

THE

CANCER LETTER

PO Box 9905 Washington DC 20016 Telephone 202-362-1809

Vol. 38 No. 5
Feb. 3, 2012

© Copyright 2012 The Cancer Letter Inc.
All rights reserved. Price \$405 Per Year.
To subscribe, call 800-513-7042
or visit www.cancerletter.com.

The Politics of Breast Cancer

The Pink Machine Sputters, Goes in Reverse: Komen Funding Decision Sparks Outrage

By Paul Goldberg

The Susan G. Komen for the Cure Foundation set off a nationwide wave of outrage by telling its affiliates that they would be precluded from funding breast screening at clinics operated by Planned Parenthood.

This change in grant-making guidelines triggered protests from Komen donors and the defiance of some of the local affiliates of the Dallas-based foundation, which stages races to raise money for mammography and breast cancer research.

Within four days of this policy becoming public, the foundation said it would change its grant-making guidelines once again, making it possible for Planned Parenthood to receive funds.

The story of Komen's decision was broken by the Associated Press Jan. 31. The group announced its about-face on Feb. 3. This brief, rapidly burning crisis gave the world an opportunity to examine the workings of the marketing organization that raised \$420.8 million in 2010.

A residual question survives the Komen public relations disaster: How did the foundation happen to make a decision that threatened its very survival?

(Continued to page 2)

Appropriations

FASEB Delivers Its Recommendations For Federal Research Funding in 2013

The Federation of American Societies for Experimental Biology submitted its funding recommendations to the federal government for 2013, saying that the country's current level of investment in research is insufficient.

The federation calls for an appropriation of at least \$32 billion for NIH, to "begin a program of sustainable growth."

The institutes were allocated \$30.6 billion for 2012—a numerical increase over 2011's \$30.4 billion, but in reality a lower funding level when accounting for inflation.

Their report also includes requests for, at minimum: \$7.3 billion for the National Science Foundation, \$5.1 billion for the Department of Energy's Office of Science, \$277 million for the Department of Agriculture's Agriculture and Food Research Initiative, and \$621 million for the Department of Veterans Affairs' Medical and Prosthetic Research Program.

(Continued to page 7)

The Politics of Breast Cancer
Brinker: Decision Not
Driven By Politics

. . . Page 2

Two Internal Komen
Memos Surface

. . . Page 5

Komen's New Funding
Guidelines Not Applied
To Penn State

. . . Page 6

JCO Retracts Potti Paper

. . . Page 7

FDA News

Agency Expands
Gleevec Label in
Gastrointestinal Cancer

. . . Page 9

Corporate Governance At Heart Of Komen's PR Troubles

(Continued from page 1)

Komen didn't stumble into this disaster by accident. It was responding to pressures from the outside—exerted by anti-abortion activists—as well as to pressures from the inside the organization.

Insiders cite internal turmoil that placed an anti-abortion conservative, Karen Handel, into a decisive policy role. The foundation's board of directors didn't object. The New York Times reported that the decision to stop funding Planned Parenthood had full support of the board: <http://www.nytimes.com/2012/02/02/us/uproar-as-komen-foundation-cuts-money-to-planned-parenthood.html?scp=3&sq=Komen&st=cse>.

Komen's preparation to stop funding of Planned Parenthood seemed meticulous. Policies were changed, talking points were drafted, and the staff was briefed.

Ultimately, the story of Komen's near-ungluing is a story about corporate governance. Komen is a special case among high-profile non-profits. Three decades into its history, the organization is still headed by its founder, Nancy Brinker, who serves as the CEO. Its board of directors is relatively small—nine members—including Brinker and her son Eric.

Komen affiliates contribute at least 25 percent of their net annual revenues to the Komen headquarters, documents obtained by The Cancer Letter show. Federal filings of the group's national operation reported total revenues of \$209 million, which means that about half

of the money Komen raises remains under control of the local affiliates.

