

THE

CANCER LETTER

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

Vol. 39 No. 9
March 1, 2013

© Copyright 2013 The Cancer Letter Inc.
All rights reserved. Price \$405 Per Year.
To subscribe, call 800-513-7042
or visit www.cancerletter.com.

Cancer Communications: The Cost

NCI Spent \$381.2 Million on PR from 2006-2012, Vastly Outspending Other NIH, FDA Units

By Paul Goldberg

NCI's spending on public relations dramatically exceeds that of any other NIH institute or center, data obtained by The Cancer Letter under the Freedom of Information Act show.

The cancer institute spent \$44.9 million on PR in fiscal 2012, employing 83.5 full-time staff members—FTEs in governmentspeak—to conduct various educational and outreach work at the Office of Communications and Education.

This number of FTEs is more than fourfold the PR workforce of the NIH Office of the Director. Yet, the NCI office also has 77 contract employees, some of them working part-time (The Cancer Letter, [Dec. 7, 2012](#)). The next largest PR office at NIH—the NIH The Office of the Director has 19.5 FTEs and no contract employees.

Documents show that, cumulatively, NCI has spent \$381.2 million on its PR operations between 2006, the year OCE was formed, and 2012. None of this spending was subjected to peer review.

(Continued to page 2)

Guest Editorial

Thoughts on Overusing Radiation in Medicine And Redeeming that Whole Body Scan Coupon

By Robert Peter Gale, Eric Lax, and F. Owen Hoffman

Wilhelm Röntgen's discovery of X-rays in 1895 was a transforming event in science and medicine.

Physicians now use various forms of ionizing radiations including light and heavy particles (protons, electrons, alpha particles, etc.), high-energy electromagnetic waves (X- and gamma rays composed of photons of diverse energies) and radionuclides (Iodine-131, Cobalt-60, Technetium-99m, etc.) to screen, diagnose, stage and treat cancers.

(Continued to page 5)

In Brief

Friedman to Retire as CEO of City of Hope

MICHAEL FRIEDMAN said he plans to retire from his role as CEO of City of Hope at the end of the year.

Friedman, who will turn 70 in August, has been at City of Hope since 2003. Robert Stone, the institution's current president, will assume the dual role of president and CEO.

(Continued to page 7)

The Cost

NCI PR Workforce
Outnumbers the NIH
Office of the Director
Four-to-One

... Page 3

OCE Budget Shrinks,
But Personnel Costs
Remain Constant

... Page 4

FDA Approvals

Avastin Combination
Approved For Metastatic
Colorectal Cancer

... Page 8

Obituaries

Christine Ann Brunswick, 60
John R. Johnson, 78
Jane Cooke Wright, 93

... Page 9

NCI PR Spending in the Range Of Controversial caBIG Venture

(Continued from page 1)

This level of spending—and the absence of outside scientific oversight—places the institute's PR into the same range as the now defunct caBIG bioinformatics program, which spent about \$350 million over eight years, before encountering scrutiny by NCI advisors in 2011 (The Cancer Letter, [March 18, 2011](#)).

The NCI bioinformatics program was trimmed to about \$33 million in 2012, and is now about \$12 million lower than OCE. In another common element, OCE and caBIG have relied heavily on consulting firms, awarding multi-million-dollar contracts for projects that exceeded the capabilities of government employees.

NCI Director Harold Varmus has been trying to cut back many of the pet projects he inherited from his predecessors. Having chopped down caBIG, he appears to have focused on the institute's PR operations. For this purpose, Varmus has revived a subcommittee of the National Cancer Advisory Board to review this vast enterprise. (The Cancer Letter, [Dec. 7, 2012](#)).

The NCAB subcommittee, which hasn't met since 2008, now promises to complete a report for the June 25 meeting of NCAB. NCI is in a rush to make the cuts in order to carve out money for research at a time of unprecedented fiscal pressure exacerbated by the looming threat of sequestration, which at this writing is scheduled to start March 1.

The National Cancer Act of 1971 mandates NCI

to conduct educational activities aimed at doctors and the public, and for a quarter of a century no one raised questions about adequacy of the institute's modest PR shop.

Explosive growth of the institute's PR functions appeared to have occurred in the late 1990s.

