

Yale CANCER CENTER *answers*

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Yale Cancer Center Answers is
a weekly broadcast on **WNPR**
Connecticut Public Radio
Sunday evenings at 6:00 PM.

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Welcome to Yale Cancer Center Answers with your hosts doctors Francine Foss, Anees Chagpar and Steven Gore. Dr. Foss is a Professor of Medicine in the Section of Medical Oncology at Yale Cancer Center. Dr. Chagpar is Associate Professor of Surgical Oncology and Director of the Breast Center at Smilow Cancer Hospital and Dr. Gore is Director of Hematological Malignancies at Smilow. Yale Cancer Center Answers features weekly conversations about the research diagnosis and treatment of cancer and if you would like to join the conversation, you can submit questions and comments to canceranswers@yale.edu or you can leave a voicemail message at 888-234-4YCC. This week you will hear a conversation about chemoprevention and breast cancer with Dr. Erin Hofstatter. Dr. Hofstatter is Assistant Professor of Medicine and Medical Oncology and Co-Director of the Genetic Counseling Program at Yale School of Medicine. Here is Dr. Steven Gore.

Gore Let us start off by defining the complicated word chemoprevention. What is that all about?

Hofstatter My clinical and research interest falls into prevention of breast cancer. One of the ways that we can prevent breast cancer is by using medications and unfortunately, it has gotten this horrible name, chemoprevention, I think that scares off a lot of people but really what it is referring to is medications that healthy women can take to reduce their risk.

Gore Is this something that all women should be taking to prevent breast cancer?

Hofstatter That is a great question. When these medications were originally studied back in the 1990s, their original design was that primary care physicians and gynecologists, at the phase of primary care, would be prescribing these to women at increased risk, those with a family history, those with biopsies of the breast that show atypical cells, but also being over the age of 60 was enough to qualify for these trials. So a lot more women qualify to take these medications than actually take them.

Gore I see, so maybe we should take a step back and talk about which patients should be considered to be at higher risk than average. And even before that, what percentage of women get breast cancer?

Hofstatter About one in eight women in the United States is diagnosed with breast cancer at some point during their lifetime. If you include DCIS, or ductal carcinoma in situ, one of the earliest forms of breast cancer, it is about one in six. So it is very common. In fact, it is the most common cancer in women diagnosed each year.

Gore And are we able to pick out a group that is at even higher risk than that?

Hofstatter Yes, definitely. Many people are surprised to hear that age is actually the strongest risk factor for breast cancer. We all know that cancer is a disease of older people, but aside from just aging, being found to carry a genetic mutation such as BRCA 1 and 2 certainly carries much higher risk of breast cancer, having a biopsy with atypical cells in the breast, commonly heard as atypical

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ductal hyperplasia is found commonly enough that it would be considered high risk. Those with a strong family history also are considered at high risk.

Gore If I were a woman of a certain age, whatever age that might be, should I be worrying about being screened, how do I even get my head around that?

Hofstatter Yeah absolutely.

Gore Let us say I have an aunt who had breast cancer, otherwise, not much of a family history.

Hofstatter Family history is complicated. I am glad that you ask that, because having an aunt, for example, with breast cancer, it depends on a lot of things, how old was that person when she got breast cancer? Certainly, a woman who is diagnosed with breast cancer pre-menopausal or before the age of 50 is a bit of a red flag from her family history, but if your aunt was diagnosed at 85, that is not so alarming, but any family history counts, and it is important for listeners to realize that family history includes both the mom's side of the family as well as the father's side of the family. Breast cancer heritability, or your chances of being at increased risk, it matters on both sides.

Gore How distant a relative is significant, a great aunt, a great, great aunt, a third cousin, twice removed?

Hofstatter The family history that we worry most about tends to be what we call first or second-degree relatives, so immediate family members, mom, sisters, daughters, but grandmothers, aunts, and even cousins are important to know about, particularly if there a breast cancer gene running through the family, if it is inherited through your father, sometimes, generations can appear to be skipped.

Gore Interesting. What about things like the age of puberty and whether people breastfed or not? I seem to remember from my medical school days that we used to talk about that stuff.