The move to make Planned Parenthood ineligible for funding created an immediate conflict between the Komen national organization and its 124 affiliates worldwide, which conduct their Races for the Cure and distribute their cut of the proceeds from these events. The Komen affiliation agreements, which were obtained by The Cancer Letter, are posted at <http://www.cancerletter.com/categories/documents>.

Recently, the American Cancer Society abandoned its federation model, which formerly gave autonomy to the society's divisions. A story about the change appeared in the Nov. 18, 2011, issue of The Cancer Letter, posted at http://www.cancerletter.com/articles/20111118_1.

Finally, Komen is one of the few organizations funded mostly through sporting events, which are expensive and inefficient to stage, which is why they are becoming less popular among non-profits.

Insiders in the non-profit world say the Komen model has been working well, creating a fundraising empire and transforming the adjective “pink” into a verb. However, for four days, the pink machine was on the verge of crumbling into a heap.

Brinker: Decision Not Driven by Politics

Changing course in the middle of a PR disaster is never easy, and as the crisis deepened, the Komen organization attempted to stand by its original position.

“We are dismayed and extremely disappointed that actions we have taken to strengthen our granting process have been widely mischaracterized,” Komen officials said in a statement sent to affiliates and posted on its website.

After the story first broke, Brinker released a video to combat what she described as “scurrilous attacks” against her organization.

With tears forming in her eyes, she followed a “talking points” document, presumably unaware that the document has leaked out of her organization: <http://www.youtube.com/watch?v=I4oOh6JhayA>.

The talking points can be found at: <http://www.theatlantic.com/health/archive/2012/02/top-susan-g-komen-official-resigned-over-planned-parenthood-cave-in/252405/>.

In her initial response, Brinker provided no factual rebuttal and refrained from mentioning Planned Parenthood by name.

Meanwhile, the imbroglio triggered millions of conversations in social media outlets, and slapped a “right-wing” label on the group whose survival hinges



® The Cancer Letter is a registered trademark.

Editor & Publisher: Paul Goldberg

Copy Editor: Conor Hale

Editorial, Subscriptions and Customer Service:

202-362-1809 Fax: 202-379-1787

PO Box 9905, Washington DC 20016

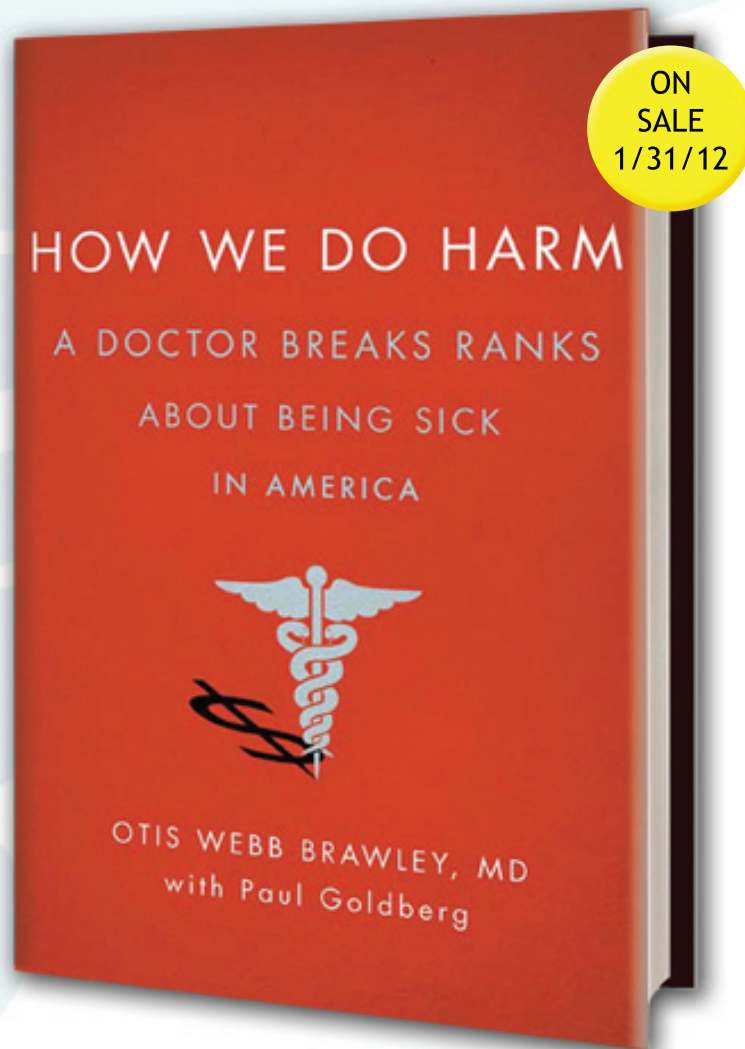
General Information: www.cancerletter.com

