tibalone. Nonetheless, because of how attractive it is, there is a trial underway, which is called the LIBERATE trial and that's Livial Intervention after Breast Cancer, Efficiency, Recurrence and Tolerability End point trial and that'll be very interesting to see its results.

Non-hormonal treatments include the SSRIs and the SSNRIs. These are antidepressants, the selective serotonin reuptake inhibitors and the selective serotonin norepinephrine reuptake inhibitors. These are antidepressants whose efficacy has been shown in several randomized trials. The first one that has been used and shown to be effective is Effexor or Venlafaxine. It showed a 61% reduction and again, you always have to remember the background placebo effect of 30 to 40% in hot flashes. However, sustained use after 12 weeks was not shown to be of continuing benefit. The other thing is there are a lot of side effects, such as weight gain, nausea, sedation in some cases. Other antidepressants such as Paxil and Celexa showed no differences except that Celexa did improve insomnia. There is no evidence that SSRIs increased the risk of breast cancer, but there is some concern that in fact, they might interfere

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with endocrine treatment for breast cancer, so that it might be that indeed these treatments may lower the effectiveness of Tamoxifen. Another treatment that has been used is Neurontin, which is effective, but again if you look at the reduction of flashes, it's 54% and that's not much greater than placebo and these are not tolerated well. A lot of sedation with Neurontin can occur. And Clonidine is antihypertensive. That was used a lot in the past, but not all studies show efficacy and there's a high rate of side effects.

What about complementary or alternative treatments? We've all seen ads and read about phytoestrogens. These are of plant origin. They're structurally similar to estrogen and have weak estrogenic effects. There is some question in epidemiological data about its role in preventing breast cancer, but unfortunately there's no randomized, controlled trials addressing its efficacy or safety after breast cancer, so then it cannot be advocated. The efficacy in healthy women hasn't been established as well. Large, randomized, control study of red clover isoflavones, which is commercially available, showed no reduction in symptoms compared to placebo and there was a very large, systemic review of many studies that showed no significant benefit about a year ago.

Black cohosh has been used a lot, and that is Remifemin commercially, although it's available in many different preparations. Trials with Remifemin or black cohosh versus placebo in breast cancer patients on Tamoxifen showed no superiority over placebo. In a mixed group of patients, there was a reduction in hot flashes by 50% and again, reviewing its use for menopausal symptoms showed no significant benefit. In addition, there are safety issues. There have been a couple of cases of liver failure reported and liver damage. These complementary treatments have minimal benefit and might actually have some dangers associated with it. Wild yams, ginseng, progesterone creams, donquai, there's a whole pharmacopoeia that have been advocated for menopausal symptoms, but they are largely ineffective. Vitamin E, one study showed that with 800 milli-international units (miu) after breast cancer the hot flashes were reduced by a mean of one per day, which doesn't sound very significant. Lifestyle and non-pharmacological treatments have also some effects that are better than placebo. Acupuncture, as one wonderful study showed, was better than placebo for flashes. Trained relaxation techniques for 20 minutes a day might be effective. Regular exercise certainly makes patients feel better and certainly helps with the bone loss. Many women learn to identify and avoid triggers of hot flashes, such as spicy or hot foods, alcohol.

Another area that I want to talk about is urogenital symptoms. These are common symptoms that affect quality of life and these are vaginal dryness, painful intercourse, and urinary symptoms. These are all caused by loss of estrogen, thinning of the vagina and in fact, vaginal moisturizers and lubricants which are non-hormonal may be helpful when used regularly. There are a lot of wonderful commercial products out, like Replens and Lubrin and lubricants like

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Astroglide. These work, when used regularly. Topical estrogens alleviate dryness and atrophy and the systemic absorption of these estrogens is very minimal. It depends on the dose and thickness of the vaginal mucosa. If there is a thinner vagina, meaning more long-term lack of estrogen, there may be more absorption. Tablets are available. There's a product call Vagifem, which is easy to use and it has very small amounts of estrogen, which is used vaginally and only a small amount of estrogen is actually absorbed systemically. And there's a nice product called Estring, which is a little ring, which has a tiny bit of estrogen that one uses for three months. These are used vaginally and small retrospective studies suggest safety after breast cancer. This is another area that, in fact, is actually something that is really helpful for patients and it would be great to have some prospective control trials illustrating its safety, but they do appear to be safe and helpful.