NIH institutes and centers don't categorize or track PR and educational activities in a uniform manner. However, it is clear that other NIH institutes have significantly smaller PR operations than NCI:

- The National Institute of Allergy and Infectious Diseases, which runs HIV/AIDS research programs, has 18 FTEs working in PR, NIH documents show.
- The National Heart Lung and Blood Institute has eight FTEs.
- The National Institute of Diabetes and Digestive and Kidney Diseases has seven.

NCI's spending on PR is nearly double that of the FDA's, an agency with a vast regulatory portfolio and a life-and-death need to reach the American public.

At FDA, the Office of External Affairs, which supports the entire agency, has an annual budget of less than \$12 million. Its Center for Drug Evaluation and Research's Office of Communications has the budget of just over \$13 million, which covers both salaries and operations.

These FDA offices are responsible for running consumer education, outreach to consumers and health care professionals, website and social media, internal communications, and drug safety announcements. These activities cover all of medicine, as well as food and tobacco.

High Pay, Low Attrition

OCE's job is to publish and mail out brochures, run the institute's websites, including the Director's Page, operate a call center, carry out forays into social media and organize NCI exhibits at meetings of professional societies.

The office also manages the NCI Physician Data Query database, an acclaimed resource that nonetheless accounts for a relatively small part of the budget, at \$3.8 million.

Until recently, it published a newsletter called the NCI Cancer Bulletin (The Cancer Letter, [Feb. 1](#)).

The nearly \$44.9 million price tag doesn't include either the institute's modest-sized press office, the PR work performed at the institute's divisions, or peer-reviewed research that involves communications.

As OCE's mandates changed and overall expenditures decreased, the staff levels have remained

THE CANCER LETTER

® The Cancer Letter is a registered trademark.

Editor & Publisher: Paul Goldberg

Associate Editor: Conor Hale

Reporter: Matthew Bin Han Ong

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.

constant.

“When you extract the personnel budget from our total budget, our operations budget is under \$31 million,” OCE Director Lenora Johnson said to the newly-reactivated subcommittee of the National Cancer Advisory Board at a meeting Feb. 7.

Even as NCI’s PR activities contracted, the staff members get reassigned.

For example, when the institute stopped publishing its newsletter, the NCI Cancer Bulletin, the four or more FTEs were moved to other jobs at the office.

“We have not hired in just about 2.5 years, and so with people retiring and attrition, we probably will see some reductions in the actual personnel budget,”

Johnson said to the NCAB subcommittee. “But right now that has been a static figure, and the operations budget has continued to go down.”

Compensation that would be considered generous by the standards of the private sector could explain the low attrition at OCE.

Here, the example of the NCI Cancer Bulletin is noteworthy, because it makes it possible to compare the compensation of NCI employees tasked to function as journalists with compensation of journalists working for top-level, bona fide independent publications.

The Bulletin’s four staff members earned between \$112,774 and \$129,758 a year, documents obtained by The Cancer Letter show.

Many senior reporters who cover Washington—including NIH and FDA—for premier national publications earn salaries of \$80,000 or less, with some earning as little as \$50,000, reporters say.

According to [the pay scale of the Independent Association of Publishers’ Employees](#), which represents the staff members of Dow Jones & Co., a “senior reporter” who has worked at a Dow Jones publication for three or more years earns at least \$69,395.

A “senior special writer” with three years of experience at the paper can have a salary as low as \$99,751.

Information obtained by The Cancer Letter shows that 87 people are employed at OCE, and 63 of them earn salaries above \$100,000. Of that group, 34 earn more than \$115,000.

Altogether, the office employs 23 health advisors

and health educators.

There are also 20 individuals described as writers, editors, content specialists and communications specialists. Program analysts, science analysts and program specialists account for 17 more staff members. Public affairs specialists are another big category; there are 14.

	FTEs	Contract Staff	Contract Dollars Spent
NCI OCE	83.5	77 (incl. part-time)	\$16,600,000
OD/OCPL	19.5	0	\$85,000
NIAID	18	5	\$3,040,170
NHLBI	8	3	\$7,032,678
NIDDK	7	0	\$661,876
NIGMS	4.6	2.7	\$859,541

How NCI's Office of Communication and Education compares with the five other NIH units that have the largest PR spending. (Source: NIH)

OCE Provided Millions for Contractors

Over the years, a succession of NCI directors amalgamated OCE into its current, massive structure. There were seven realignments between 1998 and 2007. Through most of that time, the office didn’t have a permanent director.

