Will You Be Our Hero?

FORCE serves any person of any age who faces hereditary breast and ovarian cancer. As a non-profit organization, we rely on the generosity, gratitude, and kindness of our members, the healthcare community, and our friends and family to keep our lights on.

As our impact and reach grow exponentially, we are making progress in hereditary cancer awareness, policy, and research. But for the first time in our 14+ years of service, 2013 brings a funding shortfall for our already-shoestring budget, and demand for our programs now outpaces our financial growth. So here we are, hat in hand. We try not to ask for much, but we do now ask that you take a few minutes to read this short plea and consider becoming a FORCE Hero by giving a mere 50 minutes of your time or contributing $50 to any of our nearly 70 members who have joined our Hero program.

We are here for you, but we are also here because of you. Now we need your help.

Take a moment and remember when you first encountered FORCE. Now imagine if FORCE wasn’t there when you needed it. Our efforts that provide awareness, advocacy, education, and action lead to longer lives for those at increased risk for breast, ovarian, and other inherited cancers. But lack of funding is now jeopardizing our programs. Please be a hero for FORCE, and help us to continue helping others. Visit facingourrisk.org/heroes to create and share your hero page today.

Sue

FORCE Recommended Reads

by Sue Friedman

We often say that informed decisions are the best decisions. But sometimes it can be difficult and time consuming to sort through various resources to find which is the most objective and comprehensive. Fortunately, we can recommend two books that are up-to-date, easy to read, and contain a wealth of information that is of interest to our community.

We’re very proud of Confronting Hereditary Breast and Ovarian Cancer: Identify Your Risk, Understand Your Options, Change Your Destiny, our own publication authored by Sue Friedman, Dr. Rebecca Sutphen, and Kathy Steligo. It is a labor of love and commitment that has received kudos from our community and health care professionals alike. This book is a helpful guide, no matter where you are in your BRCA journey. It dispels myths and misinformation, and presents practical risk-reducing alternatives and decision-making tools.

The new third edition of The Breast Reconstruction Guidebook: Issues and Answers from Research to Recovery is completely updated. If you’re considering mastectomy, with or without reconstruction, find out why FORCE has recommended this book for over a decade, and why so many oncologists and surgeons recommend or provide it to their patients.

Both books are published by Johns Hopkins University Press and are available on Amazon, where you can take a peek inside, review the Tables of Contents, read reviews, and order. If you order either book (or both), please take a few minutes to post a review!
BROCADE Study

Men and women aged 18 years or older who have advanced (metastatic) breast cancer due to a BRCA1 or BRCA2 gene mutation may qualify for the Brocade Study. The purpose of this medical research study is to determine the safety and effectiveness of the investigational PARP inhibitor, Veliparib in combination with chemotherapy in patients with advanced hereditary breast cancer. Each individual will be evaluated to determine his or her eligibility. Those who qualify will receive investigational medication or placebo, study-related medical exams, and lab tests at no charge. Compensation for time and travel may also be available. To see if you may qualify, call 1.855.5ONCOLOGY (1.855.566.2656) or visit BrocadeStudy.com.

PARPi References


Update: PARP Inhibitor Research

*by Sue Friedman*

PARPi inhibitors (PARPis) are experimental medications that were found in early studies to be specifically effective against BRCA-related cancers. These drugs block an enzyme used by cells to mend breaks in DNA. Cancer cells in people with BRCA mutations have problems repairing DNA already, and the PARPis make that worse. Theoretically, these drugs should spare healthy cells that have at least one working copy of the BRCA gene, with limited side effects or toxicity. Because they are not yet FDA-approved, PARPis are not available outside clinical trials, but several such trials are currently recruiting participants.

Early PARPi research generated a lot of excitement. In the first trials, the drugs effectively treated some people with BRCA mutations and advanced cancers, including those who have already undergone multiple prior treatments with standard chemotherapy drugs. Not all patients benefitted, but enough did to warrant larger trials. Overall, PARPis were well tolerated, although some patients developed fatigue, nausea, anemia, and low platelet counts. After early successes, trials that expanded to include more people without BRCA mutations were less successful and received a bit of negative attention. But closer inspection revealed several reasons why these later studies may have been less successful. These insights (shown below) provide hope that researching these agents remains worthwhile.