Decreased sexual function is a complicated area, and I think Shera will be speaking a little bit about it and certainly doesn't just relate to decreased estrogen in the vagina. There are multiple reasons for decreased sexual function related to menopause after breast cancer and best treated with a multidisciplinary approach. Certainly the first thing is to alleviate vaginal dryness and pain with intercourse, but there are generally lots of other factors involved, too, that need to be addressed.

Bone loss: another long-term consequence of loss of estrogen is bone loss. We know that mean bone density is actually greater in women who develop breast cancer and this is what Dr. Oratz had alluded to: the increased estrogen that women who are at increased risk of breast cancer may have more circulating estrogen around. That's been shown in lots of studies, that indeed actually premenopausal women with breast cancer have higher serum levels of estrogen. We know that mean bone density is greater in women who have had breast cancer. However, rapid bone loss can occur when the estrogen is abruptly withdrawn, such as with ovarian failure due to chemotherapy or with the use of aromatase inhibitors. Tamoxifen preserves bone density and reduces fractures in postmenopausal women. However, in premenopausal women, it can be associated with bone loss. Aromatase inhibitors improve recurrence free survival (RFS) compared with Tamoxifen, as Dr. Oratz had shown, but bone loss is substantial and it's greatest for women less than 65 or within four years of menopause. Obviously it's not just the bone loss itself that's associated with increased risk of fracture.

How do we prevent and treat bone loss? Calcium intake is very important. The Surgeon General just came out with a report in which it is estimated that 75% of Americans are calcium-deficient. We're looking at an intake of 1200 to 1500 mg of elemental calcium per day as being important and most women require supplements in order to provide that amount. Vitamin D is important to help metabolize the calcium, 400 mu/day and with osteoporosis 800 mu/day.

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Something that clinically always amazes me is that patients think that they're on medicines for osteoporosis and don't take their calcium, but obviously one needs both. Weight-bearing exercise of 20 to 30 minutes daily improves bone density and decreases hip fractures. The more aerobic exercise, the better the bone density response. But certainly brisk walking can do the trick, even 30 minutes of brisk walking daily will improve bone density, and avoiding bone toxins such as smoking and excessive alcohol. Providing a safe environment is always very important, especially in older patients, making sure that the rugs aren't loose, that there's good lighting in hallways, etc. These all sound very basic but can really help prevent fracture.

Assessing bone density in women who become menopausal before age 40, women over 65, if there's a family history of osteoporosis, or any woman on aromatase inhibitors should have a bone density done. That's most commonly done today by dual photon densitometry. It's widely available, insurances cover it, and the radiation is minimal. Drug therapy is indicated when bone density falls into the low range and that's diagnosed using nomograms, comparing age and bone density and using -- comparing women to the peak bone density -- the woman of age 30 at the peak of her bone density. If she's osteopenic, that means she's more than two standard deviations below young normal, at the peak of her bone density or osteoporotic, she should be treated. There is a lower threshold for intervention with bone-preserving treatment if, in fact, the patient is on an aromatase inhibitor. There is a trial underway called the Z-Fast trial which is going to be evaluating the use of a drug called Zometa, in conjunction with Femara as a synergy trial to see if prevention of bone loss can occur a priori, when a patient is on an aromatase inhibitor. Zometa is one of the bisphosphanates. It's a drug like Fosamax. However it's an I.V. infusion given once a year, so certainly if that has been shown to prevent bone loss, it'll be effective for prevention.

Drug therapies for osteoporosis includes drugs such as Alendronate and Risedronate, commonly the brand names are Fosamax and Actonel. The bone is a very living organ. People think of the bone as static and actually it's constantly building up and breaking down. It's a constant balance. Medications of bisphosphonates are anti-resorption. They prevent the breakdown from occurring and they're very effective. They do decrease fractures of the spine and hip. They're given weekly, in most cases orally, and the side effect is pill esophagitis and this is rarely a problem if the drugs are taken correctly. And there are some very rare cases now of osteonecrosis of the jaw. But these are really rare case reports. Raloxifene has been used for osteoporosis prevention and treatment. It also decreases breast cancer and perhaps for breast cancer, this is a treatment. There's also a trial, which is the STAR trial, comparing Raloxifene to Tamoxifen for breast cancer recurrence prevention. We'll be interested to see what those results are. There is now available Parathyroid Hormone (PTH) injections or Forteo and these are for high-risk patients who are

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not responding to the other medications. There are subcutaneous daily injections of PTH for two years. The safety for breast cancer patients has not been established.