Subscription \$405 per year worldwide. ISSN 0096-3917.

Published 46 times a year by The Cancer Letter Inc. Other than "fair use" as specified by U.S. copyright law, none of the content of this publication may be reproduced, stored in a retrieval system, or transmitted in any form (electronic, photocopying, or facsimile) without prior written permission of the publisher. Violators risk criminal penalties and damages. Founded Dec. 21, 1973, by Jerry D. Boyd.

“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



AVAILABLE AT:
AMAZON
BARNES & NOBLE
INDIE BOUND
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

AVAILABLE WHEREVER BOOKS ARE SOLD • ORDER YOUR COPY TODAY

 St. Martin's Press

The Cancer Letter • Feb. 3, 2012
Vol. 38 No. 5 • **Page 3**

on its ability to present breast cancer as a nonpartisan killer.

Though Brinker has never made a secret of her affiliations with the Republican Party and her connections with the Bush family, the organization she built has never been blatantly partisan.

An initial statement by Komen asserted that the decision to stop funding Planned Parenthood wasn't motivated by politics.

The charity has merely changed its grant-making procedures, the organization argued. "We regret that these new policies have impacted some longstanding grantees, such as Planned Parenthood, but want to be absolutely clear that our grant-making decisions are not about politics," the Komen statement said.

The Komen Facebook page at that time was anything but a politics-free zone. People seemed to use the site of the tax-exempt non-profit to wage war over reproductive politics:

Pro-Komen: "Planned Parenthood has been fooling Americans out of tax money for years. It's about time someone stands up. Thank you!!"

Anti-Komen: "As a one-year BC survivor and previous donator, my donations will now go to PP to help poor women who aren't fortunate enough to have access to health care that I have. Bad decision on your part."

It's safe to say that a vast number of Komen's donors don't view the Race for the Cure as a venue for expression of their political views.

Corporations that color their products pink to benefit Komen and themselves are looking for a feel-good venue, not combat.

It's not prudent—and usually not necessary—to alienate someone like Eve Ellis, a financial advisor at Morgan Stanley Smith Barney in New York.

"It is with a heavy heart and an angry mind, that I have raised and donated my last dollar for Komen," Ellis wrote on a website called Jewesses With Attitude. "I served on the Komen Board for 6 years, and Komen has been near and dear to me and our family in our fight against breast cancer. The stand that Komen National has taken on Planned Parenthood is not only misguided, but—contrary to their stated remarks—is political, or at the very least, gives the impression of being political.

"Nancy Komen Brinker, the founder and current head of Komen, is a friend of George and Laura Bush and was an ambassador named by Bush. While I knew this fact in the past, I had always felt that the organization respected its 501(c)(3) status as a non-partisan organization. I no longer believe this.

"Komen surely should become one of those

organizations that any progressive stays far away from—if we truly believe that breast cancer affects women on both sides of the aisle and that the possibilities for cures should extend across the aisle as well. I know we will all find other ways to fight breast cancer together to end this terrible disease."

Association with Komen was always intended to make everyone feel good, except perhaps the sticklers for accuracy in communication of epidemiology, who point out that the group consistently overstates the benefits of screening.

