THE CANCER LETTER

Vol. 37 No. 39
Oct. 21, 2011

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

Revamping Cooperative Groups

The Number of Adult Groups Drops to Four As NSABP, RTOG and GOG Agree To Merge

By Paul Goldberg

Three more venerable institutions engaged in cancer clinical trials are about to merge their operations.

They are:

• The National Surgical Adjuvant Breast and Bowel Project,

• The Radiation Therapy Oncology Group,

• The Gynecologic Oncology Group.

The chairs of the three groups signed a memorandum of understanding Oct. 19 that the three groups would operate under one common set of federal grants. The details of the merger will be worked out later, they said.

All three chairs will continue to run their groups—and the name of the new entity may include the word "federation."

(Continued to page 2)

The Avastin Controversy

Insurer Declines to Cover Avastin For Breast Cancer, Institutes Review Procedure For Exceptional Cases

By Paul Goldberg

Earlier this week, Blue Shield of California changed its coverage policy of the Genentech drug Avastin (bevacizumab) for advanced breast cancer.

Starting Oct. 17, a panel of oncology experts will review each new request individually, and Avastin will be covered if the panel determines it to be medically necessary, the insurer said.

The company, which has approximately 3.3 million members, will continue to cover Avastin for advanced breast cancer for any covered member that is currently under treatment with the drug, the company said.

(Continued to page 4)

In Brief:

Stephen Gruber Named Director At USC Norris; TGen & Cedars-Sinai to Coordinate Phase I Trials

STEPHEN GRUBER was named director of the **USC Norris Comprehensive Cancer Center** at the Keck School of Medicine of USC, effective Dec. 1.

He was also named the H. Leslie Hoffman and Elaine S. Hoffman Chair in Cancer Research and visiting professor of medicine at the Keck School.

Gruber will leave the University of Michigan Comprehensive Cancer

(Continued to page 9)

Three Group Chairs To Remain As "Multiple Principal Investigators"

(Continued from page 1)

RTOG and NSABP announced their merger in March (The Cancer Letter, Mar. 11). The two groups have been exploring a merger with GOG for several months (The Cancer Letter, Mar. 25).

The three group chairs reached the final agreement less than three weeks before the meeting of the NCI Board of Scientific Advisors, where institute officials will present a plan for restructuring the cooperative group system.

Now NCI appears to have gotten what it wanted: the number of clinical trials cooperative groups studying cancer in adults has been cut from nine to four.

Additional details of the NCI plan are expected to emerge at the meeting of the Board of Scientific Advisors Nov. 7-8.

The political structure of the emerging "federation" that will combine NSABP, RTOG and GOG will be almost the exact opposite of the structure of the "alliance" that has replaced the Cancer and Leukemia Group B, the North Central Cancer Treatment Group, and the American College of Surgeons Oncology Group.

CALGB, NCCTG and ACOSOG merged into a single entity called Alliance for Clinical Trials in Oncology—ACTION, for short—run by one chair, Monica Bertagnolli, a surgeon from Dana-Farber Cancer Institute (The Cancer Letter, June 17, July 15).

The Southwest Oncology Group was large enough to avoid merging with anyone. But it did change its name—a remnant of the era when groups were geographically based—to its acronym, SWOG (The Cancer Letter, Apr. 8).

Separately, Eastern Cooperative Oncology Group joined with the American College of Radiology Imaging Network, becoming ECOG-ACRIN Cancer Research Group, similarly preserving the widely recognized acronyms (The Cancer Letter, Sept. 23).

The NSABP-RTOG-GOG federation will be a "very unique cancer clinical trials research group," said Walter Curran, chair of RTOG and executive director of the Winship Cancer Institute of Emory University.

"GOG is the lead group in the world that does gynecologic oncology multicenter trials, RTOG is the leading multicenter group studying brain tumors, head-and-neck and localized prostate trials, and with the tremendous history of accomplishment in breast and colorectal cancer trials of NSABP, we have the capacity to build on one another's strengths to have a great organization," Curran said to The Cancer Letter.

The new group will also be the only new entity where specialists other than medical oncologists are likely to occupy a majority of leadership roles.

"NCI understands that to have a group where most of the leadership are from specialties other than medical oncology will be invaluable to the adult cancer cooperative group enterprise," Curran said. "And the other three groups will be more historically medical-oncology-oriented. We will be unique in the diseases we study and the conceptual approaches that we have to both disease and clinical trial design."

Philip DiSaia, chair of GOG and director of the Division of Gynecologic Oncology at the University of California, Irvine, was the only chair to openly challenge the merger (The Cancer Letter, Feb. 4). Now, DiSaia says he has accepted the inevitability of the merger and is optimistic about the new entity.

"We bring to the table uniqueness," DiSaia said to The Cancer Letter. "What I offer from my group none of the other groups have. And what Wally brings to the table is unique, and so is what [NSABP Chair] Norman [Wolmark] brings to the table. Norman has a 50-year record of getting people to study breast cancer.

"We are feeling that we will have a very strong group."

Though NCI officials have said that they were refraining from arranging the mergers, they have said publically that they would welcome the merger of NSABP, RTOG and GOG.

At the Feb. 8 meeting of the National Cancer

THE CANCER LETTER

® The Cancer Letter is a registered trademark.