The good news, just to review or to summarize, is that there are treatments for menopausal symptoms. A lot of the lifestyle treatments may be just as effective as those hormonal and non-hormonal treatments. Certainly for osteoporosis there are a lot of treatments that should not impact adversely on breast cancer or breast cancer recurrences and there certainly are very effective ways of preventing fracture and bone loss. The whole question of vaginal dryness and urogenital symptoms can be addressed basically and effectively as well today.

I'm going to touch briefly on hormones of pregnancy and breast cancer. Basically, reproductive factors influence breast cancer risk. Dr. Oratz described this already: age at menarche, no children, and a late first birth. And that, in some studies, is after age 30, which certainly doesn't seem very late in my practice, or after age 35. Studies seem to say that all these increase the risk of breast cancer. Should we look at some of the studies on a biological level that are being done, it's really the trend to delay childbearing, lack of exercise, and a Western type diet they all may combine to increase the risk of the strong proliferation of breast epithelium during early adulthood. In fact, a first pregnancy protects the breast. If we put all these things together, our current lifestyle probably has the highest risk of breast cancer. Genetics modify risks, too, and certainly as Dr. Oratz mentioned, genomic medicine is interesting and going to be the wave of the future. But there's a very interesting recent epidemiological study, which showed different influences of parity in BRCA1 and BRCA2 carriers. In fact, it showed that increasing parity and breast feeding decreased breast cancer risk in BRCA1 carriers, while it did the reverse, increasing parity increased the risk of breast cancer in BRCA2 carriers. Knowing if a patient is a BRCA2 carrier, if she has decided to have a pregnancy, she certainly should have intense surveillance the first two years after pregnancy.

We have certain questions to examine. One, is pregnancy an independent adverse prognostic factor when breast cancer is diagnosed associated with pregnancy? Two, in a patient who has had breast cancer, does it increase the risk of recurrence? Three, is there an optimum time to conceive? Dr. Oratz talked a little bit about some of these questions.

The definition of pregnancy-associated breast cancer is when diagnosis is during pregnancy, lactation, or one-year postpartum. It's rare and it's in fact the second-most common cancer in pregnancy, the first being cervix. Most studies in the past showed such women present with more advanced disease in a shorter interval between birth and diagnosis, had a poorer outcome, and suggested that the hormones of pregnancy had a bad effect on breast cancer. However, modern studies have reported equivalent survival of women with pregnancy-

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associated breast cancer and controls when they were matched, when they were the same patients, when they were apples and apples, when they were matched to age, stage, and other prognostic factors. Two studies showed worse survival, but those studies, if you look at them, the chemotherapy was delayed. Some report subsequent pregnancy has a favorable impact, that it actually lowers the risk of recurrence of early-stage breast cancer. And evidence is lacking that termination of pregnancy changes the outcome of breast cancer.

In summary, pregnant women with breast cancer have a similar prognosis to that of non-pregnant women and it obviously is important to diagnose in a timely fashion and treat appropriately, which is complicated. The effect of subsequent pregnancy on recurrence studies show no worsening of prognosis, and even better outcomes in women who become pregnant after treatment. This could be a bias, a "healthy mother" effect. A healthy mother is going to be less likely to have had a recurrence before pregnancy. Common advice is to wait two years after treatment, because most recurrences occur within the first two years. But this has been questioned recently and in fact, as Dr. Oratz showed us, if there will be impaired fertility if you wait any longer, because a patient might be approaching 40, 41, with decreased follicular reserves, it may not be advisable. There are lots of particular situations related to breast cancer treatment and pregnancy, and certainly a multidisciplinary team needs to be involved with this.

Rochelle Shoretz: Thank you, Dr. Leiter. You've given all of us participating as breast cancer survivors this evening a lot to consider in managing the quality of our lives post-cancer. Again, all of you will have an opportunity to submit questions to our panelists during the Q&A session in just a few minutes.

I'd like to introduce Shera Dubitsky, our final speaker this evening. The psychosocial issues for young women concerned about hormones and breast cancer are multifaceted. Here tonight to discuss some of the unique ways in which young women grapple with and address those issues is Shera Dubitsky, Sharsheret's Link Program Coordinator. Before joining Sharsheret's staff, Ms. Dubitsky served as a psychology resident and fellow at the Albert Einstein School of Medicine and at Memorial Sloan-Kettering Cancer Center. Many of you may have already had the pleasure of speaking with her on the telephone, if you've called in to participate in the Link Program or for our new Embrace Program. Please join me in welcoming Ms. Shera Dubitsky.

