THE CANCER LETTER

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The Marketing of Breast Cancer

Planned Parenthood May Be Doing Harm By Selling Screening To Women Under 40

By Paul Goldberg

The Susan G. Komen for the Cure Foundation and Planned Parenthood may have had their differences over reproductive politics, but they march in lockstep when they overstate the promise of breast cancer screening to young women, a group of experts said to The Cancer Letter.

Much of the controversy over screening mammography is focused on women between the ages of 40 and 49. No responsible health authorities suggest starting to screen earlier, before the age of 40.

Yet, nearly all the women Planned Parenthood serves are in their twenties and thirties—and the health claims these women see on the organization's website go far beyond the evidence-based recommendations of the U.S. Preventive Services Task Force.

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Planned Parenthood touts the promises of screening, even though these claims aren't supported by evidence for women under 40.

In Brief

60 Minutes to Air Story on "Deception at Duke"

CBS's 60 Minutes will air a story Sunday, Feb. 12, at 7 p.m. ET/PT, about Anil Potti, a former Duke University genomic researcher, who had misrepresented his credentials and whose papers are being retracted.

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Komen, Planned Parenthood Share Faith in Screening

(Continued from page 1)

The group's clinical guidelines, which presumably determine what happens in the Planned Parenthood clinics, appear to have been compiled cafeteria-style, combining elements of guidelines used by other organizations and professional societies.

Planned Parenthood's website declares that screening saves lives, a point not proven even in an older population, and prominently features a scary anecdote: a 27-year-old woman identified as Colleen L., of Loudonville, N.Y., discovers a lump in her breast. "There is no doubt in my mind that Planned Parenthood saved my life," Colleen writes in a testimonial.

On the website, Planned Parenthood's top doctor discusses clinical breast exams, breast self-exams and screening mammography in a population that is, by definition, pre-menopausal.

The fact that the data don't provide a solid justification for using clinical breast exams and self-exams to screen in any age group is not mentioned.

In 2010, more than 88 percent of women who relied on Planned Parenthood were 35 and younger, according to a spokesperson. No numbers were provided for the 40-and-above cohort.

The Cancer Letter asked experts in evidence-based medicine to review the information on the Planned Parenthood website, found at: http://www.plannedparenthood.org/health-topics/womens-health/breast-cancer-screenings-21189.htm.

Evaluations by the four experts suggest that Komen's instinct to bar Planned Parenthood from receiving future funding may have been right, albeit for wrong reasons. It would have been appropriate to withdraw the funds because Planned Parenthood apparently fails to discuss the known risks of screening for breast cancer as it promotes screening to young women, whose chances of being harmed could outweigh the chances of seeing a benefit.

These experts are:

• Donald Berry, a biostatistician at M.D. Anderson Cancer Center, who was involved in preparing the USPSTF breast cancer screening guideline.

• Russell Harris, a former USPSTF member and professor of medicine in the Division of General Medicine and Clinical Epidemiology at the University of North Carolina School of Medicine, Chapel Hill, and director of the UNC School of Medicine Program on Prevention in Education and Practice.

• Lisa Schwartz and Steven Woloshin, professors of medicine at Dartmouth Medical School, whose research is focused on communication of medical statistics and information about the benefits and harms of screening and prescription drugs.

Berry notes that the example of the 27-year-old woman who finds a lump in her breast is misleading, because it refers to diagnostic mammography, a setting very different from screening.

"It is far from clear that screening for breast cancer in the context of Planned Parenthood is an appropriate use of Komen's money or Planned Parenthood's time," Berry wrote. "Had Komen chosen to cut funding on this basis and not on the basis of a political agenda, then this would have been a powerful and important statement."

Komen's support for Planned Parenthood added up to about $680,000 last year, when 19 local Planned Parenthood programs received funding from Komen affiliates. According to Planned Parenthood, over the past five years, the Komen money paid for about 170,000 clinical breast exams and 6,400 mammogram referrals.

In 2010, Planned Parenthood saw nearly 2.7 million female clients, providing just under 750,000 breast exams, Vanessa Cullins, Planned Parenthood's vice president of external medical affairs, said in an emailed response to questions from The Cancer Letter.