“None of these changes were informed by an independent, outside review by nationally recognized experts in communication,” a subcommittee of the NCI Executive Committee found in 2006. The subcommittee report is posted at <http://www.cancerletter.com/categories/documents>.

A 2007 review by MITRE Corp., a consulting firm, found that the office had “an unclear mission and undefined strategic priorities.”

According to the report, which wasn’t intended to be released to the public, “the core mission of OCE is unclear to managers and staff, as well as [NCI divisions, offices and centers] stockholders, which has considerable impact on day-to-day operations.

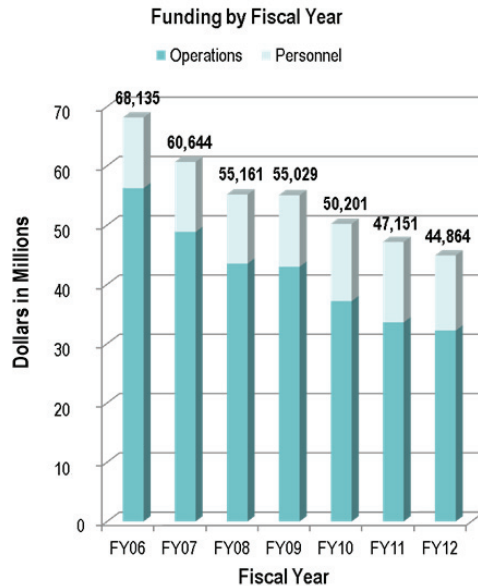
The report continues:

“Without clear overarching guidance, OCE managers have no framework for triaging requests for support or prioritizing and allocating resources. OCE, therefore, has taken on new work that has led to added responsibilities, ‘mission creep,’ and increasingly constrained resources.”

Notably, the MITRE report, [also posted on The Cancer Letter website](#), doesn’t recommend consulting an outside advisory board like NCAB.

With every reorganization, the components of the

Budget History



Overall FY2012 budget just under \$45M (25+% in personnel)

OCE Operations Budget: \$30.6M

79 Total FTEs

As NCI PR budget shrinks, personnel costs and FTEs remain unchanged.

Source: A presentation by OCE Director Lenora Johnson before the NCAB communications subcommittee, Feb. 7, 2013.

communications office brought in their FTEs and their outside contractors.

"It got so it was almost routine to move offices and change and restructure, and I can't say why that was," Johnson said at the recent NCAB subcommittee meeting.

"The last time this subcommittee [of NCAB] met was in 2008, which is when I started. I think we probably at that time had 70 or 80 contracts. And through simply consolidating contracts, letting contracts expire and getting rid of a lot of contracts and minimizing the amounts of contracts, we saved an enormous amount of resources.

"Sometimes, there were several contracts for the types of supportive services that were for the same type of service, so rather than have two or three contracts for communications support, we are now down to one contract," Johnson said. "And some of it was pure redundancy."

Documents obtained by The Cancer Letter show that in 2007, OCE's allocation for grants and contracts stood at \$42.7 million. Total spending that year was \$59.4 million.

In fiscal 2012, the sum of \$16.6 million was committed to grants and contracts. In 2011, allocation for grants and contracts stood at \$18.7 million.

At the subcommittee meeting, Robert Croyle, director of the NCI Division of Cancer Control and Population Sciences, said the turnover of NCI directors has contributed to a rapid change in communications priorities.

The NCI director, like the NIH director, is appointed by the president. The president does not appoint any other institute directors.

"There was a question earlier about the timeline and all the complexities of three, four, five reorganizations," said Croyle, whose division funds peer-reviewed research that includes cancer education and communications.

"One of the reasons for that and why there is more of this than you see at other institutes is our institute director turns over more often than at other NIH institutes, so this diagram reflects four different NCI directors, all of whom had very different priorities and very different strategies about communications.

"So one of the challenges of this institute is when there is a change in leadership, sometimes the mission and the priorities for communication in the organization change substantially, and that leads to reorganization, the staffing changes, programs being scaled up and scales down," Croyle said.

"Our communications organization has been whipsawed back and forth as these priorities change."

Guest Editorial

Does Increased Exposure To Radiation Justify the Risk?

(Continued from page 1)

Examples include mammograms, X-rays, computed tomography and positron emission tomography scans—and radionuclide studies such as thyroid, bone and liver/spleen scans. These procedures save thousands of lives every day. But, like every technology, there is the risk of adverse effects when it is used improperly or inappropriately.