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IV. Psychosocial Issues for Young Women Concerned About Hormones and Breast Cancer

Shera Dubitsky: Historically, hormones have been a topic of much discussion, the target of many jokes, and the emotional barometer for many of life's milestones. From the onset of life, hormones define us as female and it defines how we are raised, what toys we play with, what activities we engage in, and how people respond to us. And the future of our lives are very much shaped by our female hormones.

For example, in puberty it's a much anticipated time for a preadolescent girl, and I think that everyone has their "when I got my period for the first time" story. For the preadolescent girl, she's thinking, "What is menstruation like? Will I get it the same time as my friends? Will I be the same age as my mother when she first got her period? Am I like everyone else?" The heart of adolescence is a time of heightened hormonal experiences, a time where we begin to connect with our sexuality, our sense of femininity, and how we view ourselves as the female gender. Also, how we are perceived by others and again, our experience is driven by, "Am I like my peers? Is this normal? Am I normal?" Adulthood is a time when the undercurrents of hormones often influence our experiences. Women share camaraderie with each other over PMS symptoms. Boyfriends and husbands band together for mutual support when their loved one is PMS. Most women with children have their hormonally laden "crazy pregnancy" story. And again, we as women, we connect with each other and by speaking with one another we normalize these hormonal experiences. And finally, in menopause, it's yet another time for self-identification, for female bonding, for identifying with our mothers – the hot flashes, the forgetfulness, the mourning over the loss of our ability to create life, the changes in our body, changes in our sexuality. Yet even given all that, it's still a right of passage, a milestone in life, a normalizing experience and in each of these milestones, we have role models. We have our mothers. We have aunts. We have older sisters. We have cousins. We rely on our family and friends to help us navigate the unknown journey through these hormonally induced milestones.

When a woman is diagnosed with breast cancer, it immediately catapults her out of normalcy and she no longer feels like other women. Her self-definition is dramatically altered. The progression through life's milestones becomes unknown, physically straining and emotionally laden. And in many cases, there's just no one to model after. A diagnosis of breast cancer is pervasive and it impacts a woman's self-image, her body image, sexuality, fertility and pregnancy, dating, and mikvah. I would like to address these areas of concern, to also discuss some positive intervention, and to identify resources that you may find helpful in attending to your needs.

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Many women diagnosed with breast cancer undergo body-altering surgery. The women of Sharsheret have expressed ambivalence about the surgery. On the one hand, women are reporting that they feel relieved that the cancer is out of their body. But at the same time, women are also feeling a sense of being damaged, a sense of not being attractive. Women who have undergone an oophorectomy or hysterectomy express similar feelings of damage and distortion. But they also express tremendous feelings of loss, loss of their birthright to reproduce. A young woman experiencing chemo-induced menopause may feel old. She may no longer feel vibrant and young, and women in her age group may not relate to the hot flashes and to the changes in the sex drive or the mood and memory changes. She may feel that her peer group has now become women in her mother's generation.

In general we as women are raised to be nurturers. We're caregivers and we're just, by definition, we're givers. Yet a diagnosis of cancer and cancer treatment present women with a crushing dilemma that pins two forces against each other. On the one hand we have the drive to care for others versus the necessity to be self-focused. We know that women with breast cancer report feeling depleted and it is necessary to reserve and conserve energy for fighting the cancer. Even though a woman knows that, it's not uncommon for a woman to feel guilty about not being able to be there for family and friends in ways that they had been accustomed to prior to treatment. Also, these dynamics are prevalent in the marital relationships. Busy with medical appointments and often fatigued as a result of treatment, many women find that they do not have the time or the energy they are used to spending with their spouses. Spouses may be assuming additional household and child care responsibilities. The husband is feeling vulnerable and frightened. He may feel neglected. He feels he needs support. The wife is feeling depleted, unattractive. Her own sense of sexuality is diminished significantly and she may fear her husband's reaction toward her. How is a woman expected to look forward to intimacy with her husband when she's deluged with feelings of unattractiveness, fatigue and fear?

Also, as we've heard, as a result of treatment impacting a woman's hormones, there may be vaginal dryness, change in sexual desires, and change in the ability to be sexually spontaneous. The pressure to be intimate may burden the emotional ties within the relationship, often resulting in resentment and distance. Sometimes people are withdrawing into themselves and it's not uncommon for a spouse to have trouble communicating, both partners are coping alone. So, later, I would like to review guidelines and resources addressing healthier forms of communication.

