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Living proof

BASED ON A TRUE STORY

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RENÉE ZELLWEGER, CRAIG ZADAN AND NEIL MERON

SAT OCT 18th 9pm/8c

Lifetime
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Dr. Slamon (right, Harry Connick, Jr.) explains his work to his new student assistant, Jamie (left, Amanda Bynes) in "Living Proof," premiering Saturday, October 18 at 9:00 PM (ET/PT) on Lifetime Television. Photo credit: Skip Balen, Lifetime Networks, 2008

Living proof

The Lifetime Original Movie "**Living Proof**" is based on the book *Her-2*, by NBC News' Chief Health and Science Correspondent Robert Bazell, about UCLA oncologist and researcher Dr. Dennis Slamon, and how the promising breast cancer drug Herceptin was born. Beginning in 1988, Dr. Slamon's inspiring story shows the sacrifices he makes in his personal life and the obstacles that he faces to get the drug approved.

Dr. Slamon was convinced he had developed a potentially revolutionary drug, Herceptin, that could turn off cancer cells for women who have tumors that are Her-2+ (Human Epidermal growth factor Receptor 2-positive), without debilitating side effects caused by chemotherapy and radiation. With the help of Ronald Perelman, Lilly Tartikoff and the extended Revlon family, funds were raised to further his research.

While encountering red tape, Dr. Slamon loses some of the heroic women with advanced breast cancer who volunteered for the clinical trials. Relentless, he remains committed to the testing of Herceptin to help change the course of breast cancer treatment. In 1998 the FDA finally approves the treatment for the general population, which changes the lives of countless women and their families.

"Living Proof" premieres Saturday, October 18 at 9 pm/8c on Lifetime as part of the Network's Stop Breast Cancer for Life campaign. The movie will encore on Sunday, October 19 at 8pm/7c and Monday, October 20 at 9pm/8c.

Harry Connick Jr. leads an all-star cast including Amanda Bynes, Tammy Blanchard, Jennifer Coolidge, Angie Harmon, John Benjamin Hickey, Regina King, Swoosie Kurtz, Paula Cale Lisbe, Amy Madigan, Bernadette Peters and Trudie Styler.

"Living Proof" is produced by Craig Zadan and Neil Meron's Storyline Entertainment and Sony Pictures Television for Lifetime Television. Renée Zellweger, Neil Meron and Craig Zadan, and screenwriter Vivienne Radkoff are the executive producers. Dan Ireland directs from a script written by Radkoff.



The **411** on Breast Cancer Clinical Trials

Each year, thousands of breast cancer patients turn to clinical trials, in the hopes of a cure or better prognosis. Dr. Marisa Weiss, an oncologist specializing in breast cancer and president and founder of Breastcancer.org, gives the facts about breast cancer clinical trials:

Clinical trials are research studies in which people agree to try new therapies (under careful supervision) in order to help doctors identify the best treatments with the fewest side effects. These studies help improve the overall standard of care.

Breast cancer clinical trials set out to determine the safety and effectiveness of therapies or medicines related to prevention, detection, diagnosis, treatment and quality of life.

Only about 5% of women with breast cancer participate in clinical trials.

Each trial has its own eligibility criteria for patients, which may include specific cancer type and stage, age requirement, certain level of kidney or liver function and an absence of a prior history of other cancers.

Generally, hospitals with a strong commitment to clinical research are more likely to participate in trials.

There is usually no extra financial charge to enter a trial.

Some clinical trials connect to a patient's regular insurance plan and some will give medication at no extra cost.

A medication can cause side effects or it can be well tolerated.

Trials compare a new treatment to the current standard of care—and what is new has the potential to be better.

In a trial, patients receive the treatment under study, or a placebo (an inactive substance, used to substitute for the medication being studied).

If a placebo is used, patients don't know if they are taking the placebo or the treatment under study.

Generally, patients can't participate in more than one treatment clinical trial at the same time.

Clinical trials can involve a procedure not a medicine. Using the word "treatment" could include both. The treatment under study may or may not be new.

