

Feds Cancel Study Comparing Breast Cancer Drugs

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June 20, 2007, 8:21 am
Feds Cancel Study Comparing Breast Cancer Drugs
Posted by Jacob Goldstein

The National Cancer Institute pulled the plug yesterday on a planned \$100 million breast cancer study it initially endorsed, the Washington Post reports. The study would have compared the effectiveness of two drugs ? Eli Lilly?s Evista (known generically as raloxifene) and Novartis?s Femara (letrozole) ? in preventing breast cancer in women at high risk for the disease.

Evista, which is similar to the generic drug tamoxifen, has been shown to reduce the risk of cancer in high-risk women. But it hasn?t been widely used, partly because it can cause menopause-like symptoms, the Post writes. Femara is a member of a newer class of drugs known as aromatase inhibitors, which may be more effective at reducing the risk of breast cancer.

An NCI committee reviewing the study came down against the trial, because of its high cost and because two large studies comparing aromatase inhibitors against placebo are already under way. The committee also suggested that many women might choose not to use aromatase inhibitors even if they were shown to be effective, because they carry risks of their own, including causing brittle bones in some women.

Supporters of the canceled study faulted the decision. They argued it would have been an important tool in determining the best drugs to prevent breast cancer. ?We feel this trial is scientifically valid and one that has the potential to impact the health of thousands of women in this country and around the world,? said D. Lawrence Wickerham of the National Surgical Adjuvant Breast and Bowel Project in Pittsburgh, which was organizing the study.

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Comments

Kudos to NCI decision makers for asking the key question: Will results of the research have a significant impact on decision-making? Looks like they decided that if competing products each prove effective vs. placebo, then there is room in the market for both, based on other patient factors?and relative efficacy won't be as important as those other factors often enough to make the study worthwhile.

Comment by CR – June 20, 2007 at 10:30 am

With the amount of our tax dollars wasted on pointless studies, why not fund something like this that COULD actually do some good?

Really, who cares about the mating habits of field mice, or age of the earth when we have people dying from (hopefully) preventable or curable diseases?

Comment by EEJ – June 20, 2007 at 11:45 am

\$100 million is the amount which can help any African country to stand on its feet.

\$100 million can save thousands of poor with already determined and proven medicines.

I think this is only one of the positive step that NCI has taken. There are numerous high cost studies of similar nature that NCI should be giving a second thought. There are numerous studies out there , which can definitely help human kind in much larger number, that are waiting funding.

Comment by JZ – June 20, 2007 at 12:07 pm

I have had breast cancer. My mother died of breast cancer. My sisters, my nieces, and my granddaughters need a reliable way to reduce their risk of breast cancer. Is \$100 million dollars too much to help us decide which drug is most effective in preventing breast cancer with the fewest side effects? We set priorities every day, spend government dollars every day. To me and to many other women who face breast cancer the P-4 prevention study is a valuable use of those dollars.

Comment by Kate Murphy – June 20, 2007 at 12:20 pm

More chemotherapy is given for breast cancer than for any other form of cancer and there have been more published reports of clinical trials for breast cancer than for any other form of cancer.

According to the National Cancer Institute's official cancer information website on "state of the art" chemotherapy for recurrent or metastatic

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breast cancer, it is unclear whether single-agent chemotherapy or combination chemotherapy is preferable for first-line treatment. At this time, no data support the superiority of any particular regimen. So it would appear that published reports of clinical trials provide precious little in the way of guidance.

Comment by Gregory D. Pawelski – June 20, 2007 at 12:34 pm

As a woman who was a participant in the first two breast cancer chemoprevention trials I feel extremely qualified to voice my opinion of the cancelation of the STELLER Trial. This can only be described as a travesty, nothing short of a national disgrace. The first trial proved the usefulness of tamoxifen with a 48% reduction rate in the expected number of breast cancer in the more than 13,000 high risk participants. The second trial proved that raloxifene had an equal preventative effect with fewer side effects. Given these findings, the NCI is signing the death warrants of millions of women. My maternal grandmother, my grandmother, my mother and all three of her sisters died from breast cancer. My sister and two cousins have by the grace of God survived it. What answers does the NCI have for me???? NCI should be deeply ashamed of itself.

Comment by Olga Lois Wexler, Proud Participant – June 20, 2007 at 1:05 pm

I'm happy for your survival, Olga, but your experience as a survivor does not qualify you to judge the merits of research which a panel of experts have had the courage to name as "not worth it." It is certain that their decision was made in context of knowing they would get flack, which makes it all the more reasonable to assume that they are certain about the uncertain value of the results.

It is important to note, that NOT following through with the study is NOT going to keep anyone from being treated. Rather, the point was to determine if one or the other treatments was so superior that it should be given favor. Ultimately, NCI decided that the trial wouldn't add substantially to the knowledge already available through placebo-controlled studies. That is it.