Treatment can also cause interruption of the menstrual cycle, as we've heard, and there's a fear from the woman that she may become infertile. And for those women who have not had children yet, they may worry that they will be forever childless. Whether treatment postpones pregnancy or terminates the ability to

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bear children, feelings of loss and sadness are overwhelming. Again, a woman is distinguished from the sisterhood of her peers. In addition to coping with her own feelings of sadness, she may feel self conscious about how others are perceive her and respond to her. She may be surrounded by pregnant women or women with young children and not only is she feeling a sense of loss, but she may also be keenly aware of being pitied. Furthermore, some women may feel guilty about disappointing their husbands or their in-laws or their parents because of the inability to procreate, whether it's temporary or permanent.

The mitzvah of mikvah heightens these feelings. For women of childbearing age, mikvah represents the opportunity for conception. Fulfilling dreams of raising children begin on mikvah night, when a couple can try to conceive. For women who are prematurely menopausal or have to postpone having children, mikvah can trigger profound feelings of loss and sadness. Some women experiencing chemo-induced menopause experience a range of emotions about not attending the Mikvah. Again, there is that strong sense of loss, a sense of being different from their peers. They may, in fact, be relieved about not having to be exposed in front of a mikvah attendant, and the pressure to reunite with a spouse that particular evening is also eased. The prospect of going to the mikvah for the first time after treatment can be accompanied by fear and anxiety. Some women feel embarrassed and concerned about the mikvah attendant's reaction upon seeing surgical scars, perhaps the hair loss, or simply knowing that the woman has cancer. For other women, returning to the mikvah can mark the beginning of healing. A woman can feel emotional because she has another chance at life.

Changes in hormones or chemo-induced menopause can have a profound impact on the Jewish single woman. For the Jewish single woman undergoing treatments that impact hormones, there is a fear of not being a desirable choice. There is a fear of infertility. There is a sense of inadequacy. There is a sense of being different and there may be increased isolation. She may find it difficult to be with peers who are dating. Friends also may be distancing themselves because they feel guilty about their unconditional dating. When dating, there is also a stress to the woman over when to divulge information about the cancer and treatment and how to appropriately share the information in a way that won't create distance, but rather would promote a supportive response.

I'd like to talk about some intervention and some communication that I think you would find helpful. And I can't emphasize this enough: it is important to tend to your emotional health and relationships as vigilantly as you tend to your physical treatment and healing. Remember that each woman is unique and that each experience is distinct, and it's important to identify your own experience, but to do so in a way that's not isolating. There are ways of living with cancer and treatment that lessen the loneliness and decrease the feelings of isolation and differentness.

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Prior to diagnosis, it may have felt natural to openly discuss hormonal issues with other women, with your sister, with your mother, with your spouse. Post-diagnosis, barriers in communication arise due to discomfort, sadness, anger, embarrassment, and loneliness. Good communication with people you trust is essential. Don't assume that people know how you feel. Share your thoughts and feelings clearly and openly. Don't stand on ceremony. State your needs as you experience them. This is not a time to test relationships. This is a time of heightened emotions between spouses. Remember you're on the same side. You're sharing a common goal. Discuss your emotional and sexual fears, your concerns, and your needs, and agree not to go beyond your partner's physical and emotional readiness. When possible, have a sense of humor. In healthier times, it was common to poke fun at yourself and at your hormones, so try to reconnect with that part of yourself. And finally, keep your treatment team informed of any changes. Open communication with your medical team increases the options available to you in managing side effects.

How can Sharsheret be of help? Sharsheret has a Link Program that offers women facing breast cancer an opportunity to speak with other women who have been diagnosed with breast cancer and are undergoing treatment. The Link Program pairs women of similar backgrounds and diagnosis with each other. Even the areas that I discussed briefly this evening would be, for example, some of the topics that you can explore with your Link. The women of Sharsheret have found a rewarding and comforting sisterhood among themselves. Many of Sharsheret's women report feeling validated for the first time since their diagnosis. Sharing experiences with other young Jewish women with breast cancer is often a normalizing experience that was familiar prior to the diagnosis. Sharsheret also has a Quality of Life Program, including the Busy Box and Embrace, and it also has Best Face Forward, which is designed to address the cosmetic side effects of breast cancer treatment and hormonal treatments. Sharsheret has hosted symposia on a variety of topics relating to breast cancer and the transcripts of these events can be accessed and downloaded on our website, www.sharsheret.org. The topic of hormones in particular was addressed in the Breast Cancer and Fertility symposium, as well as the symposium on survivorship and I encourage you to go to the website and look at the transcripts. We are launching "Ask Sharsheret" this month in conjunction with our Family Focus Program, and it's designed for family members to call and speak with a Sharsheret staff counselor, addressing questions and concerns regarding diagnosis and treatment and even beyond treatment. As I discussed earlier, hormonal changes can impact other relationships, particularly the marital relationship and family members need support as well. Finally, Sharsheret is launching and online Forum open to women, family members, friends, health care providers, and community leaders, to explore questions and concerns relating to the topics that I addressed tonight and to breast cancer in general in a confidential and supportive Forum.