To hook up with a trial, ask your doctor or go to **National Cancer Institute** (cancer.gov or **1-800-4 CANCEr**), Breastcancer.org or clinicaltrials.gov (a service of the National Institutes of Health).

Glossary of Breast Cancer Clinical Trials

Grace Boxer, MD, hematologist/oncologist and clinical assistant professor at the University of Michigan Medical School, explains some of the clinical trial terminology:

Approved Drugs: Medications approved by the Food and Drug Administration (FDA) for treatment of specific stage or type of a disease, such as breast cancer.

Adverse Reaction: A harmful side effect of the treatment.

Blind: The patient doesn't know which treatment he or she is receiving.

Double-Blind Study: Neither the subject patient nor the investigator knows which treatment the patient is receiving.

Efficacy: The therapeutic effectiveness of a medication or treatment.

Food and Drug Administration (FDA): The federal agency responsible for the safety of food and drugs within the US

Informed Consent: A lengthy document explaining the details of the study.

Phase I Trials: Very small trials in which a new treatment is tested for safety.

Phase II Trials: Testing a larger number of patients to determine what the appropriate dose should be.

Phase III Trials: Testing a large number of people to determine whether the drug is effective in treating the condition for which it is being tested.

Placebo: An inactive substance used to substitute for the medication being studied in a trial.

Protocol: Drug trial design outlining which patients will be studied and what information will be collected to measure both efficacy and side effects of a medication.

Randomized Trial: A study in which patients are randomly assigned to the treatment they will receive, which is often decided by the equivalent of a flip of the coin.

Side Effects: Effects of the medication other than those desired, e.g., chemotherapy for breast cancer is desired to shrink the tumor size, but a side effect is lowering the white blood cell count, making the patient more susceptible to infections.

Standard Of Care: A treatment that is accepted as appropriate for a given disease and would be expected to be used for treatment to be considered adequate.

What is Compassionate Access?

In “Living Proof,” a couple of terminally ill breast cancer patients were denied Herceptin because they didn’t meet the criteria to enter the next phase of the trial. This raises the question of compassionate access (or compassionate use), where therapies and medications not yet approved by the Food and Drug Administration (FDA) are available to catastrophically sick people who, along with their doctor, believe these treatments may save their lives.

“When Herceptin was in the Phase III trial, there were a number of patients not eligible for the protocol but who wanted the drug because they had reason to believe they might benefit,” says Barbara Brenner, executive director of Breast Cancer Action. But because there wasn’t enough Herceptin available at that time, Genentech (the makers of Herceptin) created a fair, unbiased lottery system for patients who weren’t eligible for the trial but wanted the drug. “If their number came up they got it; otherwise they did not.”

According to the American Cancer Society (ACS), the FDA first approved investigational drugs to be used in this way for critically ill patients in 1987. Consent to take an unapproved drug has to be granted by the FDA, but it is also up to the individual drug companies to offer an “expanded access program.” As it stands now, drug companies can’t be forced to supply the drug out of trial. The ACS points out that producing extra medicine for people who are not in clinical trials can be expensive for the drug company, especially since there is a chance the drug won’t be approved.

With a grim prognosis and no time to wait for the drug to be approved, the benefits of compassionate access for patients with metastatic disease might be enormous, perhaps even extending the lives of patients by months or years. However, the purpose of the trial is to find out whether the drug works in very sick patients, so the benefit is unknown, and patients will be taking a risk of side effects and won’t be monitored as closely as patients in a trial. “Sometimes it takes the release to the general population to uncover rare complications,” notes Brenner.

Currently, drugs available for compassionate access are in the late stages of development—typically Phase III. But some believe medications and therapies should be accessible after Phase I or II, which has many breast cancer patient advocates concerned. One organization, the National Breast Cancer Coalition, believes that a policy expanding availability of investigational new drugs for individuals outside of clinical trials will weaken the move towards more and better research. Its president, Fran Visco, says, “Women with breast cancer should not be given false hope by treatments that are unproven. Interventions must be based on the best possible science available, and the best way to achieve that is through well-designed clinical trials.”

