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What's In A Name?

Three Venerable Acronyms Fade Away As Cooperative Groups Form "Alliance"

By Paul Goldberg

For over half a century, cancer cooperative groups evolved names that are unwieldy, pregnant with meaning—and beloved.

Reduced to acronyms, they can be a challenge. Unless someone has instructed you in proper pronunciation of CALGB, NCCTG and ACOSOG, you might not sound like a native.

Now, these three names are going away. Cancer and Leukemia Group B, the North Central Cancer Treatment Group and the American College of Surgeons Oncology Group are merging to create something called an Alliance for Clinical Trials in Oncology.

As a result of this merger, three quirky names and three consonant-heavy

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Revamping Cooperative Groups:

ASCO Urges NCI To Spell Out Metrics of Success Beyond Cutting Groups to "Arbitrary Number"

By Paul Goldberg

In his last action as president of the American Society of Clinical Oncology, George Sledge challenged NCI to provide a "clear vision of what a successful reorganization will bring about, and specific metrics for determining success" of the redesign of the clinical trials cooperative groups.

ASCO submitted the June 7 letter in response to NCI's request for public comment. However, the letter was addressed to NCI Director Harold Varmus.

Sledge focused on the institute's rationale for funding no more than four

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In Brief:

Former NCI, FDA Chief Andrew Von Eschenbach Appointed to NCCN Foundation Board

ANDREW Von ESCHENBACH was appointed to the board of directors of the **National Comprehensive Cancer Network Foundation**.

Von Eschenbach, a consultant at the Center for Health Transformation, a think tank started by former House Speaker Newt Gingrich, who recently left the organization to run for president.

Von Eschenbach is also president of Samaritan Health Initiatives, an entity based in Montgomery, Texas, about which there is little publicly available information.

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Three Groups Make Fresh Start, Which Means a New Name

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acronyms will fade into history of oncology.

No more CALGB.

No more NCCTG.

No more ACOSOG.

The new group's name will be abbreviated as ACTION, but it's okay to call it Alliance, group leaders say.

"The names, obviously, have both historical and emotional significance for lots of oncologists," said Richard Schilsky, former chair of CALGB, who wasn't involved in the renaming. "People built their careers in cooperative groups and have devoted huge amounts of time to these organizations."

Change so big makes clinical trialists weep, or at least quote Juliet, as in "Romeo and…"

"At the end of the day, it's the old Shakespearean phrase, 'What's in a name?'" said Schilsky, chief of the Section of Hematology-Oncology and deputy director of the University of Chicago Comprehensive Cancer Center. "What counts is what these organizations are able to do. But who knows, maybe 50 years from now, the word Alliance will be engrained."

On May 11, NCCTG held its semiannual meeting.

Since this meeting was final, the agenda included a "celebration of the legacy of NCCTG."

"There are people who have thoughts about losing North Central," said Charles Loprinzi, the Regis Professor of Breast Cancer Research at the Mayo Clinic, who was involved in combining the three groups and developing the new name. "How can you not have thoughts about that when things are changing? But we are hoping for the best as we are moving this process forward."

The change isn't voluntary. NCI has said that it would fund no more than five cooperative groups, which means that the number of groups that study adult cancer has to be trimmed from nine to four.

When CALGB, NCCTG and ACOSOG decided to form a new entity, they were determined to make a break with the past and build something new. Old names, love them or not, had to go.

"It's like when people get married, they can hyphenate their name or they can say this is a new chapter in my life," said Deborah Schrag, a gastrointestinal oncologist and deputy associate director, population sciences, at Dana Farber Cancer Institute, and a member of the naming committee. "It's a big step, and I am willing to take on a new name, even though it's going to take a little getting used to. From the outset, no one said, 'I am not changing my name.'

"Everyone was willing to change their names," Schrag said. "The new name isn't the name of any one group. That is really courageous, and it demonstrates the commitment of the investigators from all three groups, and particularly the leadership of the three groups."

Ultimately, members of the three groups, voting by electronic ballot, chose Alliance for Clinical Trials in Oncology. The option not chosen was Academic and Community Clinical Research Alliance.

"The biggest question now is, will it be called ACTION, or will it be called Alliance, or will it be called both names?" said Loprinzi. "It remains to be seen what happens on that."

Schrag, too, is unwilling to make predictions.

"Will people end up calling it ACTION or Alliance five years from now; who knows?" she said. "When you name a kid Richard, you are not sure how it's going to turn out. Is it going to be Richie or Dick? Do you know? That's going to depend on how people own the name."

