

# Constellation

A Newsletter for All STAR Participants

Spring 2004  
Volume 4, Issue 1

STAR  
Study of Tamoxifen  
And Raloxifene



## Turning Despair into Hope A Mother's Commitment to Her Daughters and Greatest Heroes

Photo from Left to Right:  
Judy, Betty, and Denise

My name is Betty Berra and I am a 68-year-old mother of five wonderful children. I have three sons and two daughters. Between my five children, I have sixteen grandchildren. Birthdays and holidays are very special times in the Berra household. A very close knit family, my husband and I have always felt so blessed.

The year 1997 started out great. Being busy in January, putting away all the holiday decorations, remembering all the treasured moments, and joy shared with my family. Making plans to Christmas shop for the coming year's holiday—with such a large family you could never start shopping too early. January flew by in a flash.

February was here, and I had spoken early in the month with my oldest daughter Denise. She had found another lump in her breast and was going on Friday to have a biopsy. She had gone through this several times before and everything always turned out fine. The following Monday we were set to celebrate her son's 14th birthday. I baked my grandson's birthday cake, and the family would be over at 7:30 p.m. for cake and ice cream.

When Denise and Dave and their three kids arrived, I could tell immediately that something was wrong. Everyone seemed quiet. We sat in the family room and talked for a little while, I didn't want to intrude or ask anyone what was wrong because we were celebrating a birthday. I asked who was ready for some cake and ice cream, and no one answered. There was nothing but silence. Denise then said quietly, in her calmest of voices, "I have something to tell you and Dad." She began to talk, "The biopsy I had on Friday came back and I have breast cancer." I could not speak. I just froze. My husband asked, "Are they sure?" And Denise responded, "Yes." I wanted to cry. I know my heart stopped beating for a few seconds. I could not find the words. The emotions that ran through my body at that exact moment were immense. I looked at my oldest daughter, just 39 years old, and all I wanted to do was hold her in my arms. I wanted to tell her that everything would be fine and that her mommy would fix this and make it better. As a mother, no matter how old your daughter is, in a time of need she is always your little girl. At that exact moment, I prayed that God would let me take her place. Denise began to tell us what her treatment options and course would be. We all cried, Denise, myself,

her husband, her children, and the person who was known best for holding himself together in the most difficult times, her father. We all held each other tightly and knew we would have to have faith. And also give Denise all the support she would need and to pray many, many prayers that God willing, she would be okay.

I had always been proud of my oldest daughter Denise. We were employed at the same place, so needless to say we spent a lot of time with each other. I felt fortunate, that we had a relationship that was not just mother-daughter, but we are colleagues as well. Denise is a beautiful woman inside and out. Intelligent, funny, athletic, a wonderful mother and wife. She had accomplished so much in her short life and always accepted setbacks with great optimism and courage. This day was no different. I know her heart ached with such pain with the news that she had breast cancer, but never did she become despondent or ask openly, "Why me?" She committed herself from day one to accept and move forward with her diagnosis. She retrieved all the knowledge she could about breast cancer, and educated not only herself but also everyone she knew. The choices she would make in the all to near future would be her own and the best for her personal battle. I have never been so proud to be her mother.

Denise chose to have a lumpectomy first, with the hope that the cancer was confined within the lump. We all waited patiently, for the results. Another setback, the cancer was outside the margins. Denise then chose to have the mastectomy. Throughout this whole ordeal, I did what every mother would do. I gave my daughter support, provided encouragement, and made arrangements to keep the household chores and daily lives of her three children and husband intact. And showed her love without hesitation. Denise's diagnosis affected the whole family, my four other children, their spouses, and my grandchildren. Everyone was so scared for her. The news was especially hard on my other daughter Judy, Denise's only sister.

As Denise went through her surgeries, Judy was right there beside her. Only one year younger, Judy had always looked up to Denise in admiration.