However, NBCC also believes that a breast cancer patient with no treatment options left should have access to a new intervention through an expanded access protocol if 1) the therapy has shown some effectiveness and a low risk of serious harm in a phase II trial and 2) she is not eligible for any open clinical trial investigating the therapy in question. “NBCC wants to help each and every breast cancer patient and is therefore committed to a public policy agenda that will help all women with breast cancer and those at risk,” says Visco. “Access to investigational drugs outside of clinical trials is a complex issue and must be rare. It must be carefully designed to be fair and to protect the research process that we depend on to bring us closer to eradicating breast cancer.”

Millions of people die from (cancer.) If you walk down the street, most of the people that you have seen have been affected by it.” — Harry Connick Jr.

According to some advocates, the FDA should require drug companies to offer compassionate access to patients who have no other treatment options, particularly if the drug is in late stages of drug development. “If the FDA heard from enough people about mandatory compassionate access programs, I think we would have it,” says Brenner.



Interview with Dr. Dennis Slamon

Lifetime is honored to share Dr. Slamon's story in "Living Proof." He answers some questions about the movie and his work.

The story is about your research. How did the movie come to be, as far as your involvement?

Robert Bazell's book is all about the whole development of the drug. I think that the story is about a lot of people who are involved in that, including and most importantly the patients who were involved in the testing of that drug. I think, in that sense, it's a broader story beyond just me..

How has this drug changed women's lives since its introduction?

Since the introduction of the drug, it's had a dramatic response for the women who respond to it. Not all women respond, but the ones who do seem to do very well, and we now have long-term survivors in this subtype, which we never had before. In Bob's book and in the movie, they talk about a couple of patients who really did very well, who are out now 11 or 12 years with no evidence of the disease. So we think it's been very effective. That's gratifying.

How is this movie helping to bring awareness to alternate treatments for cancer?

I think "Living Proof" does a good job of showing patients new things and researching new therapeutic approaches. There's a lot going on in clinical research. Unfortunately, in the world of cancer, maybe 3 to 4 percent of patients go on clinical trials when maybe 20 percent or more are eligible. I think the public being aware of the fact that there are these things out there, testing these new and hopefully effective treatments, is an option. And I think "Living Proof" accurately portrayed that.

Do you recommend breast cancer patients sign up for clinical trials?

I think all patients who have breast cancer—all patients who have any kind of cancer—should look at clinical trials. Patients never get anything less than the best available care and frequently get something that may be better, just by virtue of being on a clinical trial and having to be monitored so closely and so carefully. So I think there are a lot of advantages to seriously looking at a clinical trial and participating. And I think that would be a good thing if that came out of "Living Proof."

Why should people watch "Living Proof"?

The positive thing in all of this for me, in terms of having "Living Proof," out there is that it's going to give the public a view that there is effective research going on and that they can be participants, both actively and just a step back in terms of support. The portrayal of the patients that got involved in the clinical trial, the portrayal of the advocacy group that got involved on the federal level and at the industry level is accurate, and in that sense, the movie is a real success.

What's My “Living Proof?”



Courtney Bugler thought her life was going great—her husband was about to graduate from college, they had just bought a house and they were trying to have a baby. All that changed a month after her 29th birthday, when she was given the devastating news: She had breast cancer. With no family history and being so young, Courtney never thought this could happen to her, especially at this stage in her life. That was in February 2006, and within a month of being diagnosed, she had a lumpectomy, followed by eight rounds of chemotherapy.

But Bugler didn't let the cancer stop her from going on with her life. "Since breast cancer, I've posed nude for photos, swung on a trapeze, taken pole-dance lessons, joined a survivors' gospel choir ... there is nothing too wild and too crazy," says Bugler, who, halfway through her treatment, moved from Chicago to Atlanta. "Because breast cancer has already taken too much, I've decided to take my life back. After hormone-positive breast cancer and permanent menopause, and the use of my frozen embryos, I am pregnant and due in April. I have taken my passion and advocacy for young women and breast cancer and made it a career, leaving a successful position as a television scriptwriter to become the executive director of the Atlanta Affiliate of the Young Survival Coalition. I am living proof that breast cancer can hit anyone, anywhere. I am proof that you can find a new way to live."



