THE CANCER LETTER

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SPECIAL ISSUE

The Cancer Centers: Permanent Reinvention

McGivney Out at NCCN as Board Cites Management Style, Strategic Direction

This is the first installment in a series of articles that will examine the fundamental challenges to the cancer centers as they chart their future beyond 2012. The series begins with an in-depth look at the National Comprehensive Cancer Network, a non-profit umbrella group formed by America's leading cancer centers as they struggled against another set of challenges two decades ago.

By Paul Goldberg

After 15 years as CEO of the National Comprehensive Cancer Network, William McGivney "is no longer with NCCN," the nonprofit that publishes widely used cancer treatment and detection guidelines announced to its board members last week.

The drama that led to the departure of 59-year-old McGivney played out on the level of the executive committee of the NCCN board, and the rest of the board's 21 members received a sheet of "talking points" announcing the parting of ways.

"After considerable research and careful deliberation by the executive committee of NCCN, Bill McGivney is no longer with NCCN, as of Dec. 27, 2011," the group said in the document, which was obtained by The Cancer Letter.

"This change resulted from differences in opinion about management style and the strategic direction for the organization."

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Guest Editorial

Consensus of Experts No Longer Enough; ACS Revises Process for Making Guidelines

By Otis W. Brawley

The time when a small group of experts can meet and in short order develop rigorous medical guidelines is coming to an end.

Some guidelines have been appropriately criticized because the experts can be affected by prejudice as well as by emotional and financial conflicts of interest. A lack of transparency in forming a guideline can also weakened trust.

For several decades, the American Cancer Society has been a respected leader in publishing highly credible and useful cancer screening guidelines. These guidelines have been of interest to primary care providers, specialists, insurers and the lay public.

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McGivney's Successor Will Be a Physician

(Continued from page 1)

The talking points were distributed Jan. 5. The executive committee said it will look for a physician to replace McGivney, a former insurance company executive with a PhD in pharmacology. NCCN produces guidelines and a compendium used by the government and private insurers to determine which cancer drugs should be reimbursed.

McGivney's departure comes at a time when unrestricted funds from the pharmaceutical industry are becoming less plentiful, setting the limits for growth of the organization that reported $25.5 million in income in 2009, the most recent year for which tax filings are publicly available.

This was a $4.3 million drop from the $29.8 million the organization raised in 2008. Tax documents show that in 2009, NCCN spent $3.4 million more than it raised.

The tax documents also show that the organization—originally formed to promulgate the standards of care at a handful of comprehensive cancer centers, by drawing on cancer center experts to formulate practice guidelines—receives only a small portion of its revenues from the centers.

Overall, membership dues paid by the centers in 2009 added up to just $1.9 million, while all other contributions, including the funds given by pharmaceutical and other health care companies, were more than ten times that amount—at $20.5 million.

Sources said that NCCN has been losing money on its operations as it continued to expand. McGivney apparently insisted on growing the organization's international programs, which the board didn't want to do, sources said.

Fundamental Role In Cancer Care

NCCN was founded to pursue three goals:

• Market cancer centers to national and international employers and insurers.

• Issue practice guidelines in oncology, demonstrating how care is provided at cancer centers.

• Provide outcome measures to demonstrate that care at cancer centers is superior to care in the community.

Goal No. 1 was found to be unfeasible and abandoned early in the group's history.

Goal No. 3 is tough to attain. There is still no data to demonstrate conclusively that cancer centers produce superior outcomes.

However, the second goal—guideline-making—has been attained, making NCCN one of the most influential organizations in oncology. (An examination of the history of NCCN appears on p. 4, and supplemental documents and audio files are posted at http://www.cancerletter.com/categories/documents).

"We look to them as an organization to provide state-of-the-art recommendations about what is best practice," said Lee Newcomer, senior vice president of oncology, genetics and women's health at UnitedHealthcare. "They bring together people who are respected and put out documents that say this is probably best practice, based on the literature today."

NCCN convenes meetings of leading experts from cancer centers and gives them the charge to hash out the details. This is different from evidence-based guidelines, which are heavier on pre-specified process and usually include comprehensive reviews of evidence. Guideline-making organizations exclude specialists who stand to gain from performing the medical services in question.

"The process is closed, and that's always been one of its faults," Newcomer said to The Cancer Letter. "It's a consensus process, and therefore not perfect, but it is probably the best available today. It's good that someone's doing it."

UnitedHealthcare is among the payers who subscribe to the NCCN guidelines updates.

"The NCCN compendium and the guidelines allow us to launch appeals of preauthorization denials and coverage denials for care for complex and life-

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threatening diseases," said Nancy Davenport-Ennis, CEO of the Patient Advocate Foundation.

The Centers for Medicare and Medicaid Services uses the NCCN compendium, which is based on the practice guidelines, to determine appropriateness of medically-accepted indications of drugs and biologicals used off-label in an anti-cancer chemotherapeutic regimen.

If a therapy is listed by NCCN, it gets paid for. It's as simple as that.

"This is Bill's insurance background: he often said that one of the things that drives insurance companies crazy is they don't ever want to get into courtrooms about whether Mrs. Jones should get X," said Robert Young, former director of Fox Chase Cancer Center, who served as chairman of the NCCN board from 1997 to 2001.

"[Insurers] learned their lesson with bone marrow transplants," Young said. "Basically, what many—if not most—of the major insurers that cover oncology have done is said, 'Look, we are not going to make any decisions about this. We are going to [rely on] a third-party entity that has a great system for analyzing what state of the art care is, and if they say it should be covered, we will cover it. And if they say it shouldn't be covered, we won't cover it.'