- A study using the PARPi Olaparib was opened to all women with advanced ovarian cancer, rather than just women with BRCA mutations. The study showed some benefit, but not enough to receive FDA approval.
- Another Olaparib ovarian study did not show a survival benefit compared to chemotherapy. However, the group that received PARPis appeared to have more women with platinum resistance compared to the non-PARPi group, which may have affected results. Based on this study, researchers believe there is a correlation between platinum sensitivity and PARPi response in ovarian cancer.
- The drug Iniparib was studied in women with advanced triple-negative breast cancer. The drug worked for some study participants; however, Iniparib did not sufficiently improve overall survival for enough women to be granted FDA approval. Experts believe Iniparib failed in part because the study was open to all women with triple-negative breast cancer—triple-negative breast cancer may behave differently in women with BRCA mutations compared to women without mutations. More importantly, Iniparib is not considered a true PARPi inhibitor, and in fact works through a different pathway.

Despite these setbacks, PARPi research continues and is now focused on the population for which these drugs were initially developed: people with BRCA mutations. If these studies are successful, PARPi research could expand to earlier-stage cancers or prevention. Ongoing investigations of PARPis include:

- A phase II study for women with BRCA mutations diagnosed with ovarian, fallopian tube, or primary peritoneal cancer was conducted through the Gynecologic Oncology Group (GOG) examining the PARPi Veliparib. Results will be reported at the American Society of Clinical Oncology (ASCO) conference in June. If positive, this may pave the way for a larger study that would be open to hundreds of ovarian, fallopian tube, and primary peritoneal cancer patients with BRCA mutations.
- A phase II study used the PARPi Olaparib to treat almost 300 patients with BRCA mutations and different types of advanced cancers, including pancreatic prostate, breast, and ovarian cancers. The results of this study will be presented at the ASCO meeting in June, and if positive, could lead to expanded studies of PARPis in BRCA-mutated cancers.
- The large BROCADE study (see sidebar) is looking at Veliparib in combination with chemotherapy for advanced hereditary breast cancer. This effort includes many study sites across the U.S. and in other countries.

The support and participation of the HBOC community in PARPi research is critical.
Conference Recap: Personalizing Risk Assessment for BRCA1 and BRCA2 Mutation Carriers
by Sue Friedman

Presenter: Timothy Rebbeck, PhD

Estimated cancer risks for BRCA1 and BRCA2 mutation carriers vary substantially between different research studies. Breast cancer risk estimates range from 30 to 85% by age 70, while lifetime ovarian cancer risk ranges from 40 to 60% among BRCA1 mutation carriers, and between 16 to 27% in women with BRCA2 mutations. In part, these variances are the result of specific populations studied (e.g., high-risk hereditary cancer families compared to population-based individuals) and factors that modify risk in mutation carriers. These estimates are based on statistics; they apply to entire populations and may not reflect an individual's cancer risk. This disparity adds to the confusion many BRCA mutation carriers feel when they attempt to make risk-management decisions. A more accurate estimate of personal risk would be helpful as a woman may approach a 30% lifetime risk of breast cancer differently than an 85% risk.

Factors called risk modifiers increase or decrease individual risk. Modifiers for breast cancer risk include exposures to certain environmental chemicals; hormones, pregnancy, and breastfeeding; diet and exercise; and other genes that may affect cancer risk in people with BRCA mutations.

Dr. Timothy Rebbeck and others are researching whether the type and position of specific mutations in BRCA1 or BRCA2 genes could explain some cancer risk variations. In previous studies, women with mutations around the exon 11 regions of both BRCA1 and BRCA2 genes appeared to have relatively higher risk for ovarian cancer and relatively lower risk for breast cancer. Researchers refer to this area as the “ovarian cancer cluster region” (OCCR), highlighting that specific mutations confer very different cancer risks. Despite this provocative finding, the mechanism of the OCCR effect is unknown, and the information has not yet translated into more precise risk assessment.

Recently, the worldwide Consortium of Investigators of Modifiers of BRCA1/2 (CIMBA) has begun a systematic evaluation of BRCA1 and BRCA2 mutations. This effort aims to clarify risks associated with specific regions of genes or types of mutations, which may lead to more accurate risk assessment based on a mutation's location or whether a particular protein is abnormal or absent. Improved risk estimates may not eliminate the need for risk-reducing oophorectomy or strategies, but they may allow a tailored approach to the timing and type of these interventions.