In this context, we are wise to recall the comment of Röntgen's wife Anna Bertha, who said when shown the first X-ray film of her hand: "I have seen my death!"

Everyone is exposed to ionizing radiations every day. About one-half of our average annual exposure of 6.2 millisieverts comes from natural sources, and the remainder from man-made sources. Natural sources of radiation include radon in our homes; terrestrial sources such as rocks, buildings, countertops, and the like; the cosmos, including our Sun; and other humans—we are all slightly radioactive because we contain radionuclides such as Potassium-40, Thorium-232, and Uranium-238, which we ingest or inhale from the environment.

The 3.2 mSv from man-made sources includes consumer products—smoke detectors and exit signs are examples—and the nuclear fuel cycle. However, these man-made sources contribute only about 2 percent of the man-made dose.

Most readers will be surprised, shocked or horrified to learn almost our entire man-made radiation dose comes from us—your physicians.

This is a six-fold increase from the early 1980s. For example, estimated numbers of diagnostic imaging studies in the U.S. in 2012 exceeded 80 million and nuclear medicine procedures exceeded 20 million.

CT scans are the major contributor to our man-made radiation dose. For example, there were about 50 CT scans per 1,000 U.S. residents in 1996, versus about 150 in 2010, a three-fold increase. In many parts of the country, it is virtually impossible to leave the emergency department without a CT scan; some call it the new physical exam.

In considering these data, it is important to acknowledge differences in the nature of the exposed population and between the types of radiations. The entire U.S. population is exposed to background radiations (at different doses, depending on where you live, your lifestyle, etc.) and the type of radiation is mostly high-energy gamma-rays and high-energy

particles.

Persons exposed to medical radiations are generally older, more often male, and the type of radiation is mostly low-energy X-rays composed of photons.

However, a substantial volume of CT scans are done in children for headaches, seizure and abdominal pain. Also, there is some concern, based mainly on biological rather than epidemiological data, that exposure to X-rays may result in a somewhat higher risk of cancer in later life than the same exposure from high-energy gamma rays—the type of exposure received during the 1945 atomic bombings of Japan, from which most radiation cancer risk estimates are obtained.

Many lives are saved by oncologists' use of diagnostic imaging procedures using ionizing radiations. The issue is whether this striking increase in average radiation exposure from these procedures is important and whether the benefits accrued by exposing the population to more ionizing radiations from these procedures exceeds the risks incurred.

Exposures to ionizing radiations are a cause of cancer. Data supporting this come from many epidemiological in persons exposed to high-dose radiations. What is less certain is whether low radiation doses have the same risk per unit of dose of causing cancer as the risk per unit dose received at high doses.

The linear, no-threshold hypothesis, accepted by most scientific bodies and regulatory agencies and supported by considerable experimental and epidemiological data, assumes very small doses will have a proportionately smaller risk of causing cancer compared with the risk observed in populations exposed at much higher doses.

It means that any excess radiation dose we expose people to, no matter how small, increases their cancer-risk in proportion to the dose received.

Many of us do not know the average radiation dose of common diagnostic radiology procedures.

For example, the average CT-PET scan exposes a person to about 12-32 mSv. At the upper end, this is a 10-fold greater than our average annual radiation dose of 3.2 mSv. A whole body spiral CT scan can expose someone to 10-100 mSv. (That's where the whole body scan coupon comes in.)

A person having a few CT-PET scans during the course of diagnosis, staging and therapy-evaluation of cancer would receive a radiation dose comparable to a Japanese A-bomb survivor.

As a rough calculation (with admittedly many assumptions), exposure of a 30-year-old adult to 12.5

mSv results in an excess lifetime cancer risk of about less than one to a few chances per 1,000 persons exposed. If the average American receives an extra annual radiation dose of 3 mSv from diagnostic medical procedures and lives 80 years, he or she will receive an extra 240 mSv.

We roughly estimate about 10 to 60 excess cancers per 1,000 exposed persons over their lifetimes. There are 314 million Americans alive today so we might expect about three to almost 19 million cancers for the current U.S. population over the next 80 years. However, this estimate of radiation-induced cancer must be judged against larger number of lives saved, current uncertainty about effects of low-dose radiation exposures, and the background cancer rate which will be about 150 million.

In many instances, these studies are needed to diagnose and accurately stage cancers and direct therapy or prevent ineffective or unneeded therapy. Here, benefits of radiation exposure will exceed the excess cancer-risk.