Hofstatter The list of risk factors for breast cancer is quite long, but each risk factor, I would say has a different significance or different strength, so certainly family history, having a gene mutation has probably the strongest risk, along with the atypical cells we mentioned before, but certainly, any risk factor that pertains to how much estrogen you have been exposed to over your lifetime counts as well. So having early onset of your period, going through menopause late, taking combined hormone replacement therapy, having your children above the age of 30, and it does not sound old, above the age of 30.

Gore Not any more.

Hofstatter Yeah, so some of these risk factors that pertain to estrogen count as well, but they are not nearly as strong as just simply aging or having a strong family history.

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Gore What about things like smoking?

Hofstatter Good question. Smoking is debatable, but we do believe there is evidence. It is not long until we officially say that smoking is a risk factor, but alcohol use, more than one serving of alcohol per day for women does appear to increase the risk.

Gore Wasn't there something about red wine protecting against cancer, or am I making that up?

Hofstatter That I would say is debatable.

Gore But if you like red wine?

Hofstatter For your heart, it will be good, but I think in general, we try and limit servings to seven or less per week as the general recommendation.

Gore And how about obesity?

Hofstatter Yes, definitely, that was one thing I wanted to make sure the audience was aware of, that lifestyle matters, so in general whether you choose to take the medication or not, we uniformly say limit your alcohol, do not smoke, but definitely diet and exercise are very important to achieve a healthy weight, and definitely can reduce the risk both in breast cancer survivors as well as healthy women.

Gore Let's say I am 38 or 40 years old, there is one aunt or maybe a couple of people here and there in my family history, should I be getting mammograms? When should people start getting mammograms? I guess the recommendations have changed for mammograms recently?

Hofstatter If you look around at the various guidelines for primary care and OB/GYN and oncology, you will probably come across 12 or 13 different sets of guidelines about it.

Gore So it can be confusing.

Hofstatter It is very confusing. What I recommend, and I am obviously biased as I have an oncology background and this is a complicated issue, but the American Cancer Society and the American College of Radiology uniformly say to start mammograms annually at the age of 40 and to start earlier if there is cancer that is diagnosed earlier in the family. And we typically start 5 to 10 years prior to the age of onset in that family member.

Gore And so annually at age 40 and then continue annually? Does it ever go to every other year?

Hofstatter The US Preventative Task Force, if you recall the mammogram debates of 2010 and 2011, the US Preventative Task Force was recommending every other year and I do think that there are a subset

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of women out there where that may be most appropriate to start at 50 and do every other year, but I would say that those are the women who have no family history, are a healthy weight, and have a healthy lifestyle, but I think that it is still debatable and I cannot say that we are very skilled at picking out yet who truly is at lowest risk, so my recommendation to my patients is once a year, starting at age 40 and typically continuing up until a person's life expectancy falls under 10 years. That is very vague, is that 75 or 80.

Gore And do you want to tell yours patients that is the case? Right now your time is ticking.

Hofstatter It is a difficult conversation, so clearly there is more to life than age and I have got lots of vibrant 80 year olds and some not so vibrant, so I think it depends on the patient, and I think that is really the name of the game. Any recommendations for screening, prevention, really need to be tailored to the individual.

Gore Is there any problem with reimbursement for yearly mammograms given some of these guidelines?

Hofstatter No, I have not run into that. I think where the mammogram debate is evolving is in the use of adjunct ultrasound that is starting in Connecticut, and the whole issue about dense breast tissue, basically meaning that the mammogram looks white, glands show up as white on mammogram, and so it is mandated in the state of Connecticut that if a woman has dense breast tissue that it be reported out on the mammogram report and that has prompted a lot of questions both for providers and patients as to whether or not we should be getting ultrasound and MRI in addition to a mammogram to make sure that we are catching every cancer that we can. Insurance right now in the state of Connecticut is mandated to cover ultrasound, but that is not true in the rest of the country, so that is where a lot of the screening debate is going.

Gore Is the mandate to put this on the report national?

Hofstatter Not yet, but it is certainly growing. It started in Connecticut through the 'Are You Dense' movement which was started by a woman here in Connecticut, but that has spread nationwide. It is not a mandate in every state, but it would not surprise me if that is the case within a few years.

Gore And is that because the dense mammograms are hard to interpret or because those individuals are at higher risk innately of breast cancer?