Conference Recap: Genetic Testing in the Jewish Community—Are We Doing Enough?
by Jane E. Herman

Presenter: Dr. Steven Narod, MD

People of Eastern European Jewish descent have a higher prevalence of BRCA1 and BRCA2 mutations than do individuals in the general population. Renowned Canadian researcher Dr. Steven Narod discussed results from a program he initiated in 2008, which offers free BRCA testing to any unaffected adult Jewish woman in Ontario, regardless of her family history of cancer. Dr. Narod's laboratory can test for the three most common BRCA mutations among Ashkenazi Jews (known as founder mutations). As a result:

- 6,108 women were initially tested, 67 of whom were positive for a BRCA mutation
- 81 mothers and sisters were subsequently tested, 25 of whom were positive
- A total of 92 women were identified as carriers of a BRCA mutation

Dr. Narod estimates that 47 cases of breast or ovarian cancer were prevented, and 24 lives were saved from this testing. Dr. Narod concluded that his model is cost-effective (approximately $50 per test) and lifesaving, and he proposed expanding the program beyond Ontario. In the United States, testing for founder mutations is more expensive (about $450) because Myriad Genetics’ gene patent impacts the cost of widespread testing. Population-based testing is most efficient in groups with a high incidence of BRCA founder mutations, making this model more costly and less beneficial for the general (non-Jewish) population, in which BRCA mutations are more rare.

Jane E. Herman is the executive writer and editor at the Union for Reform Judaism. She is an Outreach Coordinator in New York City and writes often about her own BRCA journey at janethewriterwrites.blogspot.com.
Voices of FORCE

In each issue, we’ll invite a FORCE member to share an insightful perspective, a valuable experience, or a touching story to help others who are dealing with issues of hereditary breast and ovarian cancer.

Widening the Conversation: Previvor Discourses and the Power of Stories
by Amy Boesky

My sisters and I grew up inside a family story that felt, for all its power, isolating. On my mother’s side, an inherited pattern of ovarian cancer was unmistakable. Her mother, aunt, and first cousin all died of it in their 40s. In the 1980s, my father (a doctor) convinced my mother to have a preventative hysterectomy, and listed my sisters and me in hereditary cancer registries. But so little information was available or shared back then. I found myself describing my cancer risk to doctors. “Let’s talk about your heart,” one said, setting my chart aside.

In 1987, when my mother found a lump in her breast, we were confused. Breast cancer didn’t run in our family. Surely this cancer was disconnected from the ovarian cancers in our family. Surely she’d survive. When she died, the world changed for me. In 1994 I received a letter from Creighton University Medical Center saying they believed my family had HBOC—my mother’s story was connected to the others after all. This was my story, too; one day, it might become my children’s.

I’d long planned to have an oophorectomy once I’d had children, but after deciding on prophylactic mastectomies, I wanted advice from genetic counselors, doctors, members of FORCE—may alleviate the potential isolation of facing hereditary cancer. Your own questions and responses shape these conversations as much as any information you receive. These conversations may be open-ended, and they may change over time. Almost certainly, they will change you.

“I know how you feel,” one woman told me, though in her family, early-onset Alzheimer’s is passed down, not cancer. I became fascinated with “previvor discourses” in people beyond the BRCA community. I began to collect personal essays about the impact of genetic mutations on peoples’ sense of identity, intervention, and family. In editing these essays, I realized that the BRCA community often paves the way for others. My interview with Joanna Rudnick, producer of the remarkable documentary *In The Family*, reveals her commitment to sharing private and public conversations about BRCA mutations. Other essays, including those on Alzheimer’s, Huntington’s, and Tay Sachs, reveal challenges in testing for and living with difficult hereditary prognoses. Many other rare, “orphan” conditions can be devastating for families—and though their clinical implications vary, there remain common elements in high risk for disease. The HBOC community has much to offer, and the public much to gain, by embracing a wider community of “previvors” in our conversation.