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## In Her Own Words

My name is Sheryl Jones and I live in Arvada, Colorado, a suburb northwest of Denver about half way to Boulder. I'm a retired school teacher and love being retired. Probably because Don, my husband of 45 years, is also a retired teacher and we have the best time together. In fact, as I am writing this, we will be leaving in a little while to go to our oldest grandson's (we have four) roller hockey game. He's made goals the last two games so we hope he's "on" tonight. In March, we went to Florida for a week on the beach and to visit with friends; did some research and sightseeing in eastern Tennessee; stopped over in Murfreesboro, Tenn. to visit some more friends; spent a few days in Kansas helping Don's mother with a few things; and came home in time for Easter. It's a tough life, but someone has to do it.

I joined STAR in March 2003 because of an article by Mary Winter, who writes the weekly column "Right at Home" for the Saturday installment of the Rocky Mountain News. It's the first thing I read in the paper! Sometimes her column is funny, sometimes thoughtful, but always interesting. Mary interviewed Marti Bauman and Robin Bradley about the STAR trial at the CCOP, Colorado Cancer Research Program in Denver.

My mother was a breast cancer survivor and I thought that being a part of STAR would be worthwhile. It would be a way that I could contribute to the women who will come after me.

I wrote to Mary and told her how much I always enjoy her column and that I was participating in STAR. I remember telling her how little we know about how each of us affects others and by writing that column she might save someone down the line from breast cancer.

That following May, I went to the STAR brunch. It was the first time I had been at a gathering for STAR participants. I was greatly affected by the many women who were in STAR. Most had lost a mother, a sister, an aunt, a daughter, a much loved someone to breast cancer. A few days later I wrote this poem and dedicate it to my mother, Nadean Chambers, my aunt, Ester Remington, and to all the STAR participants.

### Center Stage

By Sheryl Jones, May 2003



There you are, every day,  
The foot lights are on, the spot follows,  
And there you stand—  
Center Stage.

Here is your fifteen minutes of fame,  
Well, fifteen seconds or so,  
But every day the same—  
Center Stage.

Who put that blue gel on the spot?  
Change it please to the rosy pink one,  
So you'll look better—  
Center Stage

There you stand, courage ready,  
Pills in one hand, glass in the other,  
Ready to drink to the future—  
Center Stage.

Some have one, some have two,  
One is false, one is true,  
But you swallow both down—  
Center Stage

Do you hear that whisper?  
On wings from the past it comes,  
From aunts and mothers gone before—  
Center Stage

From sisters and grandmothers,  
From great aunts and great grandmothers,  
Words of love to encourage you on—  
Center Stage

But wait, another sound comes wafting up  
From the audience you can't see,  
Applause from the future to you there on—  
Center Stage

From daughters and sisters and cousins, too,  
From granddaughters, great neices, just for you  
Applauding, your courage, your commitment for—  
Center Stage.

Because you stand stage center now,  
Maybe they won't ever have to be  
In that same spotlight—  
Center Stage.

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22,000  
19,000

Sample size reduced to 19,000 women (May 2003).

STAR should reach 19,000 women by July 2004. Follow-up phase continues.

**YOU ARE HERE...**  
18,582 women enrolled in STAR as of May 4, 2004.

**June 30, 2003  
Happy 4th  
Birthday STAR!**  
As of this date, 16,359 women enrolled in STAR and 158,896 women had their breast cancer risk assessed.

**June 30, 2002  
Happy 3rd  
Birthday STAR!**  
As of this date, 13,647 women enrolled in STAR and 118,797 women had their breast cancer risk assessed.

**June 30, 2001  
Happy 2nd  
Birthday STAR!**  
As of this date, 10,473 women enrolled in STAR and 89,838 women had their breast cancer risk assessed.

**June 30, 2000  
Happy 1st  
Birthday STAR!**  
As of this date, 6,136 women enrolled in STAR and more than 47,000 women had their breast cancer risk assessed.