Selecting the acronym ACTION, a word that can actually be found in the dictionary, breaks with more than a half-century-old tradition of group-naming.

Some cooperative groups were named after their geographic location, other after diseases they were studying, still others, after treatment modalities.

Names have changed over time, as the alphabet soup was stirred to reflect new schisms and new alliances.

When the precursor of today's CALGB was formed in 1956, its original name was Acute Leukemia

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Group B, ALGB. The group was focused on adult leukemia. (The group's first protocol, which Schilsky believes should be kept under glass like copies of the Magna Carta, is posted at http://www.cancerletter.com/categories/documents.)

ALGB had a companion group, called Acute Leukemia Group A, which studied childhood leukemia.

"The bottom line is, ALGB changed to CALGB," Schilsky said. "There has been evolution in these things over time.

The word "cancer" was added to the name in 1976, when Group B became involved in adjuvant breast cancer trials.

Meanwhile, Group A became the Children's Cancer Study Group, which, too, has since been merged out of existence.

NCCTG was founded in 1977 by Charles Moertel, of the Mayo Clinic, an expert in colon cancer, an advocate of rigorous testing of cancer therapies, and a critic of drug companies, which he said were charging too much for drugs that did too little.

Moertel's objective in creating NCCTG was to involve community oncologists, who are treating the vast majority of cancer patients.

"The main strength of NCCTG is that it had more involvement of community sites than academic sites," Loprinzi said.

And what would Chuck Moertel, who died in 1994, say about the group's disappearance?

"NCCTG was his baby, so there would be some loss there, but his goal was to bring community oncologists into research, and if they come to the table here and are involved with the bigger process and still have the ability to have their say be heard, then maybe that's a success."

ACOSOG was founded in 1993, at the time when NCI sought to create an alternative group to conduct the work that had been done by the National Surgical Adjuvant Breast & Bowel Project, which at that time was under investigation by Rep. John Dingell (D-Mich.) and his Committee on Energy and Commerce.

NSABP survived the Congressional attack, and is keeping its name in the merger with the Radiation Therapy Oncology Group. And ACOSOG continues to do studies that bring surgeons to the table in a variety of areas.

The three groups aren't alone in considering renaming.

The Southwest Oncology Group, now headquartered in Ann Arbor, Mich., recently jettisoned its former full name, but retained the acronym SWOG. "It's what most of the research world and many of the patients who participate in our trials already know us as," SWOG Chair Laurence Baker said at the time (The Cancer Letter, April 8).

Of course, SWOG is free to keep its name, because the group is large enough to remain unchanged as smaller groups heed the NCI mandate to reduce the number of groups from ten to five. SWOG is not known to be merging with any group.

The name Alliance was designed by a committee, which in this case was a six-member panel called the Mission, Vision and Naming Committee.

The committee had representation from two members from each group. CALGB was represented by Schrag and Deborah Collyar, a patient advocate.

NCCTG was represented by Loprinzi and John Kugler of Community Cancer Center of Normal, Ill.

The ACOSOG representatives were David Winchester, of North Shore University Health System of Evanston, Ill., and Robin McLeod, professor in the Departments of Surgery and Health Policy Management & Evaluation at the University of Toronto and the surgical lead of the Quality Improvement Program in the Surgical Oncology Program of Cancer Care Ontario.

The committee went though over 200 suggestions submitted by members. For the most part, they argued about words.

"If we had outsourced it to a marketing agency, could they have come up with a sexier, catchier name? You betcha," Schrag said. "But this was done by doctors, scientists, and we didn't spend taxpayer dollars, we just had a bunch of conference calls.

"The outcome was cathartic. Some people wanted the word translational in there. Some people wanted the word patient in there. Some people wanted the word science in there. They are all good words, they are just not in the title."

The governing boards of CALGB, NCCTG and ACOSOG have endorsed the proposed Alliance (or ACTION) constitution, bylaws and transition plan.

The first meeting of the group's board of directors will be held July 15 in Chicago. Each group has selected delegates to attend the meeting and establish the governance structure of the new group.

The Alliance scientific program leaders, along with scientific leadership from CALGB, NCCTG and ACOSOG, will meet in Chicago this September to define the group's scientific agenda.

The first joint Alliance meeting, which will include all members, will be held Nov. 17-19 in Chicago.

The group's website is www.alliancewebsite.org.