However, in other instances, estimated to be between 30-50 percent, some or all of these studies provide little useful data including data which will not affect a person's care or might result in harm. Here, the risks of excess radiation likely exceed the benefits.

The message is clear: before ordering a diagnostic radiology study, it is important we carefully weigh potential benefits and risks. Even when the procedure is justified, it should be optimized to expose a person to the lowest radiation dose reasonably achievable.

If we accept the notion that every excess radiation exposure proportionally increases cancer risk according to the amount of dose received, the next question is what is the magnitude compared to other everyday risks?

The answer to this question can make the risk seem enormous or trivial. For example, the radiation dose from an average whole body CT scan (12 mSv) is about 40,000 times greater than the dose of ionizing radiation from an airport X-ray backscatter screening device (about 0.00025 mSv). People worried about airport screening radiation should not fly at all—they will get about the same radiation dose while flying for two minutes at an altitude of 10,000 m.

We need to recall that the lifetime cancer risk of the average 50-year-old American male, presently without cancer, is about 50 percent. A conventional chest CT exposes a 30-year-old person to about 7 mSv. This is equivalent to a cancer-risk of less than one chance per 1000, about the same as that risk from smoking 100 cigarettes (not recommended), or from eating a few thousand peanut butter sandwiches (which contain aflatoxin).

And there are other possible harms of diagnostic

radiological studies which need to be carefully evaluated besides the increase in cancer-risk. Consider the current controversy over screening mammograms. The dose, about 0.13 mSv, is 100-fold less than a whole body CT scan.

Although a detailed discussion of this complex issue is beyond the scope of this editorial, almost everyone is aware of the uncertainty over the benefit-to-risk ratio of beginning screening mammograms at different ages.

More perplexing are reports from several large studies showing no reduction in breast cancer deaths despite increased detection of early breast cancers. This paradox forces us to re-think the widely accepted but unproven notion that early cancer detection must save lives.

And mammograms and breast cancer are not the only controversial area: PSA screening for prostate cancer comes immediately to mind.

For reference, the radiation dose from three low-dose spiral CT scans used for lung cancer screening is 6 mSv. Added to this is radiation from diagnostic imaging procedures using ionizing radiations triggered by false positive findings which brings the estimated dose to about 8 mSv per person screened. For a 50-year-old adult male, this translates to an excess lifetime risk of radiation induced cancer of about 0.3 to 1.3 chances per 1,000 persons screened.

Because of this, and in contrast to mammogram screening of normal women, lung cancer screening is recommended (by some) only in persons at increased cancer-risk and under special conditions altering the benefit to-risk ratio.

There are extraordinary differences in perception of risk from radiation exposures of comparable magnitude from different sources. Many people, including physicians, are somewhere between concerned and terrified of exposure to ionizing radiations from a nuclear accident, such as Chernobyl or Fukushima-Daiichi.

However, the average radiation dose to the evacuated population in the former Soviet Union was about 30 mSv over 25 years, with about 10 mSv to persons living in contaminated lands. The average dose to people in the Fukushima prefecture will be less than 10 mSv over their lifetime, and probably less than 1-2 mSv.

These doses are much lower and the cancer-risk much less than the average American will get from diagnostic medical procedures over the next 50 years. Also, the same concerned people usually do not hesitate to have a CT scan—sometimes they insist on it.

We obviously need a public education program on this subject.

Gale is a visiting professor in the Section of Haematology of the Imperial College in London. Lax is a writer in Los Angeles. Their book, Radiation. What It Is, What You Need to Know, was published by Alfred A. Knopf. Hoffman is president of the SENES Oak Ridge Center for Risk Analysis, and is an expert in radiation risk assessment.

In Brief

Michael Friedman to Retire As CEO of City of Hope

(Continued from page 1)

“Appreciating my responsibilities and the impact of my role at City of Hope, I began planning for this transition three years ago,” Friedman wrote in a letter to the staff. “I concluded that new times call for new leadership and that this centennial year is the right time for my transition. You may wonder at my choice of this time to do so when City of Hope has never been so strong and successful, our future so promising and bright.

“That is precisely the point—this is the single best moment to do so. While my engagement and commitment to City of Hope are as strong as ever, I believe that new executive leadership will help us achieve even more.”