**July 1, 1999  
Enrollment to  
STAR Began**

11,000

5,500

2,750



## What Happens **After** Five Years of STAR?

*D.L. Wickerham*

D.L. Wickerham, MD  
STAR Protocol Officer & NSABP Associate Chairman

In July 2004, women who entered the STAR trial in 1999 will begin to reach their 5-year anniversary. At the 5-year mark, these women will stop their protocol drug, but their participation in STAR will continue and is more important now more than ever.

Some STAR participants think that when they stop their protocol drug, they stop being a part of STAR. This is not true! Every STAR participant, even those women stopping their study drug, is vital to the evaluation of whether raloxifene is as good or better than tamoxifen in the prevention of breast cancer.

### WHAT WILL CHANGE WHEN I STOP MY STUDY DRUG?

Not much will change at this point. You will continue to get an annual mammogram, gynecological examination, and breast examination. However, you will no longer be required to have a 6-month breast examination. Each STAR participant and her doctor will discuss her own specific circumstances and may decide to continue the 6-month breast examination even though it will no longer be a requirement of the STAR study. Annual blood work will also stop after you stop your protocol drug at the 5-year mark.

### WHY SHOULD I STOP TAKING TAMOXIFEN OR RALOXIFENE AFTER 5 YEARS?

It is common to feel uneasy about stopping the protocol drug. If breast cancer has not occurred while on the protocol drug, then why stop taking it? Why fool around with success? It has been our experience in treating women with breast cancer with tamoxifen, that the maximum benefit from the drug occurs with 5 years of treatment. Continuing tamoxifen beyond 5 years does not show any further benefit, but it can be harmful and costly. More importantly, the benefits don't stop with the last pill.

We know through other NSABP studies that patients who took their initial dose of tamoxifen for 5 years continue to show benefit for at least 15 years after they stop taking the drug. We have every reason to believe that these benefits will last a lifetime. However, for healthy women taking tamoxifen for the prevention of breast cancer, we have less long-term follow-up data, but we do expect similar long-term benefits.

Raloxifene's long-term benefits are not as well known and therefore limited. For this reason that we chose to use raloxifene for only 5 years until more information becomes available.

### WHEN WILL I KNOW WHAT DRUG I WAS TAKING WHILE ON STAR?

STAR is a "double-blind study." This means that neither the participant nor her doctor will know which drug she is on. The trial is designed this way so that all participants receive the same level of care, follow-up, and reporting. By doing so, the results of the trial are not influenced by the knowledge of drug assignment, and any differences can be attributed only to the drug and not other factors. Even though a participant stops her drug at five years, the follow-up continues so it is important that drug assignment remains unknown until the results of the study are determined. At that time, all STAR participants will be told whether they took tamoxifen or raloxifene.

In a medical emergency, if it becomes necessary for your doctors to know which drug you were taking, that information is always readily available through the NSABP Biostatistical Center.

When the results of the STAR trial are available, it is our intention to inform you first through correspondence from your STAR physician and coordinator, not the media. At the same time, you will be told which drug you were taking and future options for your care will be discussed. What those options entail will depend on the results of the trial.

### WHAT SHOULD I DO AFTER I STOP MY PROTOCOL DRUG TO REDUCE MY CHANCE OF DEVELOPING BREAST CANCER?

It is very important to you and the STAR trial to continue your regular follow-up examinations at your STAR site. There is no other sure strategy or treatment known to be effective in breast cancer prevention, short of prophylactic mastectomy (the surgical removal of the breast to prevent disease). Such a strategy is a drastic and an irrevocable choice. The goal of the STAR trial is to identify effective options to prevent breast cancer without resorting to surgery. You are helping us find the answer to this question.