When **Mary Kelton Smith**, finished her breast cancer treatment in 2001, she turned her energy and time to reaching out to the community, arming them with information and education about the disease. Smith, 45 and a nurse in Nashville, Tennessee, took on a leadership role at Sisters Network Inc. Through ongoing activities and events, she was committed to increasing attention to the devastating impact breast cancer has in the African American communities and participated in various breast cancer awareness programs.

"My role in Sisters Network allows me to give back and be a blessing to other women along this uncertain journey," says Smith, who had surgery, radiation and three recurrences. "Having lost two sisters to breast cancer and with my oldest sister just recently diagnosed, I can truly relate to each and every helpless thought and/or emotion."

Since her diagnosis, Smith, who is married and has a 10-year-old son, has had a different outlook on life. "Life—every second, every minute, every hour—is most precious to me," she says. "Since my original breast cancer diagnosis in 2000, I have insisted on making the most of every day, and I consider each day of the rest of my life as a gift, a gift to be shared and treasured forever."



Working with Nueva Vida, **Norma Anita Davila** wants to reach out to Latina women diagnosed with breast cancer. As an emigrant of Peru and a breast cancer survivor herself, Davila, who was diagnosed 15 months ago, fears that Latina women don't have the resources to get the best care. "After my experience, I wondered what Latina women do if they lack access to the internet, are alone and have to take a bus to the hospital to get treatment, or are unfamiliar with the health benefits because nobody makes time to explain in their language," she says. "My living proof is to advocate for Latinas like me, who may need more information in Spanish about what to do if they are diagnosed with breast cancer; need guidance during the process, counseling, support and help understanding alternatives for making informed decisions."

It has been more than 10 years since Davila arrived in the United States and she says she gets inspiration from her two children. "My daughter, 24, is serving in the American Air Force, and my son, 22, works for Verizon," she says. "They inspire me to teach them all the good things you can accomplish in life with dedication and love. Now I understand I still had one more thing to teach them – to survive with dignity in tough situations."

Herceptin Facts

- 20-25% of breast cancers are Her-2 positive.
- Her-2 positive breast cancers tend to be the most aggressive kind of breast cancer.
- Cancer cells are cells that grow in an uncontrolled fashion. Herceptin, as described by Dr. Dennis Slamon, covers up the active receptor that's signaling for a cell to grow, sort of like throwing a blanket over an antenna and stopping it from sending signals.
- In 1998, the FDA approved Herceptin for treating Her-2 breast cancer that had spread to other parts of the body, afflicting nearly 15,000 women annually in the U.S.
- In 2006, the FDA approved Herceptin, along with chemotherapy, for treating early breast cancer that is aggravated by the so-called Her-2 protein, afflicting nearly 40,000 women annually in the U.S. The recommendation is that women with early stage Her-2 positive tumors—determined in the laboratory after a biopsy—take one year of Herceptin intravenously.

Tools of Detection

One in eight women will be diagnosed with breast cancer in her lifetime.

Know and use the tools of detection:

Schedule a mammogram

Once a year for women age 40 and older. When breasts are dense, the doctor may order a digital mammography, where the images are recorded electronically and stored into a computer instead of on film.

Approximately 46.6 million people in the United States are without health insurance.* The Centers for Disease Control and Prevention offers a program that provides free or low-cost mammograms to women who cannot afford them.

Learn more at www.cdc.gov/cancer.

Get a breast exam by a doctor or nurse

Once a year for women age 40 and older and women at high risk for the disease; at least once every three years for women under 40.

Learn the feel of your breasts

Report any changes to your healthcare provider—ongoing for all women.

Expert opinions vary on these detection guidelines. Lifetime encourages you to talk to your health care provider about what is best for you. Be informed. Be your own advocate.