Hofstatter Both. Cancer often shows up as little white flecks if you will, of calcium, but if you are looking for a white cancer on a white background of a dense mammogram, it is difficult to find. So in part it is the ability to interpret that mammogram, but there is data to say that those women with very dense breasts, extremely dense for an unknown reason, do appear to be at increased risk of breast cancer as well.

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Gore It is interesting. A very dear friend of my wife's and mine around our age, mid 50s, had a long history, years of very dense breasts and cystic breasts and had excellent care with lots and lots of biopsies and then presented with a back fracture or spinal fracture which was metastatic breast cancer, despite really exquisite care.

Hofstatter Yeah, that is unfortunate.

Gore She is doing well fortunately.

Hofstatter That is great. I think it is very common. I mean, many of us know someone affected with breast cancer, it is common.

Gore Let's say the person has one or more of these risk factors and they come to you, Dr. Hofstatter, and say, I heard that there are these chemopreventive drugs, I am really scared of breast cancer, and should I take them?

Hofstatter When I meet somebody for the first time who is concerned about their risk of breast cancer, it is important to get a thorough history, understanding what all of their risk factors are, particularly including their family history because I think an important thing from a prevention standpoint is finding those women with genetic mutation such as BRCA 1 and 2.

Gore And people sometimes call it BRACCA, correct?

Hofstatter Many people call it that BRA-CA or BRCA 1 and 2. They certainly comprise only a very small fraction of all breast cancers and in the general population only one in about 400 people carry a gene mutation, it is a little bit higher in the Ashkenazi Jewish population, but I think when I first meet someone, I first want to say, what is going on in your family, let us make sure there is nothing going on there. If there is a red flag such as early age of breast cancer diagnosis in the family or multiple people with breast or ovarian cancer, pancreatic cancer in the family, the first step is to go ahead and send them for genetic counseling and testing to make sure that we rule everything out, but most people do not have red flags in their family, so the next step is to really look at some of the risk factors and say, okay, is your risk high enough that it merits taking a medication to reduce your risk, and I do not know that there is an exact percentage for who qualifies and who does not but far many more women qualify to take the medications than actually do at the end of the day.

Gore What kind of risk reduction is provided by these medications?

Hofstatter It has been shown to reduce the risk by about half, so 50% reduction in risk. For example, if I am meeting with a woman and her risk over the next five years is estimated to be let us say 8%, by taking these medications one pill a day for five years, I can reduce her risk by half or make it 4%, so again, I think it depends on how you interpret risk.

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- Gore That does not sound like such a great improvement to me.
- Hofstatter Exactly.
- Gore I do not know that if I were hearing that as a patient, a medication, I mean 8% does not sound very high. Of course if I am in the 8%, it is extremely high.
- Hofstatter Exactly, and that is what I mean by we are not that great in picking out if this woman sitting in front of me, is definitely going to get cancer or definitely not.
- Gore Right.
- Hofstatter So one approach would be that we should be targeting many women to take these medications knowing that if we are not sure which ones are going to go on to get breast cancer, if we cast a broad net, we would be more likely to actually help those women who truly are at risk in the future.
- Gore I am going to want to pick up this conversation which is really fascinating and very challenging after our break. We are going to take a short break for a medical minute. Please stay tuned to learn more information about chemoprevention and breast cancer with Dr. Erin Hofstatter.

Medical

Minute The American Cancer Society estimates that in 2014 there will be over 75,000 new cases of melanoma in this country with over 1000 of these patients living in Connecticut. While melanoma accounts for only about 4% of skin cancer cases, it causes the most skin cancer deaths. Early detection is the key and when detected early, melanoma is easily treated and highly curable. Patients with advanced melanoma have more hope than ever before. Each day, patients are surviving the disease due to increased access to advance therapies and specialized care. Clinical trials are currently underway at federally designated comprehensive cancer centers, such as, Yale Cancer Center and Smilow Cancer Hospital at Yale-New Haven to test innovative new treatments for melanoma. The goal of the specialized programs of research excellence, SPORE, in skin cancer grant is to better understand the biology of skin cancer with a focus on discovering the targets that will lead to improved diagnosis and treatment. This has been a medical minute brought to you as a public service by Yale Cancer Center and Smilow Cancer Hospital at Yale-New Haven. More information is available at yalecancercenter.org. You are listening to the WNPR, Connecticut's public media source for news and ideas.