"And, basically, CMS has done the same thing; for a different reason, I think," Young said. "They don't have to worry so much about ending up in court. It's just easier for them to say, 'Look, this is a recognized organization with state of the art guidelines, and whatever they are willing to cover, we will cover.'"

Critics say that the NCCN process for writing guidelines is skewed toward finding that cancer drugs should be available, pointing more broadly toward bias in expert-based guidelines.

For example, the NCCN cancer screening guidelines are generally more likely than the evidence-based guidelines of the U.S. Preventive Services Task Force to advocate screening. One example is screening for prostate cancer.

In the treatment arena, NCCN steadfastly and dramatically stood by its recommendation to continue to use the Genentech drug Avastin (bevacizumab) in metastatic breast cancer just as FDA was removing that indication.

Since Avastin remains in the NCCN compendium, the Centers for Medicare and Medicaid Services will have to continue to cover its off-label use in breast cancer. A National Coverage Decision by CMS would be required to bar coverage.

"I think this where the process isn't as transparent as we would all like to see, because they obviously still recommend Avastin for breast cancer, yet in a very similar set of facts for ovarian cancer they do not recommend Avastin," said UnitedHealthcare's Newcomer.

Newcomer blames the consensus-seeking dynamic that can occur in a closed meeting. "It would come out with different results, depending on who is in the room," he said.

Members of the expert guideline-writing panels are as knowledgeable as members of the FDA Oncologic Drugs Advisory Committee, yet they often come up with different recommendations.

"The time when a small group of experts could meet and, in short order, develop rigorous medical guidelines, is coming to an end," said Otis Brawley, chief medical and scientific officer of the American Cancer Society, which recently changed its guideline-writing process. "Some guidelines have been appropriately criticized because the experts can be affected by prejudice as well as by emotional and financial conflicts of interest. A lack of transparency in forming a guideline can also weaken trust."

Brawley's guest editorial appears on p. 1.

Over the years, the NCCN Guidelines and Drugs and Biologics Compendium have been enormously influential with both practitioners and payers," said Gregory Curt, outgoing industry representative on ODAC and the U.S. Group Leader at AstraZeneca Oncology. "However, as the world turns, it may be turning more towards evidence-based medicine with less reliance expert opinion-based medicine."

NCCN leaders accepted these limitations knowingly.

If anything, NCCN panel members are better qualified than members of ODAC to make decisions on drug use, said Young.

"Unfortunately, ODAC has increasingly become a victim of the passion for absolute absence of conflict of interest," Young said. "And so ODAC is increasingly populated by people who are not involved on the front line of many of these clinical trials, and they often have committees where their expertise is not in breast cancer; it's in lymphomas, or in urologic cancers.

"The beauty of having 20 people decide is that it

tends to dilute any specific conflict of interest."

The decision to keep Avastin in the compendium for metastatic breast cancer was reasonable, Young said.

"These are all people who are not theoreticians," he said. "These are people who treat breast cancer on a day-to-day-basis. And I think that despite the FDA decision, they are convinced that there is clearly a benefit for some subset of patients, and, unfortunately, they can't define the subset that frequently responds.

"So they are willing to leave it as a guideline."

The Talking Points

McGivney declined to speak with The Cancer Letter, and NCCN officials said they wouldn't be able to discuss the matter by deadline.

According to tax documents, McGivney earned $668,000 in compensation in 2009.

By way of comparison, the American Society of Clinical Oncology—which had revenues of $74.9 million in 2009—paid its CEO, Allen Lichter, a total of $833,266.

The American Association for Cancer Research took in $64.6 million that year, and paid CEO Margaret Foti $590,448. In 2010, the American Cancer Society raised $956.2 million, and its CEO John Seffrin earned $2.2 million, which included a $1.5 million bonus, federal filings show.

NCCN board members were notified about McGivney's departure on Jan. 5, nine days after it occurred.

"As requested by [chair of the NCCN board Thomas] Dr. D'Amico [of Duke University], I am attaching talking points that you may find helpful as you discuss Bill McGivney's departure from NCCN with your colleagues," wrote Patricia Goldsmith, executive vice president and chief operating officer, in an email to the board members.

Goldsmith will run NCCN while a search committee seeks to identify McGivney's successor.

The talking points follow:

• After considerable research and careful deliberation by the Executive Committee of NCCN, Bill McGivney is no longer with NCCN, as of December 27, 2011.

• This change resulted from differences in opinion about management style and the strategic direction for the organization.

• NCCN is financially healthy and mission-driven and will continue all programs, products and operations under interim leadership and with the support of 87 talented employees on the leadership team and staff.

• In this interim period, Patricia Goldsmith, C.O.O., will lead operations, with the support of the executive team of NCCN and the Executive Committee of the Board of Directors of NCCN.

• The valued staff members of NCCN are fully informed of the change in leadership and comfortable with the plan to move forward under interim leadership.

• The Executive Committee and the Board will develop a plan to identify the next CEO, by working with the Board to define the recruitment process, and beginning a search for a physician executive to be the CEO of NCCN.

• A small group of public affairs staff members at NCCN and NCCN centers will assist in developing a press release to inform the public about the change in leadership, to thank Bill McGivney for his many accomplishments over the past 15 years, and for helping NCCN to take a leading role in improving the quality, effectiveness and efficiency of cancer care and to help cancer patients live better quality lives.