Consider Brinker's message on the Komen website:

"We have come a long way in our fight. When we started, the five-year survival rate was just 74 percent when breast cancer was diagnosed before it spread beyond the breast. Today, that survival rate is 98 percent... We are so close to creating a world without breast cancer. The science is there."

While this message may inspire people to run races and buy pink products, anyone familiar with the fundamentals of epidemiology knows that five-year survival is not a reliable metric of effectiveness of screening in breast cancer. When you look at cause-specific mortality, the case for screening isn't a clear win, especially for younger women.

Such claims persist even though the foundation's overselling of screening has been noted repeatedly, most recently in a profile of the organization in The New York Times: <http://www.nytimes.com/2011/10/16/business/in-the-breast-cancer-fight-the-pinking-of-america.html?pagewanted=all>.

Anyone familiar with the state of the science would have to acknowledge that the cure for all breast cancer isn't imminent. Brinker's optimism notwithstanding, the science isn't here.

Advertise your meetings and recruitments

In The Cancer Letter and The Clinical Cancer Letter
Find more information at: www.cancerletter.com

INSTITUTIONAL PLANS

allow everyone in your organization to read
The Cancer Letter and The Clinical Cancer Letter.

Find subscription plans by clicking Join Now at:
<http://www.cancerletter.com/>

No Accident: Deliberate Actions Lead to Crisis

Komen's structure is akin to a restaurant chain, where franchise-holders are allowed to display the brand as long as they adhere to stringent criteria.

Local affiliates are specifically precluded from funding research—proposals for research grants are reviewed centrally—but other than that, the money is raised and spent locally.

Altogether, 19 local Planned Parenthood programs received funding from Komen affiliates.

This money didn't pay for abortions, Planned Parenthood said.

Indeed, abortions account for about 3 percent of services performed at its clinics. According to the organization, over the past five years, Komen money paid for about 170,000 clinical breast exams and 6,400 mammogram referrals. Altogether, Komen support added up to about \$680,000.

Meanwhile, Komen has been under pressure from anti-abortion groups over funding stem cell research.

The foundation responded to that accusation last November, placing a statement on its website stating that it doesn't support research that involves the destruction of human embryos.

"Komen supports research on the isolation, derivation, production, and testing of stem cells that are capable of producing all or almost all of the cell types of the developing body and may result in improved understanding of or treatments for breast cancer, but are derived without creating a human embryo or destroying a human embryo," the statement read.

Last December, a group called LifeWay Christian Resources recalled its pink version of the Bible after learning that Komen, a beneficiary of the sales, supported Planned Parenthood.

"The sign might as well read, 'Buy a Bible and support abortion!'" proclaimed an editorial on a website called LifeNews: <http://www.lifenews.com/2011/12/12/sales-of-new-bible-help-planned-parenthood-funding-komen/>.

However, changes were occurring within the Komen organization. Many staff members were replaced.

Late last year, the organization hired Karen Handel, an unsuccessful Republican candidate for governor of Georgia. Some insiders said that Handel, who serves as senior vice president for public policy, set a new tone for the organization.

Handel has stated publicly that she is opposed to abortion.

Two Komen Memos Surface

Jeffrey Goldberg, a writer with The Atlantic, obtained two Komen memos that were distributed in preparation for the shift.

One of the memos, from Elizabeth Thompson, the organization's president, describes new criteria for awarding grants:

"In order to align the terms of the grant contract with our grant eligibility criteria and to ensure that our granting meets the highest standards, several important updates will become effective January 1, 2012. Specifically:

"Currently, a Komen grant may be terminated if, among other things, the grantee loses or changes its tax exempt status, is barred from receiving federal or state funds, or if we learn of any financial and/or administrative improprieties. Going forward, these same standards will now also be used in determining eligibility for Komen grants.

"Further, should Komen become aware that an applicant or its affiliates are under formal investigation for financial or administrative improprieties by local, state or federal authorities, the applicant will be ineligible to receive a grant. An organization may regain its eligibility once the investigation is concluded if the organization and its related affiliates are cleared of any wrongdoing."