- Gore Welcome back to Yale Cancer Center Answers. This is Dr. Steven Gore and I am joined tonight by my guest, Dr. Erin Hofstatter. We are discussing chemoprevention in breast cancer. Erin, before the break, we were talking about the relative risk and that you could reduce risk of breast

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cancer and you gave the example of using chemoprevention medication and you talked about reducing the risk in a high-risk person from 8% in the next five years, to I guess 4%. Are there groups that have even higher risk than that or is that about as high as you can predict?

Hofstatter The risks in certain groups can be much higher than 8% over the next five years. For example, those women with a BRCA 1 or 2 mutation, especially if you are talking about a young woman, her lifetime risk of breast cancer can approach 50 to 85% over her lifetime. So certainly, her risks over the next five years could exceed 8%, but most women that we end up talking to in our prevention clinic may have a five-year risk of 3%, 4% and quite honestly to be considered at increased risk enough to merit considering a medication, the 5-year risk needs to be basically 2% or higher, so to me, 8% would certainly qualify a woman to take these medications.

Gore And is the amount that the medication reduces risk always by half, or if your risk is 50%, does it reduce it to 25%, does it work like that?

Hofstatter That is what we believe, the studies obviously showed that statistic of reducing your risk by 50% based on several studies that enrolled 1000s of women and half got the medication and half got the placebo and they compared rates at which breast cancer developed in each group and so the group that got the medicine had half as much breast cancer. So, yeah, the simple way to say it is that it cuts it by half.

Gore I guess if you are still left with the 25% risk of breast cancer that is still pretty scary.

Hofstatter Yeah, and so certainly those women again at highest risk, somebody with a BRCA mutation, certainly we talk about medications and lifestyle, but there is a very select group of women where we are talking about mastectomy or preventive mastectomy, removal of the breast to reduce the risk most effectively, but like I said, that is reserved for a very select group of women.

Gore That is what happened to Angelina Jolie, is that right?

Hofstatter Correct.

Gore That was a huge public story and I was very impressed with her bravery to talk about that.

Hofstatter Absolutely. She brought BRCA really to the kitchen table in terms of conversation.

Gore That is what she has, she has the mutation?

Hofstatter She has a BRCA 1 mutation on her mother's side. My understanding is that her mother died of ovarian cancer. Again, with this strong family history, she was found to have this mutation, so she made the decisions that were appropriate for her and appropriate for her risk level, but I certainly

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do not want the women in the audience to rush to their doctors and say, I have to have surgery. That is certainly not the case for the vast majority of women.

- Gore And you mentioned this connection between breast cancer and ovarian cancer, and just while we are talking about it, having the bilateral mastectomy does not prevent Angelina from getting ovarian cancer, right?
- Hofstatter Correct. So a healthy woman with a BRCA mutation has an option to remove her breasts which reduces her risk of breast cancer by about 95%. She also would be faced with a decision about removing her ovaries ideally by the age of 40 to reduce her risk of ovarian cancer and that reduces it nearly 90% or better, but nothing can make the risk of cancer 0 no matter what you do, but certainly it would be recommended in a woman as she approaches the age of 40 with a BRCA mutation.
- Gore Those are really tough decisions to make.
- Hofstatter Yeah, they are.
- Gore Tell me about the medications that you are offering for chemoprevention. Is it like the daily baby aspirin I take, that is not a big problem?
- Hofstatter If only it were. Probably the one that is the best known medication available right now to prevent breast cancer, is tamoxifen.
- Gore That is an anti-cancer drug, is it not?
- Hofstatter It is. In fact, three of the medications, tamoxifen, Aromasin and Arimidex are three breast cancer medications that have been studied in healthy women without cancer and that is the population that has been shown to reduce the risk by half. There is another medication, a fourth medication called Evista, which is a cousin of tamoxifen, which is actually an osteoporosis medication, but again has been shown to reduce the risk in healthy women.
- Gore And are these drugs administered orally?
- Hofstatter Yes, they are all pills, and all of them would be taken as one pill a day for five years.
- Gore Just for five years?
- Hofstatter Yes, and then there is data now to say, at least we know with tamoxifen and with Evista, that once you stop that medication after five years, it does appear to continue to protect you for at least another five years.