During Friedman’s decade in the top job at City of Hope, the institution has grown:

- The number of patients treated increased from 15,000 to 24,000 per year.
- The amount of grant support rose from \$50 million to \$79 million.
- The annual budget rose from \$350 million to \$1.1 billion.
- The endowment went up from \$221 million to \$1.26 billion.
- The number of staff members went up from 2,700 to 4,250.
- The facilities grew more than 1 million square feet.
- A non-profit City of Hope Medical Foundation was created to partner with the physicians (The Cancer Letter, [June 3, 2011](#)).

The physician practice at City of Hope was previously run by a for-profit practice.

Prior to becoming president last year, Stone was the founding leader of the City of Hope Medical Foundation. As chief strategy and administrative officer,

Stone recently led the creation and development of the organization’s ten-year strategic plan. He also previously served as City of Hope’s general counsel and secretary. Friedman is a former acting commissioner of the FDA.

He came to City of Hope from his job as senior vice president of research and development, medical and public policy, for Pharmacia Corp. In addition, he served as chief medical officer for biomedical preparedness at the Pharmaceutical Research and Manufacturers of America following the events of Sept. 11, 2001.

Before FDA, Friedman worked at the NCI Division of Cancer Treatment, rising to the position of associate director of the division’s Cancer Therapy Evaluation Program. Prior to that, he directed the clinical oncology programs at University of California, San Francisco.

ELKE MARKERT joined **The Cancer Institute of New Jersey** and its Center for Systems Biology.

Markert was most recently at the Simons Center for Systems Biology at the Institute for Advanced Study in Princeton. She was an assistant professor of medicine in the Division of Medical Oncology at UMDNJ-Robert Wood Johnson Medical School.

Markert also will continue her work as a co-investigator on a project examining embryonic stem cell expression profiles and their impact on prognosis and treatment of prostate cancer.

ST. JUDE CHILDREN’S RESEARCH HOSPITAL raised more than \$72 million through their ninth annual **St. Jude Thanks and Giving** campaign.

The holiday campaign’s results represent a projected increase of nearly 14 percent over the previous year. The campaign has now raised more than \$380 million for St. Jude since its inception.

St. Jude’s corporate partners, which include more than 60 companies, raised more than \$60 million this year, an increase of more than 12 percent from last year.

The funds and awareness raised by this year’s campaign were boosted by an increased focus on emerging media and strong digital engagement. Donations from online, mobile and offline channels grew by 40 percent over the previous year, while online efforts alone grew by 63 percent.

St. Jude’s Spanish-language website, hospitalsanjudas.org, saw an increase in donations of 99.6 percent from last year.

Follow us on Twitter: @TheCancerLetter

FDA Approvals

Avastin Combination Approved For Metastatic Colorectal Cancer

FDA approved Avastin in combination with fluoropyrimidine-based irinotecan or oxaliplatin chemotherapy for patients with metastatic colorectal cancer.

The new indication will allow patients who received Avastin (bevacizumab) plus an irinotecan or oxaliplatin containing chemotherapy as an initial treatment for mCRC to continue to receive Avastin plus a different irinotecan or oxaliplatin containing chemotherapy as their second-line treatment.

Avastin in combination with fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin based chemotherapy is now indicated for the second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line Avastin containing regimen.

The approval is based on positive results from the phase III ML18147 trial, which were presented at the 2012 American Society of Clinical Oncology annual meeting and showed that people who continued to receive an Avastin-based regimen after their cancer worsened lived longer than people who switched to chemotherapy alone.

Median overall survival was 11.2 months compared to 9.8 months. The risk of death was reduced by 19 percent for people who received Avastin in combination with standard chemotherapy in both the first- and second-line compared to those who received chemotherapy alone (HR=0.81, p=0.0057).

Median progression-free survival was 5.7 months compared to 4.1 months. The risk of the cancer worsening or death was reduced by 32 percent (HR=0.68, p<0.0001). Overall survival and PFS were calculated from the time patients were randomized to the second-line treatment.

Avastin is the only biologic medicine approved by the FDA to treat people with mCRC in combination with intravenous 5FU-based chemotherapy as an initial treatment, as treatment for people whose cancer worsened after chemotherapy alone, and now as a treatment for people whose cancer has worsened after initial treatment with an Avastin-based regimen. Avastin is not indicated for adjuvant treatment of colon cancer.

Avastin is sponsored by Genentech, a member of the Roche Group.