"We offer a variety of cancer screening and prevention services (i.e., Pap test, HPV vaccines, colonoscopy, etc.), and during 2010, we performed nearly 1.6 million of those procedures and services," Cullins wrote. "Cancer screenings represented nearly

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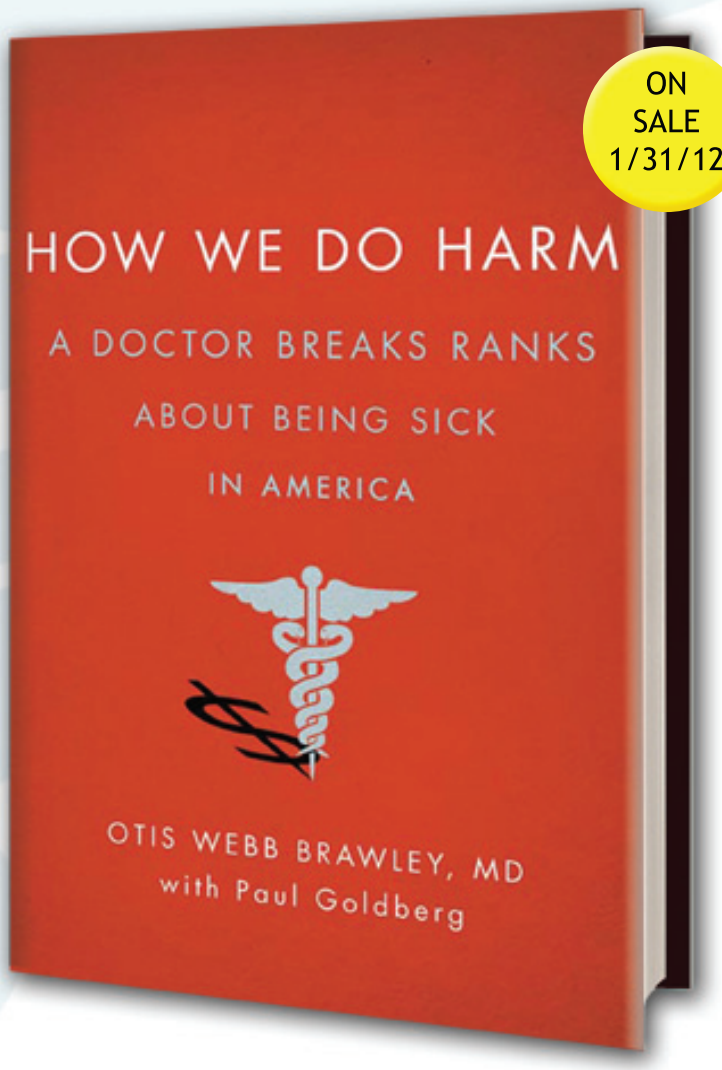
"My friend and colleague Otis Brawley has written a raw and honest portrayal of our health care system. Otis is the go-to oncologist I send so many patients to see, because he is not only a great doctor, but also a compassionate man. As we discuss the transformation of health care in this country, put Dr. Brawley's book at the top of your list."

— Sanjay Gupta, Associate Chief of Neurosurgery Grady Memorial Hospital, Chief Medical Correspondent, CNN



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POWELL'S BOOKS

Dr. Otis Brawley, chief medical and scientific officer of The American Cancer Society, calls for rational healthcare as he pulls back the curtain on how medicine is really practiced in America. In *How We Do Harm*, Brawley tells of doctors who select treatment based on the amount of payment they will receive, rather than on demonstrated scientific results; hospitals and pharmaceutical companies that seek out patients to treat even if they are not actually ill (but as long as their insurance will pay); a public primed to swallow the latest pill, no matter the cost; and rising healthcare costs for unnecessary — and often unproven — treatments.

Passionate and important, this is a startling exposé on the state of medicine, research, and healthcare today.

"Dr. Brawley is a premier academic oncologist and a minority doctor in the nation's largest inner city hospital. He makes the cogent point that more testing, screening, and interventions available to the rich does not always mean better medical care."