Revamping Cooperative Groups:

ASCO: More Detailed Metrics, More Money For Clinical Trials

(Continued from page 1)

cooperative groups studying adult cancer.

The question—why four?—emerged as a focal point of a March 21 workshop co-sponsored by the Institute of Medicine and ASCO (The Cancer Letter, March 25).

Also, Sledge's letter appears to be consistent with the "guiding principles" that chairs of the ten NCI-funded cooperative groups proposed to the institute last month (The Cancer Letter, May 20).

"Achieving consolidation and reduction in the number of cooperative groups to an arbitrary number should not be viewed as a desirable or successful outcome," Sledge wrote in the letter to Varmus.

"Pre-specified metrics of success should guide an analysis in the initial stages of implementation to ensure that the process is on track and that the outcomes can be adjusted as necessary," Sledge wrote. "Furthermore, a thorough evaluation should be performed after complete implementation to determine if the outcomes were met. This has not been done consistently in the past, and such an evaluation is even more important because of the large scale changes that are envisioned and the risk posed if the changes diminish the impact of the national system."

In an email, Sledge said his letter is a follow-up to the IOM-ASCO workshop.

"The 'anatomic reorganization' of the groups is impressive, but we cannot merge our way to success," Sledge said to The Cancer Letter. "We require 'functional reorganization' as well."

Greater investment should follow any reorganization. "Current trial participation is clearly underfunded, with physicians dropping out of the clinical trials system because of chronic underfunding, and this needs to be addressed," Sledge said.

Richard Schilsky, chair of the IOM-ASCO workshop, said the questioning of NCI's rationale emerged as a key point in the meeting. "This ASCO letter picks up on one comment that was raised at the workshop: why four?" said Schilsky, chief, of the Section of Hematology-Oncology and deputy director of the University of Chicago Comprehensive Cancer Center. "There has never been any particular rationale that has never been provided by NCI for the number four. They may have a rationale, but they have never stated what the rationale is."

Schilsky said the ASCO letter is "highly concordant" with the eight principles for reorganization proposed by the group chairs.

Schilsky said he was involved in preparing the ASCO letter, but not involved in preparing the earlier letter from group chairs.

The text of Sledge's letter to Varmus follows:

Dear Harold:

Thank you, again, for taking the time to come to ASCO's meeting and to talk with our Board of Directors and attendees. We have many exciting opportunities to work together in this time of unprecedented opportunity for cancer advances. I am writing on behalf of the American Society of Clinical Oncology to highlight one of the issues that is very important to our membership—the transformation of the Cooperative Group Program. On behalf of ASCO's 30,000 members, I appreciate the opportunity to comment on NCI's role in reorganization of the system. We have a keen interest in ensuring the long-term viability of a federally funded, national clinical trials network.

We appreciate the priority you are placing on making needed improvements to the Cooperative Group Program. The NCI and the Groups have begun to make important changes to address some of the major issues raised in the IOM report. NCI is soliciting feedback on these revisions. ASCO believes—overall—that the proposed revisions are headed in the right direction, but we are concerned that they do not appear to be based on a rationale that is derived from a strategic, scientific, or budgetary plan for the cooperative groups.

Because the NCI proposal represents significant changes, we believe it is essential that NCI articulate in advance a clear vision of what a successful reorganization will bring about and specific metrics for determining success. Achieving consolidation and reduction in the number of cooperative groups to an arbitrary number should not be viewed as a desirable or successful outcome. Pre-specified metrics of success should guide an analysis in the initial stages of implementation to ensure that the process is on track and that the outcomes can be adjusted as necessary. Furthermore, a thorough evaluation should be performed after complete implementation to determine if the outcomes were met. This has not been done consistently in the past, and such an evaluation is even more important because of the large scale changes that are envisioned and the risk posed if the changes diminish the impact of the national system.

Toward that end, ASCO suggests the following goals for reorganization that could also serve as the basis for development and adherence to metrics, which should

be transparent, and indicators of success:

1. Enhance Inclusion of Innovative and Clinically Meaningful Science and Decrease Duplication Across all NCI-Supported Clinical Trials. As you have noted in numerous presentations, we are just beginning to realize the potential of genomic-based cancer therapeutics. We must ensure that the revised Cooperative Group Program or National Clinical Trials Network (NCTN) is poised to capitalize on this innovative science. We can accomplish this, in part, by enhancing the connections between successful concepts that come out of NCI-supported translational and early-phase clinical trial mechanisms into innovative and efficient trials in the NCTN. The network should also be open to receipt of scientific concepts from outside of the NCI-supported system.