FDA approved Stivarga tablets to treat patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor who have been previously treated with imatinib mesylate and sunitinib malate.

The approval of Stivarga (regorafenib) in GIST is based on data from a phase III trial, GRID, which showed that Stivarga plus best supportive care statistically significantly improved progression-free survival compared to placebo (HR=0.27 [95% CI 0.19-0.39], p<0.0001).

The median PFS was 4.8 months in the Stivarga arm versus 0.9 months in the placebo arm (p<0.0001). There was no statistically significant difference in overall survival at the time of the planned interim analysis based on 29 percent of the total events for the final analysis. At the time of disease progression as assessed by central review, the study blind was broken and all patients were offered the opportunity to take Stivarga at the investigator's discretion. Fifty-six (85 percent) patients randomized to placebo and 41 (31 percent) patients randomized to Stivarga received open-label Stivarga.

Stivarga is an inhibitor of multiple kinases involved in normal cellular functions and oncogenesis, tumor angiogenesis, and maintenance of the tumor microenvironment.

The most frequently observed adverse drug reactions in Stivarga-treated patients were hand-foot skin reaction, hypertension, fatigue, diarrhea, mucositis, dysphonia, infection, decreased appetite and food intake, and rash.

Stivarga was approved by the FDA in September 2012 for the treatment of patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy.

Stivarga is a Bayer compound promoted by Bayer and Onyx in the U.S. Stivarga was developed under the Fast Track program and received priority review designations for GIST and mCRC from the FDA.

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>

Obituaries

Christine Ann Brunswick, 60, Co-Founder of the NBCC

Christine Ann Brunswick, vice president and one of the founders of the National Breast Cancer Coalition, died on Feb. 25. She had breast and cervical cancers.

Brunswick served as vice president of the coalition from 1991 to the present. She was 60.

She served on numerous national and international panels, including the Department of Defense Breast Cancer Research Program and was a delegate to the 1995 United Nation's Beijing Women's Conference.

She was well known as an activist and leader advocating for breast cancer research policies and funding and testified before several congressional committees.

In an email to NBCC members, the organization's president, Fran Visco, wrote:

"I first met Chris when I testified in 1992 before the Senate Appropriations Committee. She had already signed on to NBCC and was in the audience for support. We talked about how we had to empower women and men across the country to speak out for our cause.

"Chris had a more than full-time job as Executive Director of the Tax Section of the American Bar Association, and mother of a then 13-year-old son, Daniel. But she was always there for NBCC, believing without question in our mission. She wanted to bring her ferocious self to NBCC because, as she often said, she knew we would make a real difference.

"I want to share with you just some of the many things Chris did as a volunteer with NBCC. She was the embodiment of NBCC advocacy – she knew the science, she knew public policy and she knew and cherished grassroots power. Chris represented us on many committees and panels, from the DOD Breast Cancer Research Program to the Institute of Medicine. She loved to travel and cared a great deal about bringing our message around the globe. She was NBCC's delegate to the 1995 UN Beijing Women's Conference, to any number of various breast cancer science and advocacy meetings in numerous countries, and to our international Project LEAD courses. She left a trail of friends everywhere.

"Chris spent many days walking the halls of Congress on our behalf, leading teams of advocates, taking the lead on complex issues, debating with Senators and Representatives. All with one focus: to end breast cancer. She testified before several

Congressional committees and before the FDA in support of our agenda. Chris was often in the media, both print and broadcast, representing NBCC. I recall so many of those appearances, especially when she was the lone voice on our side of a controversial issue. But she had the intelligence, the grace and the courage to stand up to all of them.

"We will miss her greatly."

Brunswick was the executive director of the ABA Tax Section for 25 years and recipient of the ABA Tax Section's 2013 Distinguished Service Award.

Brunswick was born in Iron River, Mich., and was a graduate of Michigan State University.

Survivors include her son Daniel, mother Tillie, sister JoAnn Koenig, brothers Mark and Michael, and many nieces, nephews, great nieces, and great nephews.

In lieu of flowers, donations can be made to: The National Breast Cancer Coalition, Chris Brunswick Fund, 1101 17th Street NW, Suite 1300, Washington, D.C. 20036.

John R. Johnson, 78, FDA Medical Officer

John R. Johnson, a medical officer at FDA, died on Dec. 20, 2012. He was 78.

A surgeon by training, Johnson was a federal employee for 41 years.