— Bruce Chabner, M.D., Director of Clinical Research, Massachusetts General Hospital Cancer Center

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15 percent of our health services in 2010."

Each of the Planned Parenthood affiliates receiving Komen grant money has slightly different terms for the grants, but in some cases the grants cover education and screening, and in others they cover the cost of screening, mammography and diagnostic procedures, Cullins said.

However, Komen was in no position to withdraw funding for solid scientific reasons. This would have required the Dallas-based foundation to examine one of its principal articles of faith: its advocacy of screening, including in women under 40.

For example, in 2009, Komen supported an effort by Rep. Debbie Wasserman Schultz (D-Fla.) to spend $45 million over five years to start education campaigns that would include promoting regular breast self-exams to secondary school students (The Cancer Letter, April 10, 2009).

Though the Centers for Disease Control and Prevention ultimately set up a demonstration project aimed at young women, its reliance on self-exams done monthly was weakened to stress "breast awareness" and knowledge of what normal breasts should feel like.

Komen also spearheaded the outcry against the latest version of the USPSTF guidelines for breast cancer screening, which said that screening mammography should not be done routinely for all women age 40 to 49 years (The Cancer Letter, Nov. 20, Dec. 4, 2009).

In his evaluation, UNC's Harris focused on comparing information on the Komen and Planned Parenthood websites.

"Their emphasis on potential benefits of breast cancer screening, taking a one-side-of-the-coin approach, can only lead to more misinformation, leading to poorer decision making and potentially more and unnecessary harms," Harris wrote. "This is especially worrisome when the majority of women who visit Planned Parenthood are young and more likely to be harmed than helped by screening."

Dartmouth's Schwartz and Woloshin, who are experts in communication of health risks, said they were puzzled by the prominence of breast cancer messages on the Planned Parenthood website in the first place.

"Since it serves such a young population, it is unclear why breast cancer screening has such high prominence on Planned Parenthood's website," Schwartz and Woloshin wrote.

The website's front page reads: "BREAST CANCER SCREENINGS SAVE LIVES—Breast exams help detect breast cancer in its earliest, most treatable stage. Planned Parenthood is here for you."

"The website presents screening the way a screening advocacy group might—persuading women to be screened rather than helping them understand the benefits and harms—an approach at odds with Planned Parenthood's philosophy of 'respect for each individual's right to make informed, independent decisions about health, sex, and family planning,'" Schwartz and Woloshin write.

Cafeteria-Style Screening Guideline?

Planned Parenthood's Cullins said that the guidelines her organization uses combine elements of the guidelines promulgated by other organizations.

"Our guidelines are developed by our medical services department in collaboration with an expert consultant in the field and our national medical committee," Cullins said in an email.

"They are based on the American Cancer Society and the American College of Obstetricians and Gynecologists guidelines, but consideration is also given to the USPSTF, the National Cancer Institute, and the National Comprehensive Cancer Network. We are in agreement with USPSTF when it comes to breast self-exam.

"We have abandoned recommendations for self-breast exams and encourage instead, breast self awareness. This is also consistent with NCCN."

This statement notwithstanding, information on the Planned Parenthood website appears to recommend self-exams. It reads:

"A breast-self exam is similar to a clinical breast exam, except you do it yourself. The technique for performing a breast self-exam has changed over the years. It was once suggested that women perform the entire exam while standing up. But it's now known that it's best for women to lie down for part of the exam. Lying down allows the breast tissue to spread out evenly over the chest. This makes it easier to feel all of the breast tissue.

"Choose a time when your breasts are least tender—usually a few days after your period has ended."

Information on the website also appears to advocate screening mammography for women under 40. For example:

"In some cases, mammograms are helpful for women younger than 40. A mammogram may be recommended for a younger woman with:

• "Family history of early breast cancer,

• "Non-cancerous breast lumps—to make sure cancer is not hidden among harmless cysts."

Experts say that a woman under 40 is at such a low risk of breast cancer that the chances of doing harm are

greater than the chances of detecting clinically significant disease. While a woman with breast lumps may get further radiographic studies—perhaps ultrasound—a woman with a family history of breast cancer would be less likely to be subjected to radiographic screening.