It is important that the NCTN devote high priority and sufficient resources to trials that incorporate innovative science and hold the most promise for addressing practice-changing questions that have meaningful clinical benefit. The network should also focus on trials that a federally-funded system is uniquely poised to conduct or partner with industry to conduct. As the IOM report notes, federally-funded trials are particularly well suited to evaluate multi-modality treatments, adjuvant therapy, combinations of novel agents, screening and prevention strategies, and therapies for rare diseases.

NCI should continue to assess the scientific merit of the concepts each applicant Group proposes and advances, as well as each Group's contributions to the NCTN. A revised system ought to incorporate a peer review process that enables comparisons of the scientific merit of all proposals applicant organizations submit within a disease area. The review criteria for the Groups should focus on 1) scientific merit of developmental studies (i.e., randomized phase 2 concepts with novel hypotheses that lead to phase 3 trials and correlative science concepts that incorporate biomarker discovery and validation) and 2) support for and recruitment to high priority trials across the entire network (including efficiency and completion metrics). Funding to the Groups should reflect both scientific merit of the application and support for trials across the network.

2. Improve Timeliness of Concept Development and Scientific Review. Numerous analyses have demonstrated that successful accrual of a Cooperative Group trial depends on the relevancy of the scientific question. In order to ensure that our trials are poised to answer the timeliest questions, we have to improve the speed with which we accomplish scientific review – from when a concept is first proposed within the Groups through to protocol approval. NCI and the Groups have made tremendous strides in improving the efficiency of the trial initiation process from the time of concept approval to trial launch. This same intense focus should be directed to the concept development portion of the timeline. The scientific review process should focus on value-added review, not minor changes. It should also enable reviewers to understand the thought process that occurred during concept development, so that reviewers can understand ideas already incorporated and benefit from the rich discussion that occurs within the Groups. In addition, NCI and the Groups should clarify the purposes and roles of steering committees and task forces to streamline the system as much as possible.

3. Promote Efficiency Across the Network. NCI has developed important tools and devoted increased resources to provide greater transparency and accountability and modernize the protocol development and trial launch process. In a national network, the emphasis should be on standardization across the system. Any deviation from the standards (e.g., protocols, case report forms, informed consent documents, auditing, etc.) should be minimal and justified. As part of this, we urge the NCI to expedite its plans to transform its central institutional review boards (CIRBs) into freestanding IRBs and require that institutions participating in the NCTN use the CIRBs as the IRB of record. In addition, NCTN should be the chief vehicle for conducting NCI-funded phase 2 and 3 trials, and all NCI-funded mechanisms should support and be held accountable for their participation and enrollment on NCTN trials. The NCI has started this process by aligning all the review guidelines across major NCI-funded mechanisms for clinical trials. This process should be expedited and review criteria should incorporate credit and the expectation for enrollment and participation in NCTN trials.

4. Increase Funding for NCI-Supported Clinical Trials. For trials that are prioritized in the NCTN, NCI funding should be sufficient to cover actual research costs and take into account trial complexity. The Biomarker, Imaging and Quality of Life Studies Funding Program (BIQSFP) is an important component of the NCI portfolio and should be expanded to support development and validation of biomarkers. In addition, BIQSFP funding review should be simultaneous with clinical trial concept review and protocol development to ensure that a trial can launch as quickly as possible. ASCO continues to advocate for federal funding for NCI and hopes that the Institute will prioritize funding for NCTN trials and the overall infrastructure for NCI-supported clinical trials.

5. Ensure Continuation of a National Infrastructure to Enable Physician Participation. ASCO members consistently value and prioritize their participation in Cooperative Group trials. NCI has rightly recognized the tremendous volunteer hours and institutional and practice resources that are key to making the program a success. The review criteria for NCTN Groups should recognize the key role that the Groups play in training and career development. In addition, review criteria for other NCI mechanisms (e.g., SPOREs, designated cancer centers, U01 networks, etc.) should provide credit and recognition for the scientific leadership that researchers/faculty provide in the NCTN Groups.

Thank you again for the priority that you have placed on ensuring a robust national clinical trials system. Ensuring implementation of all of the IOM report recommendations is one of ASCO's highest priorities. I am including an attachment that goes into more detail about ASCO's recommendations on the specifics of the NCI proposal.

We look forward to continuing to work with NCI to ensure that all stakeholders heed the call to make needed changes to preserve and improve our federally-funded system. We stand ready to assist you and the NCI in any way that we can.