Johnson was born in Ohio and moved to the Washington, D.C., area in 1979 to join the FDA as a medical officer. He was rapidly promoted to group leader (equivalent to the current position of Medical Team Leader) in the Oncology Branch and maintained that position through reorganizations of the oncology drug review group.

Colleagues noted Johnson's ability to identify the essential issues in complex programs, his prodigious institutional memory and his dry wit.

"John has served as a mentor to many of the oncologists and hematologists throughout the FDA," said Richard Pazdur, director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "He has made an enduring and lasting impression on the agency and cancer drug development."

Johnson co-authored multiple articles clarifying the FDA's approach to the review of drugs for the treatment of cancer and provided substantial contributions to all FDA guidances on cancer drug development in the past 30 years. He has also co-

authored 20 articles on individual drug approvals.

Early in his FDA career, Johnson was recognized for his exceptional contributions to FDA's mission through the FDA's Commendable Service Award (1986); the FDA Commissioner's Special Citation for leadership in implementation of the Treatment IND regulation and the Bush Initiative (1989); and the FDA's Award of Merit for assuring rapid access to effective drugs for patients with life-threatening diseases, including cancer (1991).

Johnson has also been recognized for his contributions to enhancing FDA review activities and processes. He was awarded the FDA's Commendable Service Award for creative and effective use of Oncologic Drug Advisory Committee members in end-of-Phase II meetings for life-saving cancer drugs (1994) and CDER's Special Recognition Award for developing and implementing a program to identify and evaluate endpoints for approval in colorectal and lung cancer (2004).

In 2005, Johnson received the Dr. Frances O. Kelsey Drug Safety Excellence Award for the recognition, evaluation and resolution of complicated safety issues for Zometa (zoledronic acid).

He also was given the FDA's Scientific Achievement Award for Excellence in Review Science for the Finasteride and Dutasteride Review Team in 2012, in addition to other awards for individual drug review.

Jane Cooke Wright, 93, Co-Founder of ASCO

Jane Cooke Wright, one of the seven founders of the American Society of Clinical Oncology, died Feb. 19. She was 93.

Wright, the only woman among ASCO's founders, served as the society's secretary/treasurer.

Wright graduated with honors from New York Medical College in 1945, interned at Bellevue Hospital, and completed her residency at Harlem Hospital. Following residency, she continued on as a visiting physician at Harlem Hospital and was also hired as a staff physician with the New York City Public Schools. ASCO's CEO Allen Lichter reported Wright's death in one of the society's publications.

At a time when chemotherapy treatment was

largely thought of as experimental, Wright pioneered the use of anticancer agents and developed new techniques for administering cancer chemotherapy. In 1949, she left the New York City Public School system to work with her father, who served as the director of the Cancer Research Foundation at Harlem Hospital. Together, the two began testing a new agent on human leukemias and lymphomas, with some success. Several years later, Wright began her work at the New York University Medical Center as the Director of Cancer Chemotherapy Research.

In 1964, President Lyndon B. Johnson appointed Wright to the President's Commission on Heart Disease, Cancer, and Stroke. That same year, in Chicago, seven oncologists, including Wright, assembled for lunch in the Edgewater Beach Hotel. This diverse group of physicians—who shared an interest in the fledgling field of cancer chemotherapy with greater patient-related orientation—recognized the need for the creation of a separate society dedicated to issues unique to clinical oncology. It was the very first meeting of ASCO.

From 1964 to 1967, Wright served as the secretary/treasurer of the newly formed society. Together, the seven founding members developed a strong purpose and vision for ASCO, establishing the need for new methods to approaching the treatment of people with cancer. Much of their early meetings and discussions provided the framework for the Society's current activities. During Wright's tenure, membership of the Society grew to 175 members, and nearly every year since 1964, Wright has attended what we know today as the ASCO Annual Meeting.

At a time when African-American women physicians numbered only a few hundred in the United States, she was the highest ranked African-American woman at a nationally recognized medical institution. She was not only a pioneer in the field of cancer research and treatment, but also a leader, opening minds and doors for those who would follow after her.

In 2011, ASCO and the Conquer Cancer Foundation formally recognized Wright's contributions to the field of oncology through the creation of the Jane C. Wright, MD, Young Investigator Award. Donations in her memory can be made to the [Jane C. Wright, MD, Conquer Cancer Foundation of ASCO Young Investigator Award](#).