NCCN: A History

Evidence of Better Outcomes Remains Elusive 20 Years Later

By Paul Goldberg

The history of the National Comprehensive Cancer Network is a saga of the obstacles encountered by America's cancer centers in their efforts to demonstrate that they provide better outcomes that justify higher prices.

Also it's a story of successes, many of them unplanned and unforeseen.

Two decades ago—at the onset of the discussions that led to formation of NCCN—the top executives of comprehensive cancer centers had a lot to worry about.

The Clinton administration was ushering in an era of managed care, threatening to eliminate all but the most efficient of health care providers.

Of course, many academic oncologists believed that they provided the best care available, but they lacked data to demonstrate this.

Survival was at stake. Centers made money on patient care and spent it on research. Therefore, the loss of patient care dollars would extinguish research.

"Capitation" and "oncology carve-outs" were the buzzwords heard at oncology meetings in the early 1990s. In that dystopia, insurers would pay providers to assume all cancer risk within their portfolios.

Now, turn the clock two decades forward.

In 2012, the buzzword du jour is "comparative

effectiveness," and cancer centers are feeling even more threatened, this time by declining federal funding and the continuing onslaught of lower-cost providers of cancer care.

While the Clinton-era threat of capitation hasn't materialized, the Obama administration's health care reform plan includes provisions that make cancer centers feel less than secure.

The Affordable Care Act requires the Department of Health and Human Services to "report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care" at hospitals that were exempt from Prospective Payment System reimbursement limits. (The PPS exemption was crafted specifically to protect the centers from the impact of the 1982 reimbursement structure based on "Diagnosis-Related Groups" of medical services.)

Alas, one thing hasn't changed in that time: there is still no way to demonstrate conclusively that cancer centers do better for their patients than other providers.

"It's a story of people trying to guess what health care reform is going to do and how oncology is going to evolve—and they are all guesses," said Robert Young, former director of the Fox Chase Cancer Center and chair of the NCCN board from 1997 to 2001. "Sometime you guess right—sometimes you don't."

Audio files of The Cancer Letter's interviews with Young and the group's first executive director, Catherine Harvey, can be found at: http://www.cancerletter.com/categories/documents.

The Threat of Capitation

"When the Clinton health plan seemed likely to come down in 1992-1993, a group of [cancer center leaders] got together and said, 'Holy shit, they are going to start sending our patients out to all these community hospitals because it's cheaper,'" said Joseph Simone, who had been physician-in-chief at Memorial Sloan-Kettering Cancer Center during the early 1990s, and would become the NCCN's first chairman of the board.

The network was formed by five centers: MSKCC, MD Anderson Cancer Center, Fred Hutchinson Cancer Center, Fox Chase Cancer Center and City of Hope.

Simone remembers discussions where his colleagues stated flatly that centers provided better outcomes than local doctors and community hospitals.

"We may be better than they are, but what evidence do you have?" Simone asked at one of the initial meetings.

"Of course, there was no evidence," Simone recalled. "That started us thinking where we could get to the point where we could get that kind of information."

Conversations at preliminary meetings quickly turned to the question of measuring quality—and stayed there.

"The question of higher quality is a debatable one, of which there is—as in most things in oncology—no evidence," Young recalled. "That was the centerpiece of the issue that got everybody talking about how we could band together to (1) protect ourselves, and (2) begin to demonstrate that institutions of our type actually did deliver a high-quality product that justified the increasing cost."

The questions were urgent: How would centers remain competitive?

What kinds of patients would continue to seek care at centers?

Could centers combine to launch a business-generating effort? Would this offshoot organization be a for-profit or a non-profit?

The group first turned to entrepreneur Michael Goldberg, whose specialty was applying emerging informatics technology to oncology.

"They hired Michael to create an organization, and then, as a result, to have products that the market would want," Harvey said. Goldberg's South San Francisco-based company, Axion Health Care Inc., was also running a drug distribution business called Oncology Therapeutics Network.

OTN would later be sold to Bristol-Myers Squibb. Later still, Goldberg would run an unsuccessful venture to set up a network of oncology practices organized around information systems and clinical pathways for managing cancer care.

As he explored possible directions for NCCN, Goldberg recruited Catherine Harvey, then an administrator at the Medical University of South Carolina, to run day-to-day operations of the emerging organization. Harvey came on board in February 1994.

In the beginning, five centers had committed to join and sponsor the organization. Their initial contributions paid Harvey's salary, which was floated through Axion.

Working from her home in Charleston, S.C., Harvey helped put together a proposal that was presented at the 1994 annual meeting of the American Society of Clinical Oncology.

At the meeting, there were 17 centers in the room, Harvey recalled. The centers would have to join before the end of the year, contributing $100,000 each.

"There were three things that we proposed to the group, where there would be minimal competitive angst among us," Harvey said.

Their three goals were contracting, clinical guidelines and outcomes measurement.

"The one that was driving it more than the clinical guidelines at that point was contracting," Harvey said. "It was to create some kind of a centers-of-excellence model, where people like Blue Cross/Blue Shield would want to have the ability to send people to these centers. That was particularly a driver for people like Bob Day and Peggy Means out at Fred Hutch. They wanted bone marrow transplants to be a major focus of that."

There was also talk about second opinion services to be provided by cancer centers.

"They realized pretty quickly that if you are going to run either a second opinion service or be a center of excellence, you've got to have guidelines that prove that your care is superior and that it's following a pathway," Harvey said.