Bioinformatics:

GAO Decision Clears Way For NCI to Deploy Medidata Rave

By Paul Goldberg

The Government Accountability Office declined to reconsider the NCI decision to cancel the procurement of a data capture system.

The decision removes a potential obstacle to NCI's plans to implement a single data capture system for cooperative group trials.

Efforts to purchase the system began in 2007 and were a part of the institute's controversial caBIG bioinformatics venture. The institute selected the Medidata Rave system to win the $24.3 million contract.

However, a competing firm, Velos Inc, protested, winning two opposition proceedings.

Late last year, NCI canceled the original procurement. Instead, it split the deal in two: the licensing of the data capture system and, separately, the support services.

Velos filed another appeal, claiming that the institute canceled the procurement to avoid review of its most recent protest.

The institute argued that the procurement was cancelled because its needs changed. This time, GAO upheld NCI's decision. "On this issue, the agency's explanations appear reasonable, and are supported by the facts surrounding this procurement," the agency said in a decision May 26. "Moreover, government officials are presumed to act in good faith, and a protester's claim that contracting officials were motivated by bias or bad faith must be supported by convincing proof; our Office will not attribute unfair or prejudicial motives to procurement officials on the basis of inference or supposition."

The institute has been implementing the Medidata Rave system across the clinical trials cooperative group system (The Cancer Letter, April 22). Data managers at all cooperative groups are receiving training in using the system, sources said.

Several sources who are now going through training said it remains to be seen how the data capture system would be integrated with the back-end applications. NCI and Medidata are trying to limit—or at least manage—adaptations to the system.

Until it was selected by NCI, Medidata was used primarily by contract research organizations, which, like cooperative groups, typically run fewer trials than cancer centers. Meanwhile, Velos specializes in serving cancer centers.

Two centers—Mayo and City of Hope—use Medidata. Others use Velos, Oncor and a variety of custom products.

"We knew going into this protest that it was going to be challenging since the government had already terminated the contract for convenience for its own reasons," said John McIlwain, president and CEO of Velos. "As a result of the contract termination, there is now more of a fair market where individual organizations can select a vendor that best suits their needs. In terms of the bigger picture and caBIG, the NCI's Board of Scientific Advisors report earlier this year speaks for itself. Dr. Varmus and his team are very much to be commended."

The GAO decision is posted at http://www.cancerletter.com/categories/documents.

NCI spent at least $350 million on caBIG, which was exempt from peer review. The program is now under scrutiny by NCI officials as they look for money to fund peer-reviewed research.

Looking for signs of what might be happening with the program, bioinformatics insiders are perplexed by the fact that caBIG hasn't scheduled its annual meeting, which is usually held in September.

Efforts to obtain additional information from caBIG officials were unsuccessful.

FDA News:

FDA Updates Safety Labeling Of 5-Alpha Reductase Inhibitors

FDA changed the label of 5-alpha reductase inhibitors to include safety information about the increased risk of being diagnosed with high-grade prostate cancer.

The June 9 warning applies to the drugs finasteride and dutasteride, which have similar molecular structures and are approved for the treatment of benign prostatic hyperplasia.

Finasteride, sponsored by Merck, is also approved for male pattern baldness, and dutasteride, sponsored by GlaxoSmithKline, is often used for this indication off-label.

The warning is consistent with the Dec. 1, 2010, vote of the FDA Oncologic Drugs Advisory Committee, which set a high bar for approval of drugs that are given to asymptomatic and presumably healthy people (The Cancer Letter, Dec. 3, 2010).

The warning is also consistent with the agency's review of two large, randomized controlled trials—the Prostate Cancer Prevention Trial, and the Reduction by Dutasteride of Prostate Cancer Events trial.

The agency's recommendation reads:

FDA is informing healthcare professionals that the Warnings and Precautions section of the labels for the 5-alpha reductase inhibitor (5-ARI) class of drugs has been revised to include new safety information about the increased risk of being diagnosed with a more serious form of prostate cancer (high-grade prostate cancer). This risk appears to be low, but healthcare professionals should be aware of this safety information, and weigh the known benefits against the potential risks when deciding to start or continue treatment with 5-ARIs in men.