### WHAT CAN I DO TO PREVENT BONE LOSS AFTER I STOP MY STUDY DRUG?

Tamoxifen and raloxifene both benefit bone strength. When you discontinue these drugs, that protection is removed and it will be important that you are receiving the recommended daily amounts of calcium and vitamin D. For postmenopausal women 1500 IU (international units) per day of calcium and 400-800 IU per day of vitamin D is adequate. Many dairy foods including milk, cheese, yogurt, etc. are high in calcium, but it is better to obtain calcium from low-fat dairy products when possible. Many foods also have calcium added, including breads and fruit juices.

If you cannot get adequate calcium or vitamin D from your diet, many supplements are available without prescription. A frequent question is, what is the best calcium supplement (i.e. Coral Calcium, Calcium Citrate or Carbonate, etc.)? In most cases, as long as it has the recommended dosage, the cheapest calcium supplement is just as good and effective as an expensive supplement.

Depending on your specific circumstances, your doctor may want to evaluate your bone density (a measure of bone strength). This is a simple and easy examination. The best measure of bone density is done using a dual-energy x-ray absorptometry (DEXA). If your bone density shows osteoporosis or osteopenia (thinning of the bones), you may need to consider a prescription drug in addition to taking calcium and vitamin D.

There are numerous medications available to help maintain bone strength and the most common are bisphosphonates. The best known bisphosphonate is Fosamax, which is a pill that can be taken daily or once a week. As a STAR participant, we recommend that you not take raloxifene (Evista®) because you may have

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## Co-STAR, WHI & Women's Cognitive Health:



Pauline M. Maki, PhD

### *The Pressing Need for Pharmacotherapies in an Aging Population*

The following is an excerpt from a talk given by Pauline Maki, PhD, from the University of Illinois at Chicago, at the STAR Workshop held in Huntington Beach, CA at the 2003 NSABP Fall Meeting.

With the prevalence of Alzheimer's disease (AD) increasing, and the fact that in 2001 the death rate for women was two and a half times higher than for men, there is a pressing need for information about factors that might increase or decrease a woman's risk of getting AD.

Research studies indicate that the female hormones, estrogen and progesterone, influence cognition and brain aging. For example, the Women's Health Initiative Memory Study (WHIMS) reported that older women who initiate a popular form of hormone therapy (Prempro; conjugated equine estrogen and medroxyprogesterone acetate) are at increased risk for developing dementia. That finding raises an important concern – how do other drugs with estrogen-like properties affect brain function?

Selective estrogen receptor modulators (SERMs) such as tamoxifen and raloxifene act like estrogen in some tissues and act like anti-estrogens in other body tissues. Their effects on the brain are poorly understood. When a healthy woman uses raloxifene or tamoxifen to prevent breast cancer, does it affect her risk for cognitive decline? Do raloxifene and tamoxifen have the same effect on cognitive aging? How do they compare to hormone therapy when looking at cognitive outcomes?

Researchers at the National Institute on Aging, Wake Forest University School of Medicine (WFUSM), and the NSABP worked together to develop Co-STAR to address these critically important questions. Co-STAR builds on the unrivaled success of the NSABP in carrying out clinical trials on breast cancer prevention.

The success of Co-STAR depends on STAR personnel and their exceptional skills and experience in addressing important questions in women's health. This effort to advance research on women's cognitive health amplifies the clinical significance of STAR.

Women face difficult decisions about therapies to treat menopausal symptoms, prevent osteoporosis, and prevent cancer. Co-STAR offers a unique opportunity to help women make decisions that will help maintain their cognitive health as they age. There is no other research study in progress or planned that can answer these critical questions. **As the population ages, the need for advances in cognitive therapies cannot be overstated.**

## Reflections From Inside a Clinical Trial

**Reflections...** was submitted by Ailsa Craig of Calgary, Alberta, Canada, a STAR and Co-STAR participant at the Tom Baker Cancer Centre. She has given permission for the NSABP to print this article in *Constellation*. The thoughts are her own and we thank her for sharing them with all of us. If you would like to share your experiences "from inside a clinical trial," please send them to the NSABP (*address available on back page*) and you too may see your story highlighted in an upcoming issue of *Constellation*.