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Sharsheret's programs offer support, education, and quality of life services with the intent of normalizing and validating experiences for the women facing breast cancer and their families. In times when there is a potential to feel lonely, Sharsheret serves as a reminder that you are not alone.

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Rochelle Shoretz: Thank you, Shera, for your thoughtful insights and helpful resources for addressing some of the hormone-related issues we addressed tonight. And thank you again, to all of our panelists, who I invite back up on to the stage for what I trust will be a lively Q&A session this evening.

First, for Dr. Oratz, is there any research to suggest that drinking alcohol can affect the role of hormones in causing breast cancer? This question came in from across the country.

Dr. Ruth Oratz: Yes, there is a link between alcohol and breast cancer. The link seems to be more than one drink a day, every day. A glass of wine with dinner, a couple drinks during the week is probably safe. But daily alcohol consumption is not recommended.

Rochelle Shoretz: Thank you. Are women who test positive for alterations in the BRCA1 and BRCA2 genes any more likely to be hormone receptor-positive?

Dr. Ruth Oratz: There's some question about whether the kinds of breast cancers that women get if they have genetic mutations are the same, whether they have mutations or not. We think that BRCA1 mutation women are more likely to have estrogen receptor-negative breast cancers. But it's not 100%.

Rochelle Shoretz: For Dr. Leiter, a question came in about Tamoxifen and, in particular, weight gain from Tamoxifen. This particular question comes in as – she's tried exercise, eating less, nothing seems to work. What is the current science on maintaining a healthy weight post-Tamoxifen?

Dr. Gila Leiter: Certainly exercising will help on maintaining bone density and also weight. I don't think there are any studies about Tamoxifen in and of itself increasing weight, so I'm not so sure that that's not a consequence of breast cancer and its treatment.

Dr. Ruth Oratz: Actually, in the prevention study, which randomized several thousand women to Tamoxifen or placebo - these were healthy women at high-risk for breast cancer - and it was a double blind, randomized study, which meant the doctors and the patients didn't know who was taking Tamoxifen and who was taking the placebo. All of those women were weighed every time they came in for their checkup and interestingly, the Tamoxifen group of women actually lost weight. We know that women on HRT probably lose weight. The issue is probably estrogen depletion and menopausal symptoms that lead to weight gain and we know that chemotherapy is associated with weight gain. In my practice, we encourage patients to work with a nutritionist and really develop a healthy diet

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that's appropriate for that patient and as Dr. Leiter said, to really work on an exercise program. It is very difficult, but it is doable. I think that, as Shera said, we also have to come to terms with our sense of ourselves and our body image. We live in a culture in which we're inundated by images of skinny, young girls. Very few of us are so skinny and so young, and we have to be able to embrace that in ourselves and say it's okay if I'm five or ten pounds heavier, and still feel beautiful and still feel feminine and still feel that that's normal, because it is. I would add that I think some psychosocial factors, like Shera was talking about, I think you have to screen women who are complaining consistently of weight gain for depression. Because if there is depression, that can contribute to weight gain, depending on the particular person.

Rochelle Shoretz: A question came in about oophorectomies. Given the side effects that will obviously play a large role in one's quality of life post that kind of surgery, is there a best age for women, particularly, who are testing positive for a BRCA1 or BRCA2 mutation or have a family history of ovarian cancer? Do doctors suggest taking something like Zoladex prior to an oophorectomy to lessen the abruptness of the removal of the ovaries and can you speak to that in general?

Dr. Gila Leiter: Well, I'll just start with I think that there's no age at which oophorectomy is too late and that's been looked at in several studies. Certainly the younger a patient is, the less likely she is to develop the ovarian cancer for which she presumably is having her ovaries removed. The recommendation is once you've completed childbearing to, in fact, remove your ovaries. Bbut there is no age at which it's too late. And in fact, it's been shown that a patient can have her ovaries removed and it will have an impact on decreasing ovarian cancer, even if she does it a little bit later.