Author Amy Boesky teaches at Boston College. She has edited a new book, *The Story Within: Personal Essays On Genetics and Identity, a collection of personal narratives by numerous writers on genetic mutations associated with hereditary cancer, Huntington’s, Alzheimer’s, and many other diseases. The Story Within will be published this fall by Johns Hopkins University Press.*

Conversations on the Impact of Hereditary Cancer in Our Lives
by Amy Boesky

“Conversation” has several meanings, each illustrating aspects of how personal stories about hereditary cancer’s impact on our lives can make important contributions. Collectively, these conversations can lead to positive changes for ourselves, our families, and the wider community.

Conversation and perspective
The word “conversation” derives from the Latin *conversationem* (nominative *conversatio*), the “act of living with.” What does it mean to “live with” an inherited risk for disease?

Many in our community have lived with (or are now living with) significant disease or high risk. How can we best live with the knowledge of hereditary cancer and its potential consequences? How can we help others who are living with similar knowledge? These questions lie at the heart of conversation, in the best sense of the word. True conversation is about choices, ethics, compassion, and making a difference in the world.

Conversation and family
One definition of conversation is an “informal exchange of ideas”—private talk that often takes place in intimate circles, such as within a family. How do we initiate a conversation about BRCA with those closest to us? There are no one-size-fits-all answers, but sharing family medical history is vital to helping family members make decisions about risk management for disease.

Conversation and decision-making
Conversation can be synonymous with “dialogue.” Expanding dialogue—with genetic counselors, doctors, members of FORCE—may alleviate the potential isolation of facing hereditary cancer. Your own questions and responses shape these conversations as much as any information you receive. These conversations may be open-ended, and they may change over time. Almost certainly, they will change you.

I’ve realized that the BRCA community often paves the way for others.

…”I know how you feel,” one woman told me, though in her family, early-onset Alzheimer’s is passed down, not cancer. I became fascinated with “previvor discourses” in people beyond the BRCA community. I began to collect personal essays about the impact of genetic mutations on peoples’ sense of identity, intervention, and family. In editing these essays, I realized that the BRCA community often paves the way for others. My interview with Joanna Rudnick, producer of the remarkable documentary *In The Family*, reveals her commitment to sharing private and public conversations about BRCA mutations. Other essays, including those on Alzheimer’s, Huntington’s, and Tay Sachs, reveal challenges in testing for and living with difficult hereditary prognoses. Many other rare, “orphan” conditions can be devastating for families—and though their clinical implications vary, there remain common elements in high risk for disease. The HBOC community has much to offer, and the public much to gain, by embracing a wider community of “previvors” in our conversation.

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Share Your Story
Do you have something to say that may inform our readers or ease their experience? We invite you to share your reflections or personal story about dealing with the issues of hereditary breast or ovarian cancer. Tell us how you feel, how you cope, or what you’ve learned. E-mail stories of 500-550 words to info@faceguns.org or mail to FORCE, 16057 Tampa Palms Blvd. W., Tampa, FL 33647. Please include your name and daytime telephone number so we can contact you if we decide to publish your story in a future issue.
**Basser Research Projects**

The Basser Research Center for BRCA has funded nine 2012-2013 projects, including:

- Timothy Rebbeck, PhD is researching ways to improve the assessment of cancer risk in mutation carriers, to help women make the best decisions about prevention strategies and timing.

- Dr. Andrea Facciabene is working on development of a vaccine for BRCA-related cancers.

- Roger Greenberg, MD, PhD; Andrew Minn, MD, PhD; and Kate Nathanson, MD will use different approaches to study the molecular or genetic changes present in BRCA-related tumors. This work aims to find new targets for treatment or predicting drug sensitivity or resistance to current regimens.

- Drs. George Coukos and Chuncheng Li are investigating innovative molecular imaging techniques that visualize the tiny veins that grow to feed cancers.

- Dr. Andrew Rhim is analyzing blood samples for a possible tumor marker called circulating epithelial cells, which may be found in the blood of people with early stage BRCA-related cancers.

- Dr. Angela Bradbury is studying communication about hereditary cancer risk within families, to inform interventions aimed at increasing preventative behaviors and minimizing adverse psychological outcomes.

- Dr. Susan Domchek is investigating the consequences of risk-reducing oophorectomy, a concern that FORCE frequently hears from our members. Findings from this study will help genetics experts advise patients on the best timing for oophorectomy and establish whether interventions to treat side effects are needed.

Updates on research recruitment and findings are posted on the Basser Collaboration page on the FORCE website. Visit facingourrisk.org/basser for more information.