The new safety information is based on FDA's review of two large, randomized controlled trials—the Prostate Cancer Prevention Trial (PCPT) and the Reduction by Dutasteride of Prostate Cancer Events (REDUCE) trial—which evaluated daily use of finasteride 5 mg versus placebo for 7 years and daily use of dutasteride 0.5 mg versus placebo for 4 years, respectively, for the reduction in the risk of prostate cancer in men at least 50 years of age. The trials demonstrated an overall reduction in prostate cancer diagnoses with finasteride 5 mg and dutasteride treatment (see Data Summary below). This overall reduction was due to a decreased incidence of lower risk forms of prostate cancer. However, both trials showed an increased incidence of high-grade prostate cancer with finasteride and dutasteride treatment.

Data Summary:

The PCPT was a randomized, double-blind, placebo-controlled, multicenter trial in 18,882 men age 55 or older with a normal digital rectal examination and PSA levels $\leq$ 3 ng/mL. Men at higher risk for developing prostate cancer, such as those men with prior prostate biopsies demonstrating high-grade prostatic intraepithelial neoplasia, were excluded from the study. The trial compared the use of finasteride 5 mg (n=9423) to placebo (n=9459) for the reduction in the risk of prostate cancer.

Treatment was continued for seven years following randomization or until diagnosis of prostate cancer, initiation of treatment for BPH with a 5-ARI, or unacceptable side effects. The study protocol specified that transrectal ultrasound and sextant prostate biopsy were to be performed for an elevation in PSA level or an abnormal digital rectal examination during the study. All participants who were not previously diagnosed with prostate cancer were to undergo transrectal ultrasound and sextant core prostate biopsy after completing 7 years on study.

The results of the PCPT showed that men on the finasteride arm had a 26% overall lower risk of being diagnosed with prostate cancer when compared to the placebo arm ($p<0.0001$). The reduction in risk of prostate cancer was limited to Gleason score (GS) 6 or lower prostate cancers. However, there was an increased incidence of GS 8-10 prostate cancers with finasteride versus placebo (1.8% versus 1.1%, respectively).

The REDUCE trial was a randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of once daily dosing of dutasteride in reducing the risk of biopsy-detectable prostate cancer in men 50-75 years of age considered to be at increased risk for prostate cancer. The trial allocated 8231 men to receive either placebo (n=4126) or dutasteride 0.5 mg (n=4105) once daily for a total of four years. Prostate biopsies were performed at 2 years and 4 years. Unscheduled biopsies in addition to the protocol-mandated Year 2 or 4 biopsies were allowed if clinically indicated at the discretion of the investigator, but were discouraged.

The results of the REDUCE trial showed that men on dutasteride had a 23% overall lower risk of being diagnosed with biopsy detectable prostate cancer when compared to men on placebo ($p<0.0001$). This overall risk reduction was limited to a decrease in GS 6 or lower prostate cancers. In contrast, there was an increased incidence of GS 8-10 cancers with dutasteride versus placebo (1% versus 0.5%, respectively).

FDA News:

FDA Publishes Draft Guidance On Nanotechnology Products

FDA released **draft guidance** to provide regulated industries with greater certainty about the use of nanotechnology.

The guidance outlines the agency's view on whether regulated products contain nanomaterials or involve the application of nanotechnology.

The agency named certain characteristics–such as the size of nanomaterials used and the exhibited properties of those materials–that may be used to identify applications of nanotechnology in regulated products.

"With this guidance, we are not announcing a regulatory definition of nanotechnology," FDA Commissioner Margaret Hamburg said in a statement. "However, as a first step, we want to narrow the discussion to these points and work with industry to determine if this focus is an appropriate starting place."

For products subject to pre-market review, FDA will apply the draft guidance to better understand the properties and behavior of engineered nanomaterials.

For products not subject to pre-market review, the FDA will urge manufacturers to consult with the agency early in product development so that questions concerning a product's regulatory status, safety, effectiveness or public health impact can be adequately addressed.

In 2006, the FDA formed the Nanotechnology Task Force. The purpose of the task force was to identify and address ways that the agency could better evaluate possible adverse health effects from FDA-regulated nanotechnology products.

A report by the task force in 2007 recommended that the FDA issue additional guidance and address the potential risks and benefits of drugs, medical devices and other FDA-regulated products using nanotechnology.

The draft guidance, "Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology," is open for public comment online at: http://1.usa.gov/mGtnko.

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FDA approved the first fully automated assay for testing HER2 gene status in breast cancer patients, to aid in the assessment of patients considered for treatment with Herceptin (trastuzumab).

The INFORM HER2 Dual ISH DNA Probe cocktail assay was approved for commercialization in the United States. It was developed by Ventana Medical Systems Inc., a member of the Roche Group.