The third goal was outcomes measurement.

"After that meeting, they sent me out on a road trip, and I went and visited all the centers that were at the table," Harvey said. "In the beginning they were trying to figure out why they needed each other, and then the other challenge was getting their administration to ante up enough money to get us going."

Meanwhile, the group that was exploring the contracting possibilities ran into resistance from payers as well as internal resistance.

"There was a series of steps we went through and a lot of discussion about whether this was a business-generating effort or not, and we were split about half-and-half in those meetings," Simone recalled.

While some wanted to approach national and international companies and managed-care organizations, others were skeptical.

"Some of us were not confident that that was worthwhile," Simone said. "We didn't fully realize that most insurance is regional and local. It's not national. So no one could commit their national patients to you."

Young was similarly skeptical.

"I didn't think that market would develop in any major way," he said. "And to a certain extent it never has. There is certainly more flying or more referral to centers than there was then, but not a lot.

"The reality is, 85 percent of patients get cared for on an outpatient basis, and they get cared for near home. And that hasn't changed a lot."

There was discussion of the form the offshoot organization would take, and the idea that it could be a for-profit company ran into opposition.

"These were all not-for-profit organizations," Simone said. "There was major concern that they would have to be part of a business venture that they had no control over. And it would be a for-profit.

"People looked at it at institutions and said, 'No, it's not going to work. It's too complicated, and we lose control of our own destiny.' So that's why we ended up doing guidelines."

The pursuit of contracting continued.

"We danced with that for over a year," Harvey said.

By December 1994, the organization had 13 members, and therefore a budget of $1.3 million or so. The committees were working in all three areas. "That was my main job, to keep those committees moving," Harvey said.

The guidelines committee accomplished more than others. To Simone, focusing on standards was simple common sense.

"We have no product. What do we have to sell?" he said, recapping one of these early discussions. "We ought to have some standards. I didn't call them guidelines; I just called them standards. We have all these smart people around. We ought to develop standards.

"Ultimately, we decided that we would be better off doing that."

A focus on guidelines meant that there would be no reason for Goldberg to stay in the job of CEO of the new organization. Also, some centers said that his business ventures—setting up the Oncology Therapeutics Network—constituted conflicts of interest.

He resigned as CEO in November 1994.

"It wasn't an easy, comfortable fit for people having an outside person that had never worked in the cancer centers being the CEO," Harvey said. "That was hard for some of the leadership to reconcile. And he had his other business that he was running at the same time. He was growing a big pharmaceutical distribution business.

"There was also, on both sides, a question early on of what were we really going to be. Were we going to be another not-for-profit on steroids that never had income or just a vehicle to facilitate things like contracting? Or were going to have a business strategy of our own?"

Goldberg was replaced by Bruce Ross, a retired Bristol-Myers Squibb executive, who lived in the Philadelphia area. Ross ran NCCN from an office that moved to Fox Chase Cancer Center. Harvey stayed on, continuing to work from her home in Charleston.

Ross took the job on condition that he would stay long enough to get the organization going. He came on as a favor to Simone and Young, making it clear that he wouldn't stay in the job long.

During his time at BMS, Ross developed strong

connections in the academia. He had coordinated some key projects, including the development of the drug Taxol.

However, working as the CEO of an organization funded by the centers was a new experience for Ross.

"It was a shock for me to go from the industry into academia, because in academia everything is done by consensus," Ross said. "It's hard to make decisions. These were all academic cancer centers. I answered to a board, and I was used to making decisions. I would hear people out and say, okay, I've heard you out, and this is the way we are going to do it.

"That's not the way it works in these organizations."

Ross ran the organization as it focused on guideline-making.

The Guidelines Format Emerges

Disputation is an endeavor in which academics excel.

"The idea was that we used free horsepower—all the docs in these institutions were asked to serve on committees," Simone recalled. "We didn't have to pay them. We had to pay the travel, but we didn't have to pay them. And we could build a reputation for the organization based on having established standards."

In March 1995, the organization presented guidelines that covered cancers of the breast, colon, prostate and the lung. Also covered were acute leukemia and pediatric cancers.

Altogether, these diseases accounted for 51 percent of all cancers.

Using templates designed primarily by Rodger Winn, chairman of the NCCN Guidelines Steering Committee and an oncologist at MD Anderson at the time, the organization came up with guidelines that were both brief and easy to change.

For example, the most controversial of the guidelines at the time—the first version of the guideline for breast cancer—fit on just 25 pages.

The guideline addressed standard—as opposed to investigational—treatments. This allowed the breast cancer committee to avoid a fight over bone marrow transplantation.

"We assumed that investigational care will always take precedence over the guidelines," Robert Carlson, a Stanford University oncologist who headed the breast cancer panel, said at the time (The Cancer Letter, March 15, 1996; posted at http://www.cancerletter.com/categories/documents).

The committee didn't recognize bone marrow transplants as standard practice, and a fight was averted.

The unveiling of the guidelines established the centers as the leading voice in oncology, Simone said.

"It was a hit," he said. The first meeting of NCCN sent a message to the field: the cancer centers are setting the standards for quality care. The centers would do well by doing good.

"You would send your complex cases there, ones that you couldn't handle," Simone said.

"The biggest reason we thought it would help us is that it would give us an opportunity to look at what we were doing," said Young, who first served as vice chairman of the NCCN board and chairman of the outcomes committee. "We were pretty confident that, measured by our own guidelines of what constitutes state of the art care, we would do reasonably well.