**Our New Collaboration with Basser Research Center**

by Sue Friedman

In 2012 one family transformed the landscape of BRCA1/2 research by establishing the Basser Research Center for BRCA at the Abramson Cancer Center of the University of Pennsylvania. “Because our family suffered traumatically from this disease, we wanted to ensure that no other family out there suffered in the way that we did,” explained Mindy Gray. Mindy and Jon Gray endowed the Center in honor of her family, the Bassers, who lost Mindy’s sister Faith at age 44 to BRCA-related ovarian cancer.

FORCE is now collaborating with the Basser Research Center for BRCA to strengthen ties between people with BRCA mutations and University of Pennsylvania researchers and physicians who are devoted to finding ways to prevent and treat BRCA-related cancers. Together, we will drive research forward, develop educational resources, and hold quarterly support groups in the Philadelphia area. As part of our collaboration, the next Joining FORCEs Against Hereditary Cancer conference is scheduled for Spring 2014 in Philadelphia. (Visit facingourrisk.org/conference for more information.)

“The Basser Research Center is an example of how we go from the bench to the bedside, taking this knowledge about BRCA1 and BRCA2 and giving people information that they can act upon. But it’s also a key example of what we call bedside to bench, when patients tell us about their concerns and what they need to know, and we go back and use our research in the lab or epidemiology research to answer some of those questions for patients,” said Basser Executive Director Susan Domchek, MD.

The Center has established an annual grants program to fund research ranging from basic science studies to early detection, prevention, treatment, survivorship, communication and outreach. “Our clinical research all starts with our registry study,” said Rebecca Mueller, Basser’s outreach coordinator. “Through our registry, we track participants with BRCA mutations and can follow their outcomes and recontact them as new research questions arise and new research studies open.” So far, our collaboration has recruited over 200 people into important BRCA-specific research. FORCE will periodically provide updates on these research findings and help recruit additional participants for open studies.

Contact the Center by phone: 215-662-2748 or email: basserinfo@uphs.upenn.edu, or visit: pennmedicine.org/basser for more information about participating in Basser’s research and to subscribe to the Center’s newsletter.

**Update: PARP Inhibitor Research continued**

- Other smaller PARP inhibitor studies are open or will be opening soon, including projects for women with ovarian cancer, and research for early-stage breast cancer patients who have residual cancer after neoadjuvant chemotherapy. Phase III trials in metastatic breast and ovarian cancer are likely to open soon and could provide the data required for FDA approval.

The participation of the HBOC community in PARPi research is critical. If enrollment falls short, scientists and pharmaceutical companies may decide that the HBOC community is too difficult to research, and fewer studies will be designed. If you are interested in participating, ask your oncologist about studies in your area. Prior treatment sometimes affects participation eligibility; if you are newly diagnosed with a primary or recurring cancer, consider enrolling in a PARP inhibitor trial as early after diagnosis as possible. Share this information with friends and relatives. Review the FORCE and clinical trials.gov websites for finding PARP inhibitor studies.
Conference Recap: Breast Cancer Surveillance and Chemoprevention

by Amber Iwan and Sue Friedman

Presenters: Jennie Yoon, MD and Victoria Seewaldt, MD

Radiologist Dr. Yoon outlined standard-of-care guidelines developed by NCCN—a consortium of experts from top centers—for breast surveillance in BRCA mutation carriers:

For women:
- “Breast awareness” beginning at age 18
- Clinical breast exam every 6-12 months starting at age 25
- Breast MRI starting at age 25 or individualized based on the earliest age of onset in the family

For men:
- Breast self-exam training and education starting at age 35
- Clinical breast exam every 6-12 months starting at age 35
- Consider baseline mammogram at age 40, and annual mammogram depending on results

Because mutation carriers tend to develop breast cancers at a younger age than women without mutations, they should begin screening at a young age. But breast screening has risks and limitations. While mammography is not ideal for screening the dense breasts of young women, it is good at finding microcalcifications—small calcium deposits that may indicate early-stage cancer. The radiation dose from annual mammograms is small, but some scientists are concerned about repeated exposure in young mutation carriers who may be more sensitive to radiation. The utility of mammography for early detection of triple-negative breast cancer (the type most frequently developed by BRCA1 mutation carriers) is uncertain; only 15% of these cancers form calcifications. Breast Magnetic Resonance Imaging (MRI) is more sensitive for screening triple-negative breast cancer. Although it does not expose patients to radiation, MRI more often finds abnormalities over traditional two-dimensional mammograms. Three-dimensional breast ultrasound may find abnormalities without subjecting patients to radiation. Two other surveillance technologies, breast specific gamma imaging (BSGI) and positron emission mammography (PEM), more accurately image dense breasts, although both expose patients to additional radiation. PEM has also been used to follow response to cancer treatment.