There are many varieties of investigations, and Congressional investigations are a special case. No wrongdoing is required for a committee to launch a probe, and many such probes are launched for the sole purpose of scoring a political point.

That change in grant-making policies made it possible for Komen to declare Planned Parenthood ineligible to receive grants. As it happens, on Sept. 15, 2011, Rep. Cliff Stearns (R-Fla.), chairman of the House Committee on Energy and Commerce Subcommittee on Oversight and Investigations, launched a probe of Planned Parenthood.

It's not publically known whether Stearns and Komen officials had ever coordinated their efforts. They didn't have to. A letter in which Stearns requests documents from Planned Parenthood is posted at <http://republicans.energycommerce.house.gov/Media/file/Letters/091511%20Stearns%20to%20Planned%20Parenthood.pdf>.

Even as they were changing their grant-making policies, Komen officials said that they weren't motivated by political considerations.

Atlantic's Goldberg also obtained the "talking points" that Komen distributed to its employees in

preparation for changing the grant eligibility criteria. The memo, written in a Q&A format, states:

“Q(uestion) 7: Is Komen giving into pressure from the Catholic Church/anti-abortion groups/the political right in making this change?”

“A(nswer) 7: Komen’s decision to fund ANY grant is based on our mission priorities, a thorough community assessment, and strict eligibility and performance standards. Our granting criteria reflect our dedication to our mission and our consistent effort to invest our donors’ dollars responsibly in support of our efforts to end breast cancer.

“Q8: Planned Parenthood provides health services in many of the nation’s poorest communities. How does your new policy align with your mission of serving women who lack resources to pay for important breast health services?”

“A8: Susan G. Komen is deeply committed to providing breast health services to women throughout the U.S. It is our belief that where a woman lives should not determine whether she lives. Komen provided funds for 700,000 breast screenings last year alone, and provided financial and social support to another 100,000 women, as part of our \$93 million investment in education, public health outreach and service to vulnerable women last year alone. That work will continue. We believe these new standards will further enhance the integrity of our granting process and strengthen our overall community health program.”

The decision to stop funding Planned Parenthood caused Komen official Mollie Williams, managing director of community-health programs, to resign in protest, Goldberg reported.

His story is posted at <http://www.theatlantic.com/jeffrey-goldberg/>.

Komen’s restrictions had some unintended consequences, which were noted by the magazine Mother Jones.

The foundation gave \$7.5 million to the Penn State Milton S. Hershey Medical Center and two other institutions to study combination of low-dose antiestrogens with omega-3 fatty acids for prevention of hormone-independent breast cancer.

Penn State is the subject of a federal investigation over the sexual assault scandal involving former assistant coach Jerry Sandusky, indicted on multiple counts of sexual abuse of children.

Follow us on Twitter: @TheCancerLetter

Komen’s About-Face

Now it appears that Komen will alter its policy to ensure that only organizations found guilty in a criminal investigation would be ineligible for funding.

This would mean that the foundation will restore funding to Planned Parenthood for breast cancer screenings, announced Sen. Frank Lautenberg (D-N.J.), who, along with Sen. Patty Murray (D-Wash.), led a group of 26 senators in urging Brinker to reconsider her organization’s decision.

“With these changes to their policy, Susan G. Komen for the Cure is depoliticizing its grant-making process and refocusing itself back on its core mission: saving women’s lives,” Lautenberg said in a statement.

“The Komen Foundation is too critical to the fight against breast cancer to give up on, and I hope to see all women’s health groups put politics aside and again work together on their shared missions. I am pleased that critical funding will be allowed to flow from the Komen Foundation to Planned Parenthood and to any organization that helps further the fight against breast cancer.”

At the same time, Komen posted a statement in which it apologized for its “recent decisions,” still denying that they were politically motivated: “We want to apologize to the American public for recent decisions that cast doubt upon our commitment to our mission of saving women’s lives.