I first heard about the first Breast Cancer Prevention Trial (BCPT) twelve and a half years ago and decided that it was for me. I was interested in the research and felt it was my way to repay society for the good things and good health in my life.



**Doing well on the memory test gave a real boost to my confidence and esteem.**

I was the first participant from the Tom Baker Cancer Centre in Calgary, Alberta, Canada to enroll in the trial. The original study gave you a 50-50 chance of being on tamoxifen or a placebo, and I didn't know which drug I was taking. The research results were determined earlier than expected and we participants learned what we had been taking. I found out that I had been on a placebo. However, that fact did not take away from the significant contribution I made.

Four years ago in 2000, I learned about the Study of Tamoxifen and Raloxifene (STAR) trial. I found out that I could participate in STAR since I was on placebo in the BCPT and never took an active drug. In STAR, I learned that I would be assigned to either raloxifene or tamoxifen and I would not be told what drug I was taking. I was eager to enter the STAR trial to continue helping the team with their research.

In Fall 2003 Anita Hades, RN, the STAR contact person at Tom Baker Cancer Centre, sent me information on the Co-STAR study. This study will determine what effects, if any, raloxifene and tamoxifen have on memory and cognition.

Through my volunteer and work activities, I associate with elderly people. Some definitely have memory loss. When an elderly person forgets something—keys or an appointment—the younger people viewing this seem to tighten their lips, and in de sotto voice say, "she's forgetting so much, she's slipping you know." However, when a younger person forgets the same things, there's a great burst of hilarity and

comments such as, "you're having a senior moment," without regard for the ageism in the comment.

Memory has always been a worry for a great many people, myself included, so when Anita explained the Co-STAR study, I signed right up. I was excited about the study, and Anita arranged for me to be tested in Calgary by Vickie and Julia, two Co-STAR technicians from the Co-STAR Central Coordinating Center (CCC) at Wake Forest University Medical Center in Winston-Salem, North Carolina. Having been in research programs for about twelve years, I enrolled with little or no trepidation.

The memory portion of the Co-STAR test battery took about an hour and a half and was really interesting. The last test I had taken was my driver's test in 1973 so I felt a bit out of practice! I had some anxiety going in. However, I realized during the testing that I wasn't doing too badly. While it took a lot of energy to participate in the test, it was fun to see how much I could remember—how well I could listen and organize my thoughts. Doing well on a memory test gave a real boost to my confidence and esteem.

I hope that before my life is over, cures for breast cancer and Alzheimer's disease can be found. It feels wonderful knowing that in some small way I've contributed to these worthy goals. **My daughters and granddaughters are very proud of my participation and they are of an age where they might benefit from the research results.**

*If you would like to participate in the Co-STAR study, please contact your STAR Coordinator or the Co-STAR CCC at (866) 716-9094.*

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## Turning Despair into Hope

Seeing her older sister go through this nightmare made Judy become the strong sister. It was a reversal of roles. Judy cared for Denise's children, made meals for the family, and consoled her heartbroken brother-in-law. I was so proud of Judy. The courage shown by Judy amazed me, because I know inside she was petrified for her sister.

After her mastectomy, Denise went on to get four treatments of chemotherapy at three-week intervals. I remember at the first treatment, she was so scared she nearly passed out. She watched the chemotherapy travel through her veins, the red color traveling up her arm. The treatments made her weak and nauseous. A few weeks went by and her hair began to fall out. Denise asked her husband to shave her head. She went and got fitted for a wig, but never wore it. By now it was mid-May and the weather was warm. The wig was too warm to wear, so she would just put on a hat or scarf. Once summer hit, she had a nice tone on her bald head so she wore nothing. She looked so beautiful.