To learn more, go to
www.myLifetime.com.

*U.S. Census Bureau: *Income, Poverty, and Health Insurance Coverage in the United States: 2005*.

The National Cancer Institute estimates that a woman in the United States has a 1 in 8 chance of developing invasive breast cancer during her lifetime.



Resources and Support

You can make a difference and help *Stop Breast Cancer for Life*. Learn more about these organizations; volunteer; participate in their fundraising events; and make charitable donations to help sustain their critical work. For more information, go to myLifetime.com.

American Cancer Society - www.cancer.org (800) ACS-2345

is one of the oldest and largest voluntary health agencies in the United States, with over 3,400 local offices throughout the country. The ACS provides research, education, patient care and clinical trial information.

Breast Cancer Action - www.bcaction.org/www.thinkbeforeyoupink.org (877) 2STOPBC

is a grassroots education and advocacy organization that works to ensure people have access to more effective, less toxic treatments. They also address social, economic, racial and political injustices that affect breast cancer outcomes.

Breastcancer.org - www.breastcancer.org (610) 642-6550

is an online resource for breast health and breast cancer information, with 70 professional advisors. They provide vital information and support to those affected by breast cancer.

Breast Cancer Network of Strength - www.networkofstrength.org (800) 221-2141

(formerly known as Y-Me) provides emotional relief to anyone affected by breast cancer through "YourShoes," a 24/7 breast cancer support center staffed exclusively by breast cancer survivors.

Jonsson Comprehensive Cancer Center - www.cancer.ucla.edu

UCLA Cancer Hotline (888) ONC-UCLA

The Revlon/UCLA Womens Cancer Research Program at UCLA's Jonsson Comprehensive Cancer Center has established an international reputation for developing new cancer therapies, providing the best in experimental and traditional cancer treatments and expertly guiding and training the next generation of medical researchers.

National Breast Cancer Coalition - www.stopbreastcancer.org (800) 622 2838

is dedicated to ending breast cancer through the power of action and advocacy. Their main goals are to increase federal funding for breast cancer research, and improve access to high-quality health care and breast cancer clinical trials for all women.

National Cancer Institute - www.cancer.gov (800) 422-6237

is a component of the National Institutes of Health, the federal government's principal agency for cancer research and training. The NCI disseminates health information in regard to the diagnosis, prevention and treatment of cancer and is a good resource for clinical trials.

Nueva Vida - www.nueva-vida.org (202) 223-9100

empowers, informs and supports Latinas who are affected by cancer. Their goal is to advocate for and facilitate access to state-of-the-art care for Latinas while also providing emotional support.

SHARE (Self-help for Women with Breast or Ovarian Cancer) - www.sharecancersupport.org (866) 891-2392

provides peer-led support, information, including availability and access to clinical trials, resources and hope through its multilingual hotlines, support groups, educational programs, survivor patient navigator initiatives and advocacy opportunities through its SHARE LEADERS program.

Sisters Network, Inc. - www.sistersnetworkinc.org (866) 781-1808

is the leading voice and only national African American breast cancer survivorship organization in the U.S. They provide important standardized breast health education program

Young Survival Coalition - www.youngsurvival.org (877) YSC-1011

is dedicated to the concerns and issues unique to young women and breast cancer. Through action, advocacy and awareness, the YSC seeks to educate the medical, research, breast cancer and legislative communities and to persuade them to address breast cancer in women 40 and under.

Zeta Tau Alpha Fraternity - www.zetataualpha.org

for women has supported breast cancer education and awareness as the national philanthropy for its 146 collegiate and 250 alumnae chapters since 1992. ZTA's trademarked "Think Pink" efforts promote early detection through breast self-examinations and mammography.



In 2008, Lifetime enters the 14th year of its award-winning "Stop Breast Cancer for Life" campaign, dedicated to promoting breast health, increasing awareness of breast cancer and sharing with women and families the information and resources they need.

Learn more at www.mylifetime.com.

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