The guidelines were unique in medicine.

"You have guidelines written by state-of-the-art experts in their fields, covering all cancers, updated on the monthly basis," Young said. "And that doesn't exist anywhere, and probably couldn't, with any other group. And it certainly doesn't exist in any other disease."

It would be impossible to accomplish this breadth with evidence-based guidelines. Such guidelines "tended to be developed, published, and ended up on shelves gathering dust," Young said. "And they lacked a number of things we believed were critical. One, they ought to be guidelines that could be read in a very short period of time. Simple guidelines. They ought to build in the capacity for encouraging patients to enter clinical trials.

"And two, they needed to be comprehensive, because it wasn't very helpful to have one guideline on breast cancer treatment and one on diffuse lymphoma and one on colon cancer—and nothing else.

"I think oncologists realize that if you just used evidence-based medicine, you wouldn't have guidelines on much of anything. A few in adjuvant therapy, and breast cancer, and colon cancer, and that's about it.

"We said, 'Look, we want evidence-based medicine as much as we can use it, we want criteria for the strength of particular recommendations, but we want recommendations of what a group of experts believe is state of the art care that day.'

"The other thing that we built into it early on is the capacity to provide feedback to the institutions. If they found themselves either as a group or individual doctors within their institutions lacking adherence to our own agreed-upon guidelines, they would be encouraged either to conform or explain why the guideline is inappropriate and thereby encourage having it be changed.

"It was a continuous quality improvement strategy."

McGivney Tapped to Lead NCCN

Ross left NCCN at the end of 1996. This was an orderly changing of the guard.

Ross, who took part in choosing his successor, believes McGivney was an excellent candidate.

"We interviewed a whole bunch of people," Ross said to The Cancer Letter. "At the time, he was with Aetna, and he knew a lot about the health care industry. He seemed to be quite well qualified.

"I think, for the most part, he did extremely well. I think what did him in was his inability to keep making money for the organization. These are tough times for cancer centers."

At the time he was hired, McGivney was the vice president for clinical and coverage policy at Aetna Health Plans.

Soon after taking the job, McGivney told The Cancer Letter that academic cancer centers and managed care companies have a common interest: developing the capability to make decisions based on outcomes data.

"Both communities, in terms of decision-making, are interested in basing their decisions on outcomes data, and that's a common theme we need to sit down and talk about more," he said at the time. "There is a potential for a better relationship, if you can get by some of the standoffishness and doubts about the other side."

The profile of McGivney, which appeared in the Jan. 24, 1997, issue of The Cancer Letter, is posted at http://www.cancerletter.com/categories/documents.

A timeline provided by NCCN follows:

NCCN Clinical Practice Guidelines in Oncology:

• NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) are the recognized standard for clinical policy in oncology in both the academic and community settings and significantly influence appropriate practice patterns and prescribing behavior. The evidence-based NCCN Guidelines are developed and updated by 47 individual panels, composed of over 900 multidisciplinary clinicians and oncology researchers from the 21 NCCN Member Institutions geographically dispersed across the country. Panel members possess in-depth knowledge of the biomedical literature and awareness of, if not actual leadership and/or participation in, the trials that provide the evidence for the NCCN Guidelines. NCCN annually surveys clinicians to determine how they use the guidelines.

• The first seven NCCN Guidelines, covering breast, lung, ovarian, prostate, colon, rectal, and pediatric cancers were released in 1996. NCCN Guidelines covering melanoma, sarcomas, lymphomas, bladder, central nervous system, head and neck, and pancreatic cancer were first developed in 1997. The first NCCN supportive care guidelines covering use of anti-emetics also were introduced in 1997. In 1998, the NCCN Guidelines for Hodgkin's disease, endometrial and cervical cancers, esophageal and stomach cancers, testicular and renal cancers, myeloma, chronic myelogenous leukemia, and neutropenic sepsis were first published. NCCN also introduced its first screening guidelines in 1998 covering breast, prostate, and colon cancers screening, including the use of genetic testing.

• As of 2012, NCCN has produced 55 clinical practice guidelines covering 97% of all malignancies affecting individuals with cancer, including separate guidelines for prevention and screening as well as supportive care for patients. There are 136 separate algorithms covered within the guidelines mentioned above.

• The quantity and sophistication of information in the NCCN Guidelines have become much greater over the years. The guidelines have moved from generic recommendations to detailed recommendations for the multidisciplinary management of cancer. In 2003, Principles of Chemotherapy, Radiation, and Surgery were first included in the guidelines, and this information has become widespread throughout the program. The NCCN Guidelines have become increasingly rich with discussions of pathology, biomarker testing, and imaging. NCCN now also offers NCCN Chemotherapy Order Templates (NCCN Templates) for regimens recommended in

the guidelines to improve the safe and effective use of drugs and biologics in cancer care.

• NCCN has been a leader in identifying arrangements involving NCCN Guidelines Panel Members who have a significant financial or fiduciary interest in an outside entity where such arrangements may represent a source of conflict or an appearance of conflict in the participation in the development of the NCCN Guidelines. The NCCN disclosure policy requires disclosure of external relationships and recusal of NCCN Guidelines Panel Members with significant conflicting interests so that the integrity of the NCCN Guidelines is not compromised or diminished by conflicts or by the perception of conflicts. NCCN began collecting this information from NCCN Guidelines Panel Members, NCCN Guidelines staff, and the NCCN management team in 2006, and the results are posted on NCCN.org.