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- Gore How does that work?
- Hofstatter It is a great question, and I wish I knew, but what the belief is, is that when we are ‘preventing’ these cancers, is it possible that if there is a microscopic breast cancer cell already present in the breast, could we actually be treating that breast cancer before we even know it’s there, so perhaps if it were to show up later on, that may not show up for another 10 or 15 years.
- Gore These drugs that you mentioned, if I am not mistaken, are anti-estrogens, is that right?
- Hofstatter More or less, yes. So tamoxifen and Evista both work to basically blind the body’s ability to see the estrogen that is floating around. They are in a class of medication called SERMs or selective estrogen receptor modulators. Basically, it masks the receptors that see the estrogen in the body. Aromasin and Arimidex actually work to lower the estrogen in your body, so of course, this is what we know to be effective, but it does come with side effects.
- Gore I was going to say, it sounds like you are inducing menopause, no?
- Hofstatter In many ways the side effects profile does mimic menopause, particularly with the Aromasin and the Arimidex, so in those medications lowering the estrogen levels in your body, hot flashes, night sweats, some achiness, muscle aches and rare, but more serious side effect, of potentially thinning the bones more rapidly than what naturally happens. The side effect profile with SERMs or the tamoxifen and Evista of the world, hot flashes, night sweats, leg cramps and then there are rare but more serious side effects including a very low risk of uterine cancer with tamoxifen, about one in a 1000 per year and a very small risk of blood clots like a clot in your leg called a DVT or a stroke, these again one in a 1000 per year.
- Gore It sounds great. Where do I sign up?
- Hofstatter Well, this is where it is challenging and even though these medications are very effective, I do wonder if the future of chemoprevention or the prevention of breast cancer really needs to look at something more benign such as aspirin, as you mentioned, or some other herbal medications that are under study. For example, Omega-3 is under study; there are a lot of studies going on right now because we have realized that chemoprevention had such promise in the 1990s and when it got rolled out to real life, very few healthy women chose to take it because of the side effect profile. So they are great medications, and I am a believer, but I think we can do better.
- Gore Can you take these medications if you are premenopausal?
- Hofstatter Yes, you can take tamoxifen as a premenopausal woman and many women choose not to but certainly, there are women like I said with a BRCA mutation or those with a very strong family history who are motivated to take it.

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Gore I guess for any woman, there are potentially sexual side effects as well.

Hofstatter Absolutely, I think vaginal dryness is the big problem, you are basically inducing menopause all over again. It is a problem especially with healthy women. You want to live your life, you want to live well but you also want to reduce the risk of breast cancer and sometimes the trade-offs are challenging. My philosophy when I counsel women about these medications is to give it a try, fortunately with all the unpleasant side effects, short of a blood clot, which is rare, if you do not like it or you feel terrible, you can stop. I prepare women for the side effects and they go into it expecting to feel terrible and actually many women feel okay on them.

Gore That is nice.

Hofstatter That is generally my advice.

Gore I am guessing that if we have the vaginal dryness, you cannot treat it with an estrogen cream.

Hofstatter That is also a challenging question, but generally speaking, the answer is yes, you can.

Gore: Really?

Hofstatter Yes, even my breast cancer patients are on some of these medications. If you are experiencing significant side effects, certainly we try nonhormonal based substances, but if that does not work, a small amount of vaginal estrogen has not been proven to worsen recurrence rates and is an option in healthy women.

Gore Fascinating. So do you also take care of people with established breast cancer?

Hofstatter Yes, I do, so half of my life is spent trying to prevent breast cancer in the first place and the other half of my life is spent treating women with breast cancer.

Gore: Is there any particular area that you are more interested in than others or just general breast cancer?

Hofstatter In general, breast cancer, BRCA mutations or BRCA related cancers and prevention of cancer in that subset of women is of a particular interest, but I think there are a lot of great researchers out there working on breast cancer. There is not a whole lot going on in breast cancer prevention, so I think that is my desired future.

Gore It is a good one.

Hofstatter Yeah, I am excited about it.

Gore Are you working with genetic counselors or do you do that piece yourself?