“The events of this week have been deeply unsettling for our supporters, partners and friends and all of us at Susan G. Komen. We have been distressed at the presumption that the changes made to our funding criteria were done for political reasons or to specifically penalize Planned Parenthood. They were not.

“Our original desire was to fulfill our fiduciary duty to our donors by not funding grant applications made by organizations under investigation. We will amend the criteria to make clear that disqualifying investigations must be criminal and conclusive in nature and not political. That is what is right and fair.

“Our only goal for our granting process is to support women and families in the fight against breast cancer. Amending our criteria will ensure that politics has no place in our grant process. We will continue to fund existing grants, including those of Planned Parenthood, and preserve their eligibility to apply for future grants, while maintaining the ability of our affiliates to make funding decisions that meet the needs of their communities.

“It is our hope and we believe it is time for everyone involved to pause, slow down and reflect

on how grants can most effectively and directly be administered without controversies that hurt the cause of women. We urge everyone who has participated in this conversation across the country over the last few days to help us move past this issue. We do not want our mission marred or affected by politics—anyone’s politics.

“Starting this afternoon, we will have calls with our network and key supporters to refocus our attention on our mission and get back to doing our work. We ask for the public’s understanding and patience as we gather our Komen affiliates from around the country to determine how to move forward in the best interests of the women and people we serve.

“We extend our deepest thanks for the outpouring of support we have received from so many in the past few days and we sincerely hope that these changes will be welcomed by those who have expressed their concern.”

Donations Surge to Planned Parenthood

In the end, Komen’s PR disaster likely benefited Planned Parenthood.

Planned Parenthood set up a Breast Health Emergency Fund, which received \$250,000 gift from Amy and Lee Fikes’ foundation. New York Mayor Michael Bloomberg said he would donate a dollar for every dollar Planned Parenthood raises, up to \$250,000.

“Politics have no place in health care,” Bloomberg said in a statement. “Breast cancer screening saves lives and hundreds of thousands of women rely on Planned Parenthood for access to care. We should be helping women access that care, not placing barriers in their way.”

The decision is causing a shakeup on a local level, as several officials at Komen affiliates have resigned in protest.

All seven California officials issued a statement that they opposed the decision to stop funding Planned Parenthood. Their statement is posted at http://www.washingtonpost.com/blogs/ezra-klein/post/seven-california-komen-affiliates-oppose-defunding-planned-parenthood/2012/02/02/gIQAncMJlQ_blog.html.

A tweet a Komen's Oregon affiliate read: "Komen Oregon OPPOSES Headquarters' Decision...<http://fb.me/1fYoAjxu6>."

Another tweet continued: "This policy compromises Affiliates' ability to provide access to screening and treatment for women greatest in need. #KomenOregonOpposes."

Officials at some affiliates were perusing section 9

of their affiliation agreements with the Komen national organization:

"Remedies for Affiliate Breach; Suspension/Revocation of Affiliate Charter; Dissolution of Affiliate."

The affiliation agreements can be found at <http://www.cancerletter.com/documents>.

Appropriations **FASEB Calls For \$2 Billion Increase In NIH Funding**

(Continued from page 1)

“As other nations ramp up their investments in R&D, it would be very costly to cede our leadership in critical areas of science and technology,” said Joseph LaManna, president of FASEB.

“We recognize that these are difficult economic times. Nonetheless, it remains abundantly clear that research-based innovation has dramatically improved the quality of life for billions of people, and that our best hope for future progress remains a strong commitment to science and technology.”

FASEB’s recommendation cites a report from the Department of Commerce, The Competitive and Innovative Capacity of the U.S., which said that: “federal support for basic research has not kept pace with the growth of the economy, the education system has not done a good enough job preparing students to become skilled workers, and the nation’s infrastructure has not kept up with growing needs of the U.S. population and U.S. businesses.”

The federation’s recommendation highlights NIH research into less invasive cancer treatments—using light therapy to selectively destroy cancer cells in mice—as research with great potential.

The president plans to submit his 2013 budget request to Congress February 13.