• In response to the Centers for Medicare and Medicaid Services (CMS) requirements for compendia to have a publicly transparent process for evaluating therapies and for identifying potential conflicts of interest, NCCN has become more transparent with respect to how decisions are made and what data support those decisions. NCCN has published the criteria used for evaluating NCCN Guideline recommendations, the names of the NCCN Guidelines Panel Members who participated in the development of the guideline recommendations, submissions of data to the panel, the votes for recommendations, and the panel's disclosures.

• A number of the NCCN Guidelines are available in Chinese, Japanese, Korean, Portuguese, and Spanish. Approximately 47% registered users on NCCN.org who access the NCCN Guidelines, NCCN Drugs & Biologics Compendium (NCCN Compendium), and NCCN Templates reside outside the United States.

• NCCN's continuing medical education programs began with the NCCN Annual Conference in February 1996 and expanded in 2002 to include NCCN Regional Guidelines Symposia. These half-day programs aimed to make physicians aware of the data upon which the guidelines were based. The new NCCN Guidelines Update Webinar Series is designed to quickly communicate significant updates to the NCCN Guidelines. During these disease-specific webinars, NCCN Guidelines Panel Members discuss the issues considered by the panels that resulted in changes to the NCCN Guidelines, new data is compared with existing standards of care, and significant studies that supported modification of the recommendations are reviewed. All of these programs inform clinicians of which data NCCN Guidelines Panels regarded as persuasive and why, increasing the transparency of decision-making.

NCCN Drugs & Biologics Compendium:

• The NCCN Drugs & Biologics Compendium, derived directly from the NCCN Clinical Practice Guidelines in Oncology, provides authoritative, scientifically derived information designed to support decision-making about the appropriate use of drugs and biologics in patients with cancer.

• On August 9, 2005, NCCN petitioned the CMS Administrator for CMS to officially recognize and use the NCCN Compendium as one mandated reference among others for coverage decisions about the appropriate use of drugs and biologics in cancer care.

• CMS convened a meeting on March 30, 2006 of the Medicare Evidence Development and Coverage Advisory Committee that identified 13 basic characteristics of a good compendium and then voted giving the NCCN Compendium the best score on each characteristic.

• The Secretary of Health and Human Services has the authority to add compendia to Part B. NCCN petitioned the Secretary on October 19, 2006 to do so with supporting letters from many major national organizations (e.g., American Medical Association, American Society of Clinical Oncology, Association of Community Cancer Centers, Oncology Nursing Society, National Patient Advocate Foundation, Cancer Leadership Council).

• Private payors such as the Blue Cross Blue Shield plans, UnitedHealthcare, Aetna, Cigna, and Humana utilize the NCCN Guidelines to make coverage determinations for drugs and biologicals used in an anti-cancer chemotherapeutic regimen. On January 16, 2008, UnitedHealthcare announced that it would be the first payor to base its benefit coverage for chemotherapy drugs used in outpatient settings on the NCCN Compendium, effective March 15, 2008.

• On June 5, 2008, CMS recognized the NCCN Compendium as a mandated reference for establishment of coverage policy and coverage decisions regarding the use of drugs and biologics in cancer care. The NCCN Compendium will be utilized by CMS for national coverage determinations and by intermediaries and carriers for locoregional determinations. The major application will be in determinations about coverage for the use of drugs and biologics beyond the FDA-approved indication. The use of drugs and biologics for indications in cancer care beyond the

FDA-approved label is a common, appropriate, and important mechanism to provide the most effective care to patients.

NCCN Guidelines for Patients:

• Since September 23, 2010, NCCN has developed eight NCCN Guidelines for Patients, consumer-friendly translations of the NCCN Guidelines, on breast cancer, chronic myelogenous leukemia, malignant pleural mesothelioma, melanoma, multiple myeloma, non-small cell lung cancer, ovarian cancer, and prostate cancer. NCCN Guidelines for Patients are now available in a flip-book format on NCCN.com and NCCN.org. Many of these guidelines are also available in print copy.

Collaboration with National Business Group on Health:

• On December 16, 2010, the National Business Group on Health (NBGH) announced its collaboration with NCCN on a three-year project to develop *An Employer's Guide to Cancer Treatment & Prevention* – resources and tools in benefit design to be utilized for employers to address cancer care in the workplace. The first project deliverable, the *Quick Reference Guide and Assessment Tool*, was released in April 2011. The second resource, the *Benefit Design and Assessment Tool,* was released in July 2011. Additional tools include the *Request for Proposal and Proposal Scoring Tool*, the *Vendor Contracting and Administration Tool*, and the *Vendor and Program Evaluation Tool*.

NCCN Oncology Research Program:

• The NCCN Oncology Research Program (ORP) is organized to obtain funding to support scientifically meritorious research projects at NCCN Member Institutions. The NCCN ORP has received more than $34 million in research grants to support investigator-initiated trials. These trials explore new venues of clinical investigation that answer important scientific questions. Studies evaluate innovative combinations and sequencing regimens of drugs, drug resistance, mechanisms of action of specific agents or explore extended uses for specific agents.