The Cancer Letter asked whether information on the Planned Parenthood website was consistent with the services provided at the organization's clinics, but no answer was received by deadline.

Experts in writing guidelines for early detection say that the idea of combining elements of the guidelines promulgated by other organizations presents methodological problems and, ultimately, subjects healthy people to unreasonable medical interventions.

"The idea of selecting and combining items from different guidelines is fascinating and problematic," said David Ransohoff, a gastroenterologist and clinical epidemiologist at UNC. "While guidelines are supposed to reflect a profession's most refined and rigorous assessment of evidence, the reality in 2012 is that there are hundreds of guidelines-making organizations making thousands of guidelines, and for any one problem, specific guidelines may vary enormously in quality or—to use the concept the Institute of Medicine says—in 'trustworthiness.'

"Selecting from different guidelines-making groups risks being arbitrary and mixing trustworthy with not-trustworthy: if you look hard enough, you may be able to find some guidelines-making group that recommends what you want," Ransohoff said.

"Also, a major organization like Planned Parenthood should consider—for whatever guidelines it uses—explaining to patients something about the balance of benefits vs. harms involved in that screening decision."

The reviews follow:

Donald Berry:

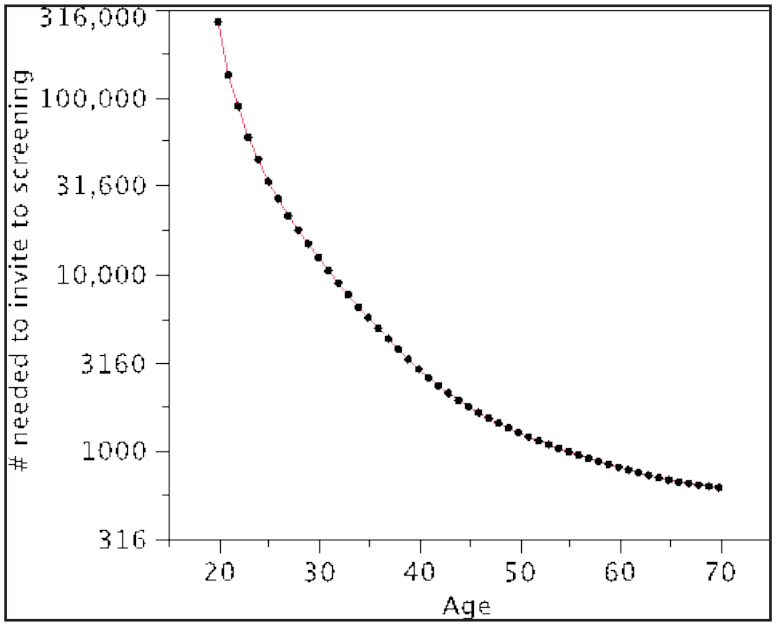
There are many disquieting aspects of the recent brouhaha regarding Komen for the Cure deciding to stop funding Planned Parenthood. First and foremost is the infusion of politics into issues of health policy. But there are others.

A story on the Planned Parenthood website is related by a 27-year old woman who "had no family history" of cancer and who discovered a lump in her breast. She "remembered Planned Parenthood."

Clearly, having access to mammographic and eventually surgical and pathological assessment of her lump was a good thing. But in view of her symptoms the mammogram she got at Planned Parenthood was diagnostic and not screening.

Every woman should have access to diagnostic mammograms, but whether Planned Parenthood is the appropriate place to offer them is less clear.

Regarding screening mammography, women in their twenties and thirties have never been shown to benefit. Indeed, the incidence of breast cancer is so low in this group—with or without screening—that millions and perhaps tens of millions of women would have to be randomized and followed up for extended periods to have any hope of showing a reduction in mortality—if there is one.



A 2009 USPSTF publication indicated that the "number needed to invite for screening to extend one woman's life [is] 1,904 for women aged 40 to 49 years and 1,339 for women aged 50 to 59 years."