FASEB’s recommendation can be found at <http://bit.ly/xinCKm>.

INSTITUTIONAL PLANS

allow everyone in your organization to read
The Cancer Letter and The Clinical Cancer Letter.

Find subscription plans by clicking Join Now at:

<http://www.cancerletter.com/>

Journal of Clinical Oncology Retracts Second Potti Paper

The Journal of Clinical Oncology retracted another paper co-written by former Duke University researcher Anil Potti and his mentor Joseph Nevins.

The article, “An Integrated Genomic-Based Approach to Individualized Treatment of Patients with Advanced-Stage Ovarian Cancer” (J Clin Oncol 25:517-525, 2007), was retracted because a majority of the paper’s authors felt they had “identified several instances of misalignment of genomic and clinical outcome data.”

The authors said that a reanalysis of the correctly aligned data was still able to predict patient response using genomic data, but that accuracy declines to 72.2 percent, from 77.8 percent.

The decision to retract was not unanimous. Potti and Nevins agreed with the retraction decision.

Papers based on this genomic research have been retracted in The New England Journal of Medicine, Nature Medicine, The Lancet Oncology, PLoS ONE and Blood. JCO had retracted another paper in late 2010.

Duke officials have said that they expect more retractions in the future (The Cancer Letter, Sept. 9, 2011).

The text of the retraction follows:

“An Integrated Genomic-Based Approach to Individualized Treatment of Patients With Advanced-Stage Ovarian Cancer” by Holly K. Dressman, Andrew Berchuck, Gina Chan, Jun Zhai, Andrea Bild, Robyn Sayer, Janiel Cragun, Jennifer Clarke, Regina S. Whitaker, LiHua Li, Jonathan Gray, Jeffrey Marks, Geoffrey S. Ginsburg, Anil Potti, Mike West, Joseph R. Nevins, and Johnathan M. Lancaster (J Clin Oncol 25:517-525, 2007)

The majority of the authors wish to retract this article because they have identified several instances of misalignment of genomic and clinical outcome data. Although a reanalysis of correctly aligned data still demonstrated a capacity to predict patient response

to platinum -based therapy, the accuracy of these predictions has been reduced from 77.8% to 72.2%, and as a result, the original conclusions have been compromised. The authors deeply regret the impact of this action on the work of other investigators.

The following authors agreed with this retraction decision: Andrew Berchuck, Gina Chan, Janiel Cragun, Holly K. Dressman, Geoffrey S. Ginsburg, Jonathan Gray, Johnathan M. Lancaster, Jeffrey Marks, Joseph R. Nevins, Anil Potti, Mike West, and Regina S. Whitaker.

The following authors disagreed with this retraction decision: Andrea Bild, Jennifer Clarke, LiHua Li, and Jun Zhai.

The following author could not be reached for comment: Robyn Sayer.

This article was retracted on Jan. 27, 2012.

95% of Surveyed Oncologists Affected by Drug Shortages

Nearly half of surveyed oncologists reported grave consequences due to drug shortages, with 95 percent reporting delays in treatment and 85 percent saying they have had patients who were unable to receive the best treatment altogether.

At the same time, many oncologists were optimistic about advancements in cancer therapy, but doubted that patients would be able to afford the high costs.

Nearly half of those surveyed, 48 percent, felt their patients’ tumor recurrence was due to drug shortages, and 40 percent felt their patients died sooner.

Fifty percent of the oncologists surveyed expected to see these trends continue—and only 14 percent felt the trend would be reversed.

The survey, conducted by National Analysts Worldwide, polled 204 U.S. oncologists, and said that 71 percent see a professional future that is less personally and professionally satisfying, and 65 percent said they felt that there would be a shortage of oncologists in the coming decades.

Nearly eight in 10 oncologists reported having treated patients with what they believe is suboptimal therapy due to lack of health insurance, with 73 percent said they treated patients with something short of the most effective therapy due to patient inability to afford drug co-payments.