The assay detects both HER2 and chromosome 17 on a single slide using a standard light microscope. Unlike fluorescent in situ hybridization assays, this method delivers a easily interpretable result and produces signals that don't fade over time, said Ventana.

"By having both signals visible on a single slide using light microscopy, we can determine the HER2 gene status within the morphological context of the tumor," said Eric Walk, chief medical officer at Ventana. "We believe this adds significant medical value for the patient and is an important advance toward improved patient focused solutions."

Cancer Statistics:

ACS: Decline In Cancer Mortality Saved 898,000 Lives Since 1990

A steady reduction in overall cancer death rates, between 1990 and 2007, has saved 898,000 lives, according to the latest statistics from the American Cancer Society.

The society projects a total of 1,596,670 new cancer cases and 571,950 deaths from cancer in the U.S. in 2011, a rate of over 1,500 deaths per day.

The report—Cancer Statistics 2011, published early online in CA: A Cancer Journal for Clinicians—found that individuals with the least education died from cancer at almost double the rate of the most educated—and that closing that gap could have prevented 37 percent of the premature cancer deaths that occurred in 2007: 60,370 people between the ages of 25 and 64.

Overall cancer incidence rates became stable in men after decreasing 1.9 percent each year from 2001 to 2005. In women, incidence rates have declined by 0.6 percent annually since 1998.

Overall cancer death rates continued to decrease in all ethnic groups in both men and women, with the exception of American Indian/Alaska Native women,

whose rates were stable. African-American and Hispanic men showed the largest annual decreases in cancer death rates, dropping by 2.6 percent and 2.5 percent, respectively.

Other highlights of the report include:

• Between 1990 and 2007, cancer death rates decreased by 22.2 percent in men and by 13.9 percent in women.

• The three most commonly diagnosed types of cancer among women were breast, lung, and colorectum, accounting for about 53 percent of estimated cancer cases in women. Breast cancer alone is expected to account for 30 percent (230,480) of all new cancer cases among women.

• Among men, cancers of the prostate, lung, and colorectum account for more than half of all newly diagnosed cancers. Prostate cancer alone accounts for 29 percent (240,890) of incident cases in men.

• The lifetime probability of being diagnosed with an invasive cancer is higher for men—at 44 percent—than it is for women, at 38 percent.

• Cancers of the lung, prostate and colorectum in men, and cancers of the lung, breast and colorectum in women continue to be the most common causes of cancer death. These four cancers account for almost half of the total cancer deaths among men and women.

• Among men, the reduction in death rates for lung, prostate, and colorectal cancers account for nearly 80 percent of the total decrease in the cancer death rate, while among women, a reduction in death rates for breast and colorectal cancers account for almost 60 percent of the decrease.

"The nearly 900,000 cancer deaths avoided over a 17-year period stand in stark contrast to the repeated claim that cancer death rates have not budged," said John Seffrin, chief executive officer of the American Cancer Society and its advocacy affiliate, the American Cancer Society Cancer Action Network.

"Nonetheless, we refuse to be satisfied, and are committed to doing whatever it takes, not only to ensure cancer death rates continue to drop, but to accelerate the decline."

The report features a section on the impact of eliminating disparities in cancer deaths. In 2007, cancer death rates in the least educated segment of the population were 2.6 times higher than those in the most educated.

This disparity was largest for lung cancer, with a death rate five times higher.

The difference in lung cancer death rates reflects the rate of smoking prevalence: 31 percent of men with 12 or fewer years of education are current smokers, compared to 12 percent of college graduates and 5 percent of men with graduate degrees.

Each year, the American Cancer Society estimates the numbers of new cancer cases and deaths expected in the United States in the current year and compiles the most recent data on cancer incidence, mortality, and survival based on incidence data from NCI, Centers for Disease Control and Prevention, and the North American Association of Central Cancer Registries, and mortality data from the National Center for Health Statistics.

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Obituary:

SU2C Co-Founder Laura Ziskin Dies of Breast Cancer at 61

Laura Ziskin, a co-founder of Stand Up To Cancer died from complications from her disease. She was 61.

Ziskin was a producer and studio executive whose films included "Pretty Woman," "What About Bob," "No Way Out," "The Doctor," and the "Spider Man" trilogy. She also produced the 74th and 79th Academy Awards.

She was diagnosed with stage III breast cancer in 2004. After diagnosis, she co-founded SU2C.