Dr. Ruth Oratz: I think, also, we have to look at, in women who are mutation carriers, which specific mutation they have. The age of onset of ovarian cancer in mutation carries is a little bit older than the age of onset of breast cancer. Usually the ovarian cancers don't show up until the 40's. Now, does that mean on your 40th birthday you should have an oophorectomy? On your 41st? 42nd? I mean, as Dr. Leiter says, it's very difficult to estimate this. There may be some differences between the age of onset in BRCA1 and BRCA2 patients as well. The decision-making needs to be a little bit individualized. That's a provocative question, Rochelle. Should a patient try Zoladex before starting the oophorectomy in terms of trying to mimic a more natural onset of menopausal symptoms and maybe lessen that abrupt, "oh, I just got hit by a train" feeling. This is a feeling with surgical oophorectomy. I have no experience with that. Have you tried that?

Dr. Gila Leiter: I don't think there are any studies of that.

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Rochelle Shoretz: Two questions have come up to the front about birth control, one with respect to a person taking birth control pills in particular when they're gene-positive and its relationship to ovarian cancer, if someone could address that. And then, in general, the interplay between birth control and Tamoxifen.

Dr. Gila Leiter: Oral contraceptives decrease the risk of ovarian cancer and that decreases by 50% and its effect will last for 10 to 15 years. It actually has the protective effect for a long time. There is no real data, although a suggestion is that it does decrease the risk, similarly in patients who are BRCA1 or BRCA2 positive.

Rochelle Shoretz: The second question was the relationship between Tamoxifen and birth control pills.

Dr. Gila Leiter: A patient who is on Tamoxifen would not be on birth control pills. There are other contraceptive devices that can be used, barrier methods. There's actually a recent study, this month, in the Journal of OB/GYN on using a progesterone IUD in breast cancer patients, which actually, at least the retrospective study shows, is not harmful. They actually studied it in Finland where every single breast cancer patient is registered. It's like a complete country study. But there are obviously other methods other than birth control pills for patients who are taking Tamoxifen.

Rochelle Shoretz: What about post-Tamoxifen, though, once their five years is up, going back on the pill?

Dr. Gila Leiter: The whole question of what about oral contraception in breast cancer – there seems to be a slight increased risk of breast cancer in current users of oral contraceptives. That's in young women it's been shown and it's the current use. In other words, once a couple years have gone by it's effective, but is no longer there. In fact, this is a very important question, because there are so many millions of women on oral contraceptives and there seems to be a slight increased risk in current use in young women. But no overall increased risk long-term. I think everybody would be quite reluctant, based on that, to advise a breast cancer patient to take oral contraceptives, because you wouldn't want to have that slight increased risk of breast cancer recurring. Maybe a select case in a young woman who maybe have had a very mild disease, but I can't imagine. And there are other effective contraceptives available.

Rochelle Shoretz: Shera, I'm going to share a question with you. The question is, "Given the desire for large families, is there data in the Orthodox community on breast cancer survival rates following multiple births after a primary diagnosis?" I'm fairly confident that the answer is no. Unfortunately, we're not a very well studied population, Jewish women with breast cancer, generally, and certainly the subset of Orthodox women with breast cancer. But maybe you

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could address some of the psychosocial issues that play into the Orthodox community, the Chassidic community, in which raising a family is a primary goal, and the impact of breast cancer on that part of one's life?

Shera Dubitsky: There is a cultural feeling among the Jewish and the Orthodox and certainly the Chassidic communities to have many children. For women who are not living up to that, there may be a feeling of lacking or feelings of shame. It could be particularly difficult for a woman in the community to be within a community where there happens to be large families. I also know that in Chassidic communities, the issue of having open discussions around breast cancer is very difficult because people worry about Shiducchim [arranged marriages] for their children and then it becomes a very private issue. Now you're leaving women open to speculation as to why they don't have larger families. And I think that a woman, again, is keenly aware of people wondering about what's going on with her and about fitting in the community and also keeping the breast cancer a private issue for her.

Dr. Ruth Oratz: Rochelle, I'd like to comment on that also. There is, because of information now about BRCA1 and BRCA2, about its abnormalities, a notion out there that if a young woman has breast cancer or if a woman has a family history of breast cancer - her mother, her sister, her aunt, her cousin had breast cancer - that she must have a genetic abnormality. That is, in fact, not true. Only 10 or 15% of breast cancers are associated with a definable genetic abnormality in the BRCA1 or BRCA2 genes. In Jewish women, that incidence may be a little bit higher. There may be other genes yet to be discovered that will be associated with the risk of breast cancer or other cancers or other illnesses. I think that as a community, we have to be very, very careful not to label one another. We learned a very good lesson with Tay-Sachs screening and I think that we learned that we can protect, to some extent, from marriages that might be at very high-risk for producing babies that would be very, very sick. But I think we have to be very, very careful not to extrapolate that to a woman who either has had breast cancer herself or has a family member who has had breast or ovarian cancer and presume that that woman is going to have cancer, or that she's going to have children who will have cancer, or that she would be an inappropriate match. I think that's very, very unfair and is not really based on the facts.