NCCN Oncology Outcomes Database:

• The NCCN Oncology Outcomes Database is a network-based data collection, reporting, and analytic system that describes the patterns and outcomes of care delivered in the management of patients with cancer. The concept for the Database was established in 1996, and the operation of the first database in breast cancer was initiated in July 1997. With the NCCN Oncology Outcomes Database, NCCN seeks to implement the NCCN Clinical Practice Guidelines in Oncology through performance measurement. Presently, the NCCN Oncology Outcomes Database has five active database components: breast, colon/rectal, non-small cell lung, and ovarian cancers as well as non-Hodgkin's lymphomas. The Database follows approximately 85,000 patients with data elements collected on each patient in areas of sociodemographics, clinical interventions, and clinical and non-clinical outcomes. The data is high-quality and research-worthy as on-site audits of data occur within three months of a site joining the database and on an annual basis thereafter.

Guest Editorial

ACS: Introduces Seven Principles For Screening Recommendations

(Continued from page 1)

After much examination, the society is revising its process for developing screening guidelines. The new process is outlined in a Special Communication published in the Dec. 14, 2011, issue of the Journal of the American Medical Association.

As medical science advances, larger amounts of scientific data are being generated and the synthesis of information is becoming more complicated. At the same time science is provided better ways of analyzing large amounts of data.

With the evolution of science, the medical guideline process must also evolve. This is a challenge for all who publish healthcare guidelines, be they for treatment or prevention of illness. For years, these guidelines were written by gathering a small group of experts and coming to a consensus of opinion. Indeed, this is how most cancer treatment and screening guidelines are currently developed.

In 2010, the ACS board of directors commissioned a workgroup to review the methods used by the Society to create and communicate cancer screening guidelines and determine if and how these methods should change. While this group was working, the Institute of Medicine issued new standards for guidelines development.

In summary, the workgroup believes that past ACS guidelines have been of high quality, but the process must evolve. A challenge for the future will be to assure consistency across different disease

guidelines, transparency of the process, and objectivity relative to the evidence base.

The ACS board of directors approved final recommendations that include seven core principles. ACS staff and volunteer leadership are now engaged in setting up the infrastructure to implement the new process. This may take a year to implement.

The seven core principles are:

• Transparency. The work of the committee will be detailed online on a section of the ACS website to be dedicated to cancer screening guideline development. ACS will solicit input and comment from relevant experts, as well as professional and special interest groups on near final drafts guidelines prior to their publication.

• Conflicts of interest. The most difficult issue in cancer screening guideline development and the issue most heavily debated by the workgroup was the proper management of professional conflicts of interest. Clearly, the expertise of specialists is needed to develop an acceptable guideline but the perception of conflict of interest can erode confidence in that guideline. Specialists can have economic and emotional conflicts of interest. Sometimes experts cannot objectively assess data, because they suffer from prejudice.

For these reasons, ACS will separate the process of receiving expert input from the process of writing guidelines. The process of writing guidelines will be left to the ACS Cancer Screening Guidelines Development Group. This Group will be composed of 12 members, including one patient advocate and 11 generalist health professionals with expertise in the interpretation of evidence. Each member will serve a specified term. The Group will invite content-specific input from expert subspecialists for each guideline to help inform their process of interpretation of evidence, but those ad hoc advisors will not be directly involved in guideline writing. In this way expert opinion can inform guidelines without the appearance of professional conflict of interest.

• Systematic evidence review. A systematic structured review of the published scientific evidence is an essential component of a credible guidelines development process. The ACS Cancer Screening Guidelines Development Group will create contractual relationships with experienced systematic review authors, who will objectively summarize and grade the strength of the evidence. These evidence summaries will then serve as the basis for the guidelines to be written by the Group.

• Grading the strength of the recommendations. The ACS Cancer Screening Guidelines Development Group will formally grade the strength of its recommendations to better support shared decision making by guideline users.

• Articulation of the recommendations. ACS guidelines will clearly describe both the benefits and the harms of screening. A clear explanation of the values that have affected recommendations will help ACS to assist both providers and the general public to make their own decisions about cancer screening.

• External review. Before the process of peer review for publication each ACS cancer screening guideline will undergo a formal review process that includes opportunities for experts, professional organizations, and advocacy groups to provide review and comment. The published guidelines will summarize any differing opinions, and provide a discussion of reasons for any differences to assist readers with their personal, practice, and policy decisions.

• Updating. There will be a formal review and re-writing of every ACS cancer screening guideline at least every five years. The ACS will also perform an informal yearly update of the scientific evidence, and more frequently as needed, depending on the emergence of important new clinical evidence or new technologies.

It is my hope that other organizations that issue prevention, screening and treatment guidelines will examine their procedures and evolve toward a similar philosophy.

The author is the chief medical and scientific officer of the American Cancer Society.

DISCLOSURE: Brawley and Paul Goldberg, editor and publisher of The Cancer Letter, are co-authors of HOW WE DO HARM: A Doctor Breaks Ranks About Being Sick in America, scheduled for publication by St. Martin's Press on Jan. 31.

In Brief

New Codes for Planning Treatment; JAMA Retracts Potti Paper

THE CENTERS FOR MEDICARE AND MEDICAID SERVICES will establish two codes in the Healthcare Common Procedure Coding System for cancer treatment planning and care coordination. The codes go into effect April 1.

The HCPCS codes include treatment planning and coordination services for a patient's initial treatment and for patients who change their treatment regimen.

The National Coalition for Cancer Survivorship commended CMS, calling the new codes a "first step toward reimbursement of healthcare providers for the time and expertise they dedicate to treatment planning and care coordination for cancer patients."

"We at NCCS believe that a quality cancer care experience begins with development of a treatment plan and a patient-provider discussion of that plan," said Ellen Stovall, a health policy advisor for the coalition.

THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION published a retraction by the authors of work based on the research of former Duke University cancer researcher Anil Potti.

The authors retracted "Gene Expression Signatures, Clinicopathological Features, and Individualized Therapy in Breast Cancer," by Acharya CR, et al. (JAMA. 2008;299(13):1574-1587), because components of the article were based on Potti's work published in Nature Medicine in 2006, which had been recently retracted because the results were unable to be reproduced.

JAMA represents the eighth retraction in a list of journals.

Previously, papers have been retracted in The Journal of Clinical Oncology, The Lancet Oncology, Blood, PLoS One, PNAS, Nature Medicine, and The New England Journal of Medicine.

Altogether, about 13 full retractions and 13 partial retractions are expected.

The retraction was published online Jan. 6., and is available here: http://jama.ama-assn.org/content/early/2012/01/05/jama.2012.2.full

The text of the retraction follows:

To the Editor: We would like to retract the article entitled "Gene Expression Signatures, Clinicopathological Features, and Individualized Therapy in Breast Cancer," which was published in the April 2, 2008, issue of JAMA. A component of this article reported the use of chemotherapy sensitivity predictions based on an approach described by Potti et al. in Nature Medicine in 2006. The Nature Medicine article was recently retracted due to an inability to reproduce the results with the chemotherapy signatures. Because a significant component of this JAMA article was based on the use of chemotherapy signatures reported in the Nature Medicine paper, we have decided to retract the JAMA article. We apologize for any negative impact on scientific research or clinical care caused by the publication of our article in JAMA.

MAHER ALBITAR was appointed chieft medical officer and director of research and development of NeoGenomics Inc.

Albitar was as medical director for hematopathology and oncology and chief of research and development for Quest Diagnostics Nichols Institute from 2003 to 2010. Before that, he served as director of the Leukemia and Molecular Laboratory in the Division of Laboratory Medicine and Pathology Medicine, as well as in various faculty positions, at MD Anderson Cancer Center.

Most recently, he served as chief medical officer of Health Discovery Corporation, and he will remain as a member of the board of directors.

THE PACIFIC MESO CENTER opened a new, free-standing mesothelioma research laboratory focusing on novel treatments for and prevention of malignant pleural mesothelioma. The center is a division of the Pacific Heart, Lung & Blood Institute.

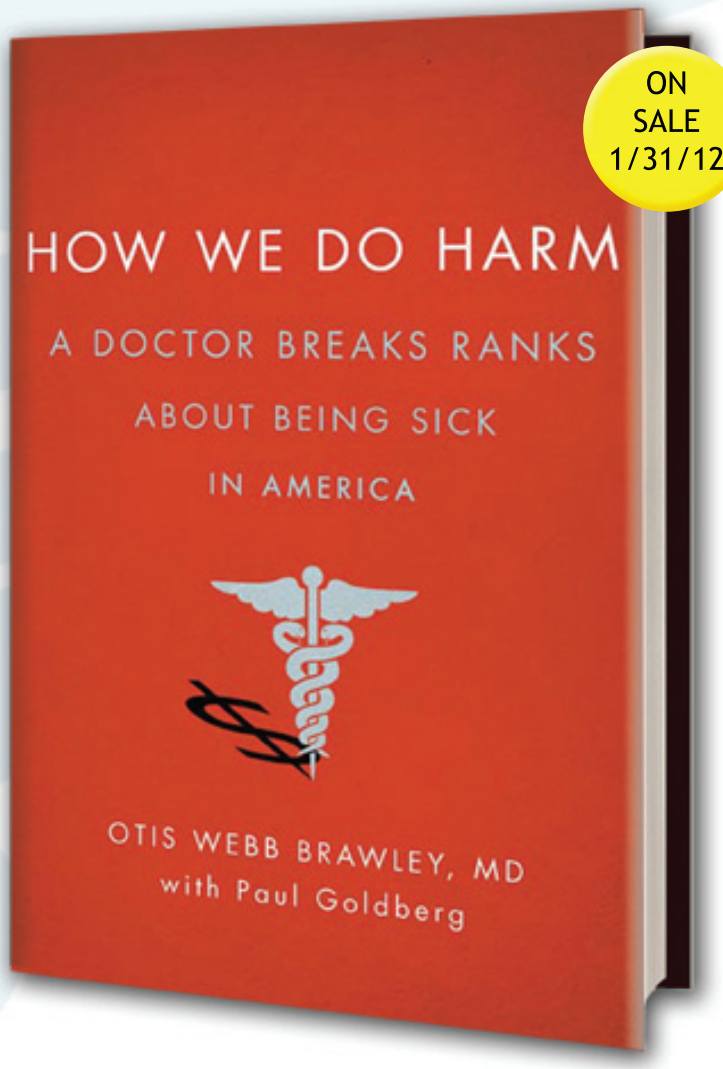
The laboratory will establish an international tissue bank, develop intraoperative cryotherapy, begin a stromal cell modification project, and attempt to identify a predictive model for drug prevention.

The laboratory will host a team of physicians and researchers, including Robert Cameron, director of the UCLA Comprehensive Mesothelioma Program at the David Geffen School of Medicine at UCLA, and chief of thoracic surgery at the West Los Angeles Veterans' Administration Medical Center.

"I believe these exciting projects quickly will give us valuable information, some of which I anticipate will be covered in our 2nd International Symposium scheduled for May 12, in Santa Monica, California," said Cameron.

"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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