Of course there is no abrupt change at age 50 and so these numbers are not constant over their respective intervals. The figure above interpolates within these intervals and extrapolates outside the intervals based on breast cancer incidence in the U.S.

I used a logarithmic scale in the figure because for women in their twenties the number needed to invite is so large.

The USPSTF conclusion that "screening mammography should not be done routinely for all

women age 40 to 49 years" was controversial, and that's putting it mildly. However, the basis of the controversy was never the evidence they used, but how they decided on the cutpoint at age 50.

No one argues for starting mammographic screening before age 40 for women at normal risk of breast cancer. (Well, never say never—essentially no one.) The rub, of course, is that younger women are precisely the ones served by Planned Parenthood.

This is clear from the Planned Parenthood website and other sources. The proportions of women they serve who are older than 40 and older than 50 are less clear. But since few postmenopausal women are planning parenthood(!), I can only surmise that these proportions are small.

The USPSTF chose the cutpoint age of 50 on the basis of weighing harms and benefits. They concluded that "women and their doctors should base the decision to start mammography before age 50 years on the risk for breast cancer and preferences about the benefits and harms."

The Planned Parenthood website uses the work "risk" in lieu of "harm," and this is all Planned Parenthood says on the subject:

"Are There Any Risks to Getting a Mammogram?

"Some women are concerned about their exposure to radiation from the x-ray. But the amount of radiation from a mammogram is very small. Most experts agree that the benefit of finding breast cancer is much more important than the very small risk of being exposed to radiation during a mammogram."

Indeed, radiation is a minor risk. But overtreatment, overdiagnosis, and false positives are major risks—and major harms. Ignoring them in helping women decide whether to get screening is inconsistent with delivering good medical care.

Further evidence that Planned Parenthood advice regarding breast cancer leaves something to be desired is the following from their website: "Breast self-exams are another tool you can use to detect cancer. They can help you know if you have a lump or other change in your breast that you should get checked out."

Breast self-exams have been studied in randomized trials and found wanting. To quote the USPSTF: "Adequate evidence suggests that [breast self-examination] does not reduce breast cancer mortality."

But there is adequate evidence of harm in false positives and overtreatment. And these harms may be greatest in young women. On the basis of evidence this advice from Planned Parenthood does more harm than good. The possibility that it does any good at all is based on hope and whim.

In sum, it is far from clear that screening for breast cancer in the context of Planned Parenthood is an appropriate use of Komen's money or Planned Parenthood's time.

Had Komen chosen to cut funding on this basis and not on the basis of a political agenda, then this would have been a powerful and important statement.

Russell Harris:

Screening in general can be thought of as a coin with two sides.

There are always potential benefits and potential harms. When potential benefits generally outweigh potential harms, and the financial and opportunity costs are reasonable, then screening becomes an individual choice. Unfortunately, many people think of screening as a one-sided coin with only benefits. Breast cancer screening is no exception.

The recent controversy between the Komen Foundation and Planned Parenthood shows how far we have to go in helping people in general (and, in this case, women in particular) to understand both sides of the screening coin. An examination of the Komen and Planned Parenthood websites is enlightening:

● Neither website makes any serious attempt to help women understand that screening is a choice, or that there are real potential harms from screening. The Komen website does (briefly) refer to the U.S. Preventive Services Task Force recommendation, but notes its disagreement.

● Neither website has a good discussion of such important potential harms as the experience of having a false-positive screening test (mentioned briefly in the Komen website), or of the experience of being over-diagnosed and over-treated for a breast cancer (or DCIS) that would never have caused the women an important problem.

● The Planned Parenthood website discusses mammography for women under age 40 years. This is especially worrisome as this is the primary age group that visits Planned Parenthood, and also the group with very low incidence of breast cancer and high probability of false positive mammograms.

● The Planned Parenthood website suggests breast self-exam as "another tool you may use to detect changes in your breasts," going further to say: "you may want to start doing breast self-exams in your 20s." The Komen website does not recommend BSE as a screening tool, although it suggests self-examination as a way to "become familiar with the way your breasts normally

look and feel." The USPSTF correctly cites studies showing the lack of benefit of BSE.