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VI. Symposium Conclusion

Rochelle Shoretz: As we wrap up this evening, please join me in thanking our speakers for generously sharing their time and expertise with us. I'd also like to thank our sponsors once again for bringing us all together: the Greater New York City Affiliate of the Susan G. Komen Breast Cancer Foundation and the Mount Sinai Medical Center. Thank you all again for joining us this evening to discuss hormones and breast cancer. A webcast of this event will be available for 90 days, so please let others know that they can still take part in this important symposium. A transcript of the event will appear on Sharsheret's website, www.sharsheret.org, in just a few weeks.

We look forward to continuing this important conversation with you in the years ahead.

Good night.

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Shera Dubitsky, M.Ed., M.A., is Sharsheret's Link Program Coordinator. Ms. Dubitsky served as a Psychology Resident and Fellow at the Bronx Psychiatric Center of the Albert Einstein School of Medicine and as an Associate Psychologist for the Jewish Board of Family and Children's Services. She has also worked as a researcher at Memorial Sloan-Kettering Cancer Center.

Dr. Gila Leiter is an Assistant Professor at the Mount Sinai School of Medicine and an Attending at the Mount Sinai Hospital. She maintains a private practice in New York City in obstetrics and gynecology. She is active in numerous professional societies and community boards. She is the author of *Everything You Need To Know To Have a Healthy Twin Pregnancy*, published by Random House, and has edited many books and articles on pregnancy and childbirth.

Dr. Ruth Oratz is Associate Professor of Clinical Medicine at the NYU School of Medicine. She specializes in treating women with breast cancer and other malignancies, and those at risk for cancer. Dr. Oratz is the Founder and Director of The Women's Oncology & Wellness Practice in New York City. She has been named one of "The Best Doctors in America" in *Redbook Magazine* and has been recognized among the best doctors in New York by *New York Magazine*. This year, Dr. Oratz was honored by Cancer*Care* as Physician of the Year. Dr. Oratz is especially committed to helping the woman with cancer continue to live her life actively and fully, placing significant attention on flexible treatment programs that comprehensively address a woman's personal needs, including career, family life, and sexuality.

Rochelle Shoretz, Executive Director, founded Sharsheret in November 2001 while undergoing chemotherapy treatment for breast cancer at the age of 28. She has been named a Woman to Watch by *Jewish Women Magazine* and a Yoplait Champion in the Fight Against Breast Cancer by Yoplait, *Self Magazine*, and the Susan G. Komen Breast Cancer Foundation. Ms. Shoretz has lectured across the country, addressing issues facing young women with breast cancer. She has appeared on the Today Show and CBS News, and in more than 100 articles published online and in newspapers, including the *Wall Street Journal* and *USA Today*.

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VIII. About Sharsheret

Sharsheret is a national not-for-profit organization linking young Jewish women in their fight against breast cancer. Sharsheret (Hebrew for chain) pairs young women facing breast cancer with volunteers who can share their experiences, both personal and medical.

Sharsheret's programs respond to the needs of the women we serve and include:

- **The Link Program**, a peer support network connecting young women newly diagnosed or at high risk of developing breast cancer with others who share similar diagnoses and experiences.

- **Education and Outreach Programs**, including health care symposia addressing the concerns of young women facing breast cancer. Recent events addressed the subjects of breast cancer and fertility, parenting through breast cancer, breast cancer genetics, and surviving breast cancer. Transcripts of all symposia are available on Sharsheret's website, www.sharsheret.org.

- **Quality of Life Programs**, including the Busy Box for young parents facing breast cancer, Best Face Forward to address the cosmetic side effects of treatment, and Embrace for young women living with advanced breast cancer.

For more information about participating in Sharsheret's programs, please call toll-free (866) 474-2774. All phone calls are confidential.

Sharsheret is grateful for the generous support of:

The Greater New York City Affiliate of the
Susan G. Komen Breast Cancer Foundation
and
Mount Sinai Medical Center

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IX. Disclaimer

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