NCCN guidelines include other risk-management options, such as chemoprevention (medications that lower the risk for cancer), risk-reducing salpingo-oophorectomy (removal of the ovaries and tubes, which lowers the risk for breast and ovarian cancers) and prophylactic mastectomy.

Dr. Seewaldt discussed tamoxifen and raloxifene, currently the only FDA-approved breast cancer chemoprevention options. Both drugs work by blocking hormones in the body. Only tamoxifen is approved for premenopausal women; some evidence suggests that it may prevent breast cancer in women with BRCA2 mutations, but it may not have the same protective benefit for carriers of BRCA1 mutations. PARP inhibitors, (see page 2) are a new class of drugs being tested in people with hereditary cancers. Currently there are safety concerns regarding the use of PARP inhibitors in previvors without cancer. More research is needed before PARP inhibitors can be considered for prevention. Metformin, a drug approved for treating type 2 diabetes, is being studied for preventing breast cancer. It affects cellular pathways that might lead to cancer, especially in people with BRCA1 mutations. Metformin’s safety has already been established from use in diabetics; it also appears to be safe for people without diabetes. Its mechanism for cancer prevention may be similar to the effect of exercise, which lowers breast cancer risk in high-risk women. Dr. Seewaldt will lead a breast cancer prevention study of Metformin later this year. Check the FORCE Featured Research webpage for updates.

Amber is a self-described “lab rat” who lives in Minneapolis with her husband and two dogs. She inherited a BRCA1 mutation from her mother, who successfully completed treatment for breast cancer at the age of 49. In her spare time, Amber works on a modern fiction novel with a BRCA-positive protagonist.
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Your generous donations allow us to provide this newsletter at no charge to people at high-risk. Philanthropic support is critical to FORCE's survival and ensures our continuing ability to provide publications like our newsletter to our community. Your charitable gift can help save lives—please consider making your gift today! To learn more about helping FORCE, visit www.facingourrisk.org/how_to_help.

This Joining FORCE newsletter was made possible by a generous grant from Genentech.

We Want to Hear From You

What's on your mind? What would most help you understand or cope with issues of prevention, diagnosis or treatment? Perhaps you've recently tested positive for a BRCA gene mutation and don't know where to turn. Maybe you're dealing with breast or ovarian cancer, or care about someone who is. Send your input, ideas and comments to info@facingourrisk.org or mail to FORCE, 16057 Tampa Palms Blvd. W., Tampa, FL 33647.

Help FORCE Go Green

Want to save some trees? Help FORCE save dollars? To receive an electronic version of this newsletter rather than a print copy e-mail us at: newsletter@facingourrisk.org. Include your name and city and state in the e-mail.

What's New @ FORCE

Publication for High-risk Men

Thanks in part to a generous grant from Genomic Health, FORCE will develop an important communication for high-risk men: a brochure that will cover the cancer risks and standard-of-care recommendations for screening.

Electronic Newsletter Updates for Health Care Providers

In addition to our monthly national and regional update bulletins, we now provide a quarterly email bulletin for health care providers and researchers. This new communication features content that is tailored specifically for these health professionals to share articles about hereditary breast and ovarian cancer, research, advocacy initiatives, programs and resources. Visit facingourrisk.org/connect if you would like to join our print or electronic mailing list.

Team FORCE Marine Corps Marathon Bibs Available

FORCE has been chosen as a charity partner of the 2013 Marine Corps Marathon, a 26.2-mile race through our nation's capital, on October 27, 2013. Team FORCE members are guaranteed a spot in this sold-out race; if you're a runner, help us raise funds to support FORCE's lifesaving work for the HBOC community. A limited number of race bibs are available, so act fast! Contact Tina Krall at tinak@facingourrisk.org for more information.