Meanwhile, over 80 percent of these oncologists expressed optimism about new drug discoveries, advancements in understanding the biology of cancer and were hopeful about tailored anti-tumor therapies. Unfortunately, 70 percent felt that these new treatments

Advertise your meetings and recruitments

In The Cancer Letter and The Clinical Cancer Letter
Find more information at: www.cancerletter.com

Follow us on Twitter: @TheCancerLetter

would be affordable for patients.

“There has been much concern about drug shortages but these findings confirm some of our worst fears,” said Susan Schwartz McDonald, president and CEO of National Analysts Worldwide and a lead researcher on the survey. “At a time when important advances promise new hope in many forms of cancer, chronic drug shortages and reduced access to care threaten to undermine our ability to combat disease.”

“Oncologists foresee fewer physicians, more drug shortages, and an increasing inability to pay for care. These trends will be converging at a time when we already know there will be more older patients—and more cancer patients—than ever before,” said co-investigator Debra Kossman, senior vice president of National Analysts Worldwide.

FDA News

Agency Expands Gleevec Label To Include Rare GIST Subset

FDA approved Gleevec for expanded use in patients with a rare subset of gastrointestinal stromal tumor.

FDA granted Gleevec (imatinib) regular approval for use in adult patients following surgical removal of CD117-positive gastrointestinal stromal tumors.

Clinical data from a large, randomized clinical study comparing 12 to 36 months of Gleevec showed that 36 months of the drug significantly prolonged overall survival and progression-free survival.

At 60 months, 92 percent of patients who received 36 months of Gleevec were alive, compared to 82 percent of patients who received 12 months of Gleevec.

“The development of Gleevec over the past decade highlights the need to further study drugs after approval to truly characterize their benefits,” said Richard Pazdur, director of the Office of Hematology and Oncology Products in the FDA’s Center for Drug Evaluation and Research. “Although originally approved in the metastatic disease setting, this subsequent trial has demonstrated that longer use of Gleevec can prolong patient’s lives in earlier disease settings.”

Gleevec was originally granted accelerated approval in 2002 for the treatment of advanced or metastatic GIST. In 2008, Gleevec received accelerated approval for the adjuvant treatment of patients with GIST who had potentially curative resection of tumors,

but were at increased risk of recurrence. Regular approval for the metastatic GIST indication was also granted in 2008.

Gleevec was first approved in 2001 to treat patients with advanced, Philadelphia chromosome-positive, chronic myeloid leukemia. Gleevec is marketed by Novartis Pharmaceuticals Corp.

* * *

FDA and industry representatives reached an agreement in principle on recommendations for the third reauthorization of a medical device user fee program.

The proposed recommendations would authorize FDA to collect \$595 million in user fees over five years, plus adjustments for inflation. The details of the agreement are expected to be finalized soon, according to a statement from FDA. The current Medical Device User Fee Act of 2007 is set to expire Sept. 30.

The agreement comes after a year of negotiations between the agency and the industry. With the additional funding, FDA plans to hire over 200 full-time equivalent works by the end of the program, and the agency expects that the agreement will result in a reduction in average total review times.

FDA says the agreement would result in greater accountability, predictability and transparency, and would include improvements such as a more structured pre-submission process and earlier interactions between the agency and applicants.

The industry associations who have reached an agreement in principle with the FDA include the Advanced Medical Technology Association, the Medical Device Manufacturers Association and the Medical Imaging and Technology Alliance.

Once the final details of the agreement are completed, FDA will present a package of proposed recommendations for public comment, before submitting them to Congress for approval. The date of the public meeting has yet to be determined.

INSTITUTIONAL PLANS

allow everyone in your organization to read
The Cancer Letter and The Clinical Cancer Letter.

Find subscription plans by clicking Join Now at:

<http://www.cancerletter.com/>

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, most recently in The New England Journal of Medicine.

Give **The Cancer Letter** a try.
You will benefit from our experience
and expertise.

Check out our Public section
for a look inside each issue at:
<http://www.cancerletter.com>

Yours,



- Paul Goldberg