There is much good information on both the Komen and Planned Parenthood websites, and I am a strong supporter of their roles in increasing access to breast and other women's health services.

But their emphasis on potential benefits of breast cancer screening, taking a one-side-of-the-coin approach, can only lead to more misinformation—leading to poorer decision making and potentially more and unnecessary harms.

This is especially worrisome when the majority of women who visit Planned Parenthood are young and more likely to be harmed than helped by screening.

Lisa Schwartz and Steven Woloshin:

"All screening programmes do harm; some do good as well." —Sir Muir Gray, chief knowledge officer of the UK National Health Service.

Breast cancer screening is no exception. But you wouldn't know it based on Planned Parenthood's website.

The website presents screening the way a screening advocacy group might—persuading women to be screened rather than helping them understand the benefits and harms—an approach at odds with Planned Parenthood's philosophy of "respect for each individual's right to make informed, independent decisions about health, sex, and family planning."

Persuading rather than informing is a problem, since no screening modality has been proven to help—and all can cause substantial harm—for the population served by Planned Parenthood, mostly women younger than age 40.

Planned Parenthood doesn't let people know that important organizations call for less aggressive screening, most notably the U.S. Preventive Services Task Force.

The task force recommends against self breast exam, giving it a "D" grade, and says there is insufficient data to recommend for or against clinical breast exam for women of any age, and suggests mammography only for women age 50-74.

Since it serves such a young population, it is unclear why breast cancer screening has such high prominence on Planned Parenthood's website. A large box on the home page reads: "BREAST CANCER SCREENINGS SAVE LIVES—Breast exams help detect breast cancer in its earliest, most treatable stage. Planned Parenthood is here for you."

If the organization wants to help women understand their breast cancer risk and whether screening is right for them, the website should be clear about:

• Which screening modalities—e.g. clinical exams, self exams, and mammograms—are supported by strong evidence for women at various ages?

• What are the important harms of screening, including false positives and overdiagnosis, and how likely are they?

While the site briefly dismisses the risk of radiation and false alarms, there is no mention of the invasive testing—biopsies—that follow after false alarms; or of the most important harm, overdiagnosis.

• Not overstating the benefit. The website includes many stories of young women (younger than 40, many in twenties) who have lumps detected by clinical exam, and gives the sense that these are always curable but would have been deadly otherwise.

• Avoid confusing screening and diagnostic mammograms. The controversy about the balance of the benefit and harms is about screening women who are well, i.e., that do not have a lump or any other symptoms suggestive of breast cancer. Many of the anecdotes are about diagnostic mammograms—testing in women who have a lump.

There is absolutely no controversy that lumps need to be evaluated.

In Brief

60 Minutes Examines Duke Scandal

(Continued from page 1)

According to CBS, Potti's former mentor, Joseph Nevins, now states that the former faculty star had manipulated data.

Two statisticians—Keith Baggerly and Kevin Coombes, both of M.D. Anderson—devoted thousands of hours to verifying Potti's claims. However, Duke officials defended Potti until The Cancer Letter reported irregularities in his credentials (The Cancer Letter, July 10, 2010: http://www.cancerletter.com/articles/20100803_2).

These included an inaccurate claim by Potti that he had been a Rhodes Scholar. Potti's papers have since been retracted by the world's premier medical journals, and Duke is facing malpractice claims from patients who had been enrolled in the university-sponsored trials.

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The Komen Foundation

Komen Board Approved Defunding Planned Parenthood, Handel Says

Karen Handel has resigned from her position as senior vice president for public policy at the Susan G. Komen for the Cure Foundation.

In her letter of resignation, Handel, who once ran for governor of Georgia, said she was not responsible for Komen's decision to make Planned Parenthood ineligible to receive funding from the Dallas-based charity (The Cancer Letter, Feb. 3).

The letter, addressed to Komen founder and CEO Nancy Brinker and dated Feb. 7, states that the decision was approved by the charity's board at its meeting in November 2011. This revelation strengthens the argument that the problems at Komen stem from its governance structure.