Since its launch in May 2008, the organization has produced two telecasts—airing Sept. 5, 2008 and Sept. 10, 2010—raising $180 million.

With these critical funds, SU2C has funded 26 Innovative Research Grants and five interdisciplinary, multi-institutional Dream Teams—comprised of 355 scientists and other professionals from 55 institutions.

"We are extraordinarily grateful for Laura's unwavering commitment to a revolutionary approach to funding and conducting cancer research," Judy Garber, president of the American Association for Cancer Research, said in a statement.

"Her impact on our field has already been enormous and will endure as a tribute to her astonishing energy and vision. As the scientific partner of SU2C, we are proud to have had the privilege of working with Laura in her quest to eradicate cancer."

In the Cancer Centers:

Hortobágyi Wins Pinedo Prize; Ruotolo Recieves Waters Award

(Continued from page 1)

At NCI, von Eschenbach pledged to eliminate "suffering and death due to cancer" by the year 2015.

"His experience and wisdom bridges the worlds of clinical research and patient care which is in perfect alignment with the mission of the NCCN Foundation," Sam Donaldson, chair of the foundation's board and former ABC News anchor, said in a statement.

The foundation was formed in 2010 to raise money for the development and distribution of NCCN guidelines to patients. Currently they offer seven guidelines, and nine more are expected to be released in the coming year.

PETER FREDERICK was appointed director of minimally invasive surgery, a newly created position, in the Department of Gynecologic Ongcology at **Roswell Park Cancer Institute.**

Frederick is assistant professor in the Division of Surgical Subspecialties within the department. As director, Frederick will oversee robotic and laparascopic surgery at RPCI.

"We've seen a surge in the volume of laparoscopic and robotic surgeries we're performing since [Frederick] joined the department, and we are looking to expand the program further so that more women in Western New York have a trusted option for these complex minimally invasive approaches," Kunle Odunsi, chair of the Department of Gynecologic Oncology, said in a statement.

GABRIEL HORTOBÁGYI was awarded the **2011 Pinedo Cancer Care Prize** by the **Society for Translational Oncology**.

In the course of his career, Hortobágyi developed combined modality therapy for previously inoperable breast tumors; conducted clinical trials to develop treatment regimens that are now in standard use; and published over 1,000 articles, edited 13 books, contributed over 140 chapters to textbooks, and serves as an editor for over 23 publications. Hortobágyi is a senior editor for The Oncologist and a medical advisory committee member for the society.

Hortobágyi, former president of ASCO, is the Nellie B. Connally Chair of Breast Medical Oncology at MD Anderson Cancer Center.

The prize honors H.M. (Bob) Pinedo, founder of the VU University Medical Center Cancer Center Amsterdam.

BRANDON RUOTOLO received the Waters Research Award from the **American Society for Mass Spectrometry**.

Ruotolo is an assistant professor of chemistry at the University of Michigan. His research uses ion mobility-mass spectrometry to determine which large multi-protein complexes are responsible for amyloid/protein-aggregation diseases (such as Alzheimer's, diabetes type-2, ALS, and cancer).

The award ceremony was held at the society's annual meeting in Denver, June 8.

ROBERT HAUSER was named senior director of **ASCO's Quality Department**.

ASCO established the department in early 2011 to prepare its clinical practice guidelines; to assist oncology practices in adopting electronic health records and other health information technology; and to expand the Quality Oncology Practice Initiative.

"Informatics is playing an increasingly large role in cancer care and the demand for real time knowledge is essential to the future of quality care. We are pleased that Dr. Hauser has brought his rich background of experience and knowledge to ASCO," Allen Lichter, CEO of ASCO, said in a statement.

Before joining ASCO, Hauser served as director of Operations and Informatics at the International Oncology Network. He was also vice president and chief operating officer for the Geriatric Oncology Consortium Inc., an organization focused on age-based disparities in cancer research, education and treatment.

The Cancer Letter Wins Award For Duke Scandal Coverage

THE CANCER LETTER won a 2011 Dateline Award for Excellence in Local Journalism from the Washington, D.C.,Cchapter of the Society of Professional Journalists.

The publication won a second place award in the newsletter category, for a srries of stories titled "The Duke Genomics Scandal." The stories were written by editor and publisher Paul Goldberg.

The Cancer Letter's coverage of the Duke story led to formation of a committee of the Institute of Medicine, and the retraction of papers by The New England Journal of Medicine, Nature Medicine, The Lancet Oncology and The Journal of Clinical Oncology.

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