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- Hofstatter I am, and the program has recently undergone a bit of a transition and is now the Smilow Cancer Genetics and Prevention Program. It is an effort to have the genetic counselors and the physicians working together, not only to provide genetic counseling for patients but also to translate the findings of the genetic counselors into an actionable plan so that the cancer can be prevented, not only for breast and ovarian, but GI, endocrine tumors, GU tumors, it is really a coming together of the minds.
- Gore Do people see you and genetic counselors at the same time or they see you for screening?
- Hofstatter It depends on what the patient is coming in with. Those women with a breast biopsy showing atypical cells but someone without a family history might see me only, but certainly those women with a family history may see the genetic counselor and the genetic counselor only, or if it is a person certainly with a mutation or with a strong family history, they may see the genetic counselor first and then come to me to maintain their screening program and talk to them about medications.
- Gore How do you test for these mutations? You need to have a breast biopsy correct?
- Hofstatter Absolutely not. If a person comes in with a strong family history and is suspicious for a genetic syndrome, the ways to test for that would typically be a blood draw but more commonly we are doing saliva studies or buccal swabs, Q-tip on the inside of the cheek.
- Gore That does not sound like a very invasive procedure at all.
- Hofstatter No, actually it is not and insurance is much better nowadays about covering these tests as well.
- Gore Do you screen just for the particular genes of interest of breast cancer or do you do one of these whole genome sequence things we read about that are so cool?
- Hofstatter Very complicated question. Certainly there has been a movement in the past year or two to be sending off panels of genes instead of just looking at BRCA 1 and 2, we are looking at 6 genes or 20 genes that could be related to cancer, not only breast but colon and ovarian and the trouble is that it is a bit of a Pandora's box. The more you look for, the more you find and the more grey results you get, you might get what we call a variant in a gene that we do not know what to do with and so it gets very challenging in terms of if you get a variant, is that why this person got breast cancer, does that mean that a healthy family member should test, does that mean if you do not get it, we should screen you more aggressively, it is a lot of unanswered questions that I think will be answered in the next 5 to 10 years but we are right at the beginning of understanding how to do that kind of panel testing. So sometimes it is appropriate, and sometimes quite frankly, it is not.
- Gore And can people sign up for studies which track this or contribute to this evolving area of science?

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- Hofstatter Yes, nationwide and internationally they are starting to compile databases of people with strong family histories who may have tested positive for say a variant in a gene, it is not quite a mutation but it is not quite normal and Yale is participating in the PROMPT study.
- Gore PROMPT, that is a good acronym.
- Hofstatter Yeah there you go. That is one example of studies that are going on to really try and figure out how to classify some of these variants that we find.
- Gore So who is eligible for a study like PROMPT?
- Hofstatter Many of the women coming in, and we are actually opening up these research protocols hopefully in the next six months where anybody coming to us with a family history, we would be able to assemble a pedigree, a medical history as well as collect DNA sample and prospectively moving forward so that when we find that next interesting gene down the road, we can go back to our database or repository and test some of the intriguing families.
- Gore And that is just for breast cancer?
- Hofstatter It is for all cancers. As part of the Genetics and Prevention Program we are basically building a research database, so we would be looking for anybody coming in to see us to collect a DNA sample.
- Gore That sounds really fascinating, but people worry about that too right about somebody having their DNA, and if their insurance is going to tingle them because they were found to have this variant that you do not even know what it means, and stuff like that, is there a risk for patients that way?
- Hofstatter That has been an important issue I would say in the last 20 years, especially with the BRCA movement. Fortunately, the federal government passed the GINA Act or the Genetic Information Nondiscrimination Act a few years ago to protect against employment and health insurance discrimination, so fortunately, there is legislation in place. Life insurance, unfortunately, is not protected, so if a person comes to us and they actually look pretty suspicious for having something, we generally recommend they get life insurance first. From a research perspective, it is very easy to de-identify data so the concern that someone's DNA is going to mysteriously show up 20 years from now, the concern for that is much less.

Dr. Erin Hofstatter is Assistant Professor of Medicine and Medical Oncology and Co-Director of the Genetic Counseling Program at Yale School of Medicine. We invite you to share your questions and comments, you can send them to canceranswers@yale.edu or you can leave a voicemail message at 888-234-4YCC. As an additional resource, archived programs are available in both audio and written format at yalecancercenter.org. I am Bruce Barber hoping you will join us again next Sunday evening at 6:00 for another addition of Yale Cancer Center Answers here on WNPR, Connecticut's Public Media Source for news and ideas.