After completing her treatments, by September, her hair began to grow back. It was not the same straight light brown-blondish hair she used to have. Denise's hair was coming in black and curly—another very minor adjustment. Denise was new. The cancer had indeed changed her.

The seasons changed and so did my daughter. Thanksgiving would be emotional. There was so much to be thankful for, so much to hope for. Denise had routine monthly checkups with the oncologist. And, would have to remain cancer free for a year before she could undergo reconstructive surgery. My family was relishing life and everything it had to offer. We would all be together to celebrate Christmas 1997 and hoped that 1998 would be much better.

1998 was nearing the end and I was preparing for the upcoming holidays with all my children, their spouses, and my grandchildren coming over for Christmas. Every one was healthy, Denise had gotten through the year with no setbacks and she was doing great. I finally felt that I didn't have to worry about her. We would soon all be together to celebrate this joyous season and give thanks to God for all of our many blessings.

It was the first week of December and I was at work. I had gone outside to drop some letters in the mailbox when I heard a familiar voice say, "Hey Betty!" I looked behind to see my youngest daughter Judy—she likes to call me Betty. I thought she was going to have lunch with Denise and I, but she immediately started crying. I grabbed her and she was shaking uncontrollably. Her teeth were chattering and she could not talk. I took her to Denise's office. We both were asking, "What's wrong?" After a few minutes we got Judy calmed down enough that she could talk. She told us that she almost wasn't able to drive herself over. Judy then told us both that her doctor had called her at work and said her mammogram results looked bad and she needed to get a biopsy. I fell into a chair and began to cry immediately. Judy started crying and shaking again. My mind simply ran rampant. I could not believe or accept the possibility that Judy could have breast cancer too. After we all calmed down, we realized that nothing was certain until the biopsy was done and the results came back. Denise quickly took control and said, "Let's not get all worked up over the unknown."

One week later we knew, my younger daughter, Judy had breast cancer. Judy was 38 years old. Her father, once again, could not hold back the tears of pain for his daughter. Those same emotions I felt with Denise flooded my mind. Dear God, how could You put a mother through this nightmare twice. I felt lost and empty. But I quickly turned my despair into hope. I had learned so much in this past year about the disease. I knew Judy's cancer had been detected early and she was lucky in a strange sort of way to have had a sister who had already gone through what was now her destiny. I prayed for Judy and in my prayers I gave thanks. As bad as the news was I knew what lay ahead. And I knew Judy, like her sister Denise before her, could make it through this. I never lost hope with Denise and I would not lose hope with Judy.

Christmas that year was even more special and filled with great emotion. The love of family and friends surrounded us. It was a beautiful holiday—somewhat surreal. We would again draw strength and faith from each other. I would say many, many prayers for both Judy and Denise now. And Judy would now have to make choices on how to battle her cancer. I would not bring in the New Year of 1999 with my usual zest, but I was determined to welcome it with continued hope.

In January of 1999, Judy would undergo a lumpectomy, but she too ended up needing a mastectomy. Her big sister was there for her every step of the way just as when they were little. Judy looked to Denise for both guidance and affirmation in all of her decisions. Denise would let Judy know that everything would be okay and even if there were setbacks there were many more options for women facing breast cancer today. Denise consoled Judy's husband Tom. And again, we as a family along with many caring friends held Judy's household together and helped care for her young children. Tom had quite a difficult time explaining to their kids that mommy has cancer. They couldn't understand. He had to reassure them that cancer does not mean death. We were fortunate that Judy's type of breast cancer would not require any follow up chemotherapy or radiation. After healing from her mastectomy, Judy would be able to have reconstructive surgery three months later.

On January 20, 1999 my daughter Denise celebrated her 40<sup>th</sup> birthday, two days later on January 22, Judy turned 39. In April of 1999, both of my daughters underwent reconstructive surgery. Their father, concerned about another surgery, told both his girls that, "A piece of skin does not a woman make." They both felt that the reconstructive surgery would in some way make them feel whole again. The surgeries went well.