The decision to stop funding Planned Parenthood was a public relations disaster for Komen and a bonanza for Planned Parenthood. Immediately afterward, Planned Parenthood set up a Breast Health Emergency Fund, which received $250,000 gift from Amy and Lee Fikes' foundation.

New York City Mayor Michael Bloomberg said he would donate a dollar for every dollar Planned Parenthood raises, up to $250,000, and the Lance Armstrong Foundation gave $100,000 to match Bloomberg's pledge.

Komen reversed its funding decision four days after it was made public.

The text of Handel's letter follows:

Dear Ambassador Brinker:

Susan G. Komen for the Cure has been the recognized leader for more 30 years in the fight against breast cancer here in the US—and increasingly around the world.

As you know, I have always kept Komen's mission and the women we serve as my highest priority—as they have been for the entire organization, the Komen Affiliates, our many supporters and donors, and the entire community of breast cancer survivors. I have carried out my responsibilities faithfully and in line with the Board's objectives and the direction provided by you and Liz.

We can all agree that this is a challenging and deeply unsettling situation for all involved in the fight against breast cancer. However, Komen's decision to change its granting strategy and exit the controversy surrounding Planned Parenthood and its grants was fully vetted by every appropriate level within the organization. At the November Board meeting, the Board received a detailed review of the new model and related criteria. As you will recall, the Board specifically discussed various issues, including the need to protect our mission by ensuring we were not distracted or negatively affected by any other organization's real or perceived challenges. No objections were made to moving forward.

I am deeply disappointed by the gross mischaracterizations of the strategy, its rationale, and my involvement in it. I openly acknowledge my role in the matter and continue to believe our decision was the best one for Komen's future and the women we serve. However, the decision to update our granting model was made before I joined Komen, and the controversy related to Planned Parenthood has long been a concern to the organization. Neither the decision nor the changes themselves were based on anyone's political beliefs or ideology. Rather, both were based on Komen's mission and how to better serve women, as well as a realization of the need to distance Komen from controversy. I believe that Komen, like any other nonprofit organization, has the right and the responsibility to set criteria and highest standards for how and to whom it grants.

What was a thoughtful and thoroughly reviewed decision—one that would have indeed enabled Komen to deliver even greater community impact—has unfortunately been turned into something about politics. This is entirely untrue. This development should sadden us all greatly.

Just as Komen's best interests and the fight against breast cancer have always been foremost in every aspect of my work, so too are these my priorities in coming to the decision to resign effective immediately. While I appreciate your raising a possible severance package, I respectfully decline. It is my most sincere hope that Komen is allowed to now refocus its attention and energies on its mission.

A note from Paul Goldberg, editor and publisher of The Cancer Letter

Dear Reader,

Our coverage of the Susan G. Komen Foundation's decision to stop funding of Planned Parenthood exposes the inner workings of the fundraising juggernaut. This is a panoramic story and we treat it as such.

These are matters everyone in oncology should be aware of. Therefore, I made the decision to make this Special Issue of **The Cancer Letter** available to everyone.

Over the past 38 years, **The Cancer Letter** has broken many a been a story on cancer research and drug development. We have won many an award for investigative journalism.

We give you information you need, coverage you can't get anyplace else. And we promise a page-turner. Week after week. Because the truth is a good read.

Here are some of the other big stories we are tracking:

- **The Cancer Centers: Permanent Reinvention.** The Cancer Letter is running a series of stories that focuses on the cancer centers as they chart their future through 2012 and beyond.

- **The NCI Budgetary Disaster.** Congress is determined to cut spending, and biomedical research will not be spared. The cuts may affect you. We will warn you.

- **Rethinking caBIG.** NCI spent $350 million on this venture in bioinformatics. The Cancer Letter takes a deep dive to examine it. Recently, we published a three-part series on this expensive, controversial project.

- **The Duke Scandal.** We broke it, and now we lead the way in examining the pitfalls and abuses in genomics and personalized medicine. We reported on a falsely claimed Rhodes Scholarship, ultimately causing a cascade of retractions in the world's premier medical journals.

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Yours,

- Paul Goldberg