Comment by CR – June 20, 2007 at 2:14 pm

I would suggest the CR re-read my posting. I am NOT a survivor nor did I claim to be. I have not had breast cancer. I said I was a participant in the first two trials. That said, who better than me to judge the merits. I have directly benefited from the trials. I have made a contribution. Having taken part, having put my life on the line is an act that requires courage.

Comment by Olga Wexler – June 20, 2007 at 3:02 pm

Good move on the NCI. Big Pharma will fund and pay for the research if they believe it is worth it and effective. How do you prove something prevents any cancer when those who participate in the study don't get cancer (breast, prostate, colon, etc.) Just because they are in high risk, they may not have gotten the disease any way. Also people in these kind of studies get continual followup and monitored much more closely than the general public, so precancerous or abnormalities are managed much earlier

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on.

\$100 Million would go a long way to providing mammograms, MRI, etc to women who need them and can't afford them. While these tests do not prevent cancer, done on a regular basis for the right reason find it much earlier, make it much more survivable and have proven to be an effective use of federal funds. When the government spends billions on drug research funding, the big pharma groups get the positive results and positive revenue to the tune of \$billions for little out of pocket expense.

As a wise old pharma CEO once told me, "It is a proven fact that cancer is the leading cause of research?"

Comment by JT – June 20, 2007 at 3:22 pm

Sorry for misinterpreting your trial participation for something else, Olga. Your participation still does not qualify you any more than driving a car qualifies me to judge the merits of road construction projects.

My bigger point here is that testimonials are powerful, and powerfully mis-used. Individual examples of miraculous cures or incredible suffering are important to impart the human element on the analysis of data, but we cannot be ruled by sentiment, no matter how compelling?not when it comes to the investment of public health dollars, for which there is a substantial opportunity cost every time.

Comment by CR – June 20, 2007 at 3:31 pm

CR

So true. I can sleep in the garage but that will not make me a 1967 Mustang Classic.

Comment by JT – June 20, 2007 at 4:02 pm

Well JT and CR both of you should read the Cancer Letter. It seems the head of the NCI, Dr. Neiderhuber did exactly that. He depended upon a breast cancer survivor organization to judge the merits of STELLAR! The science of this trial is sound, live with it. It was peer reviewed and approved and Dr.

Neiderhuber revoked the approval in an unprecedented, never before move. Sound familiar? He is the great decider not unlike another person in the DC area who bends the truth to fit his cause. The NSABP is the same research organization that proved a woman could opt for breast conserving surgery instead of a mastectomy. They have many, many years of quality ethical research in their history; go ahead and check them out at www.nsabp.pitt.edu Saving women's breasts from a research study! What a heresy! Would that you went after tobacco lobbyists the way you attack clinical trial research.

Comment by Olga Wexler – June 20, 2007 at 4:44 pm

I'm sure the NSABP is a capable organization. And, I'm sure that NSABP's researchers were counting on the cancelled project to answer what they believe to be very interesting questions. I'm also sure that the cancellation of the research has NSABP's CFO and member organizations scratching their heads and wondering how they'll adjust for the reduction in revenue.

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The core question that you seem to refuse to address is: Is the money better spent on research that is clearly marginal at best?and apparently not a good enough value to deserve funding? Or, should that money be spent on other research that is of clearer value?perhaps research to prove the efficacy of a new drug, or to substantiate off-label use of an existing treatment for another cancer to improve survival.

There is not bottomless bucket of research money. I'm glad NCI is demonstrating an ability to make tough calls with what we do have.
Comment by CR – June 20, 2007 at 5:01 pm

I am a nurse who enrolled patients in the STAR study who were very relieved that they were doing something to reduce their breast cancer risk. I am also a breast cancer survivor – dx'd at age 39. Granted, nobody wants a premature menopause but absolutely nobody wants breast cancer either. I would much rather deal with hot flashes and bone density tests than to develop breast cancer if I had not already had breast cancer. The more options women of all ages have to reduce their risk, the better.
Comment by RVG – June 21, 2007 at 4:28 pm

Great comments by great people on this page but I do have to say CR is a wise person with some wise knowledge among all others on this blog. CR's points make sense than any other's points. Few of the ladies here are thinking that NCI has forgotten about women & breast cancer prevention and has moved in a completely different direction. Well my dear ladies that's not true ? NCI is always one step ahead in looking for better usage of money. CR is right that NCI board gave a deep thought before making this decision and the thought was given by the best in this field. We should all understand if NCI had million of millions extra in hand they might have not stopped this trial even if it was giving way less output benefit but when the budget is limited than the wise decision makers in NCI board has to find the best use of money for the benefit of all the nation ? and preventing breast cancer is always their first priority. NCI board is all specialized doctors and they know that Prevention is better than cure. I trust NCI and I believe they made this decision for our benefit and we should all trust and respect their decision.
Comment by JZ – June 25, 2007 at 12:57 am