No one could have ever prepared me for what would happen in my family within 22 months time, that my two daughters under the age of 40 would both be diagnosed with breast cancer. I would see the fear in their faces when they went for a monthly checkup. I would see the joy gleaming from their eyes when all the news was good. I would listen, as my husband would pick up the phone now on a weekly basis to call his girls, just to talk and comfort them—and himself. My three sons were there for their sisters not really knowing what to do. Giving the both of them the needed pep talks when spirits were low. I watched as these two courageous women faced cancer head on. I was so proud of them. They are my greatest heroes.

In 2002, Denise had been cancer free for five years and Judy for nearly three. They have fought and continue to fight their toughest battle. Each passing year is a victory. As I have watched them fight, I have prayed for them to God, Saint Theresa, and to The Mother of Perpetual Help, which I know has helped them and myself through the worst time of my life. I am committed to help fight this battle against breast cancer. I want to be a soldier for them.

I was selected to participate in STAR at St. John's Mercy Hospital in St. Louis, Missouri, because I am at increased risk for developing breast cancer. I joined without hesitation. I am in my third year of this trial and though there are times when it is difficult—since I cannot take medications for my severe hot flashes—I know that my little bit of suffering and sacrificing is minimal. It does not compare to the pain, agony, and fear my daughters have gone through. It is my hope that STAR will bring with it advancements in the prevention of breast cancer and hope for the next generation. As four of my sixteen grandchildren are girls, I hope my small part will someday make a difference. In addition to STAR, my entire family (husband, daughters, sons, sons-in-law, daughters-in-law, and grandchildren) participates each year in the Susan G. Komen Breast Cancer Foundation's Race for the Cure. **I will continue to do my part for the fight against breast cancer, because I want to see the finish line!**



**Judy & Denise celebrate their birthdays in January 2003.**

**We wish you many more!**

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## What Happens After Five Years of STAR?

already been on this drug in the STAR trial. Tamoxifen and raloxifene are very similar chemically and if you have developed osteoporosis or osteopenia while on STAR, it may be better to take an alternative medication such as a bisphosphonate to treat these conditions. Remember, too much of a good thing is often not very good at all and taking additional tamoxifen or raloxifene for bone may do more harm than good.

### ARE THERE THINGS THAT I SHOULD NOT DO AFTER 5 YEARS OF PROTOCOL DRUG?

There are no other formal restrictions that are part of STAR. While participating in STAR you were asked to avoid hormone replacement therapy (HRT) or estrogen replacement therapy (ERT) (i.e. Premarin, Prempro, etc.). We do not recommend that you start these drugs now, although it is okay to use low-estrogen products such as, Estrin® or Vagifem® to reduce vaginal symptoms. These products result in very little absorption of estrogen into the blood stream, but are effective in controlling vaginal dryness.

Recent results from the Women's Health Initiative (WHI) study have shown that hormone or estrogen replacement therapy has no benefit in cardiovascular disease, stroke, or memory. WHI also showed an increase in breast cancers among women taking estrogen and progestin (Prempro). If your doctor recommends HRT or ERT, ask why and whether or not a non-hormonal therapy is available. An alternative treatment may be better.

Both tamoxifen and raloxifene reduce cholesterol levels. Your doctors may wish to check your cholesterol levels several months after you have stopped your protocol drug. If your cholesterol levels are elevated, your doctors may recommend treatment. Maintaining or lowering your weight through a low-fat diet and exercise is healthy advice for anyone, but at the moment it is not known to reduce your risk of breast cancer.

### IN SUMMARY

In the STAR trial at 5 years, protocol therapy will be discontinued, but your protocol participation does not. Your STAR doctors and coordinators will continue to follow you and answer your questions and in working together, allow the successful completion of the study in as rapid a time as possible. This will allow us to provide answers that would benefit you and thousands of other women just like yourself.

**Thank you for your participation.**

## Constellation

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