Editor & Publisher: Paul Goldberg
Copy Editor: Conor Hale
Intern: Lucas Thomas

Editorial, Subscriptions and Customer Service:
202-362-1809 Fax: 202-379-1787
PO Box 9905, Washington DC 20016
General Information: www.cancerletter.com

Subscription $395 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc.

Advisory Board, James Doroshow, director of the Division of Cancer Treatment and Diagnosis, hinted that specialized expertise of the three groups would be valuable in merged groups and would result in better review scores.

"We are trying very hard to facilitate the process, provide incentives for the process but in no way to dictate the process," Doroshow said at the time. "We need to do studies in women's cancers. We need to do studies in brain tumors. There is one group that is very invested in the former, and the other group that basically does most of our accrual in the latter.

"We think that a forward-thinking organization would put some of those organizations in the lead, because they would be unique, as opposed to medical oncology-only groups, in the context of review.

"But this is all hypothetical." (The Cancer Letter, Feb. 11).

Details to be Worked Out

The name of the new group will be one of the first details that would need to be worked out, and all three groups have submitted proposals.

"We can't use the word 'alliance,' because Monica stole that one," DiSaia said. However, the word "federation" is still up for grabs.

"I like federation," DiSaia said. "In the absence of an agreed-upon name, I have been calling it the National Clinical Trials Federation."

Combining the current acronyms into a single name may create too much of a tongue-twister even for the most devoted aficionados of oncology nostalgia. "We can stick those up in the corner of a page somewhere," DiSaia said.

The name of the new organization will be finalized in November.

The groups have been meeting and holding teleconferences to identify the operational functions that can be combined.

The NSABP operations office is located in Pittsburgh, RTOG's in Philadelphia, and GOG's in Philadelphia and Buffalo.

"There will be inevitable consolidation of processes, but at this point no one office among any of our entities that could conduct the scope and scale—and has the expertise—to take over the trials in all these areas," Curran said.

"The NCI is allowing there to be what they call multiple principal investigators, and right now the plan is to have that arrangement initially," he said. "Over time, there may be an evolution to having one principal investigator."

The decision-making structure would have to reflect the areas of strengths of the three groups.

"The GOG leadership doesn't need the other groups to help influence what are the best ovarian cancer trials to do," Curran said. "We will rely on their expertise."

The informatics structure would be a challenge to put together.

"We've made it clear to NCI that all of the groups need stronger support for medical and bioinformatics," Curran said. "There is a commitment on the part of NCI to support that, particularly as it relates to our tumor banks. We expect to hear more about that at a meeting that we are going to have with NCI in late November."

That meeting will focus mainly on tissue banks, Curran said.

DiSaia said it would make sense to combine IT functions. Combining statistical centers would be more difficult.

"Statistics, I don't see how we can do that," he said. "We need so many statisticians. Maybe with time. I think it has to evolve. I don't think this is going to happen tomorrow, or even in 2014. It's going to be a decade before the three groups are working in harmony with optimum efficiency."

Curran said the new structure within the new group could create new struggles in prioritization of trials.

"The challenge that I see is that there will be finite resources, and how will we prioritize which trials to move forward," Curran said. "Our present view is that that will be the real role and responsibility of the executive team.

"Our goal is to be able to make strategic decisions. We will have a very strong brain tumor committee leadership within RTOG—that team will have to choose among the many opportunities to put forth the most outstanding concepts.

"This will be true in the new era whether or not we would be consolidating functions. It has been pretty clear for NCI that the budget for cooperative groups is not going to expand. The number of patients enrolled in cooperative group trials—at least under federal dollars—is not going to expand."

However, the new federation would be better positioned to collaborate with the pharmaceutical industry.

"Each one of use has complementary strengths in partnering with other groups beyond the NCI to conduct research," Curran said. "We view those relationships and those capacities as complementary in a way that might

allow us to create a portfolio of trials that's well beyond what NCI alone would be able to support.

"A group with the breadth and capacity that we have would be a group that industry would be very interested in partnering with."

Working out the details of what happens at member institutions is also a challenge. For example, what happens at a cancer center that is involved in studies conducted by all three groups?

"One of the big challenges we have is how to define institutional membership and leadership," Curran said.

"We realize that all those people and their continued engagement is critical to our success. So some kind of a top-down merger of these groups—where we tell a university medical center, 'Oh, just pick one of you and you will be the leader, and we will thank the other two,'—is not the way to keep engagement.

"There are some creative solutions coming out."

Maintaining the cultures of the groups at member institutions would be crucial, DiSaia said.

"Each of us has contributed a great deal," DiSaia said. "As long as we don't throw the baby out with the bath water, but instead create a child that we can all be proud of, I think we will be fine."

The Avastin Controversy

Insurer Says Avastin Restriction Due To FDA Panel Vote in June

(Continued from page 1)

"Blue Shield's decision follows an FDA advisory panel's unanimous determination in June that Avastin is ineffective and unsafe for advanced breast cancer," said Steve Shivinsky, vice president of corporate communications at Blue Shield of California.

The future of Avastin's metastatic breast cancer indication is uncertain. The drug is going through the process in which FDA is seeking to remove the indication while the company is hoping to retain it while conducting another confirmatory trial.

No drug has lost an accelerated approval, and with the new process having run its course, FDA Commissioner Margaret Hamburg is expected to issue a decision (The Cancer Letter, May 27).

It's not publicly known when this decision will be made.

Genentech said coverage should continue. "Avastin is still FDA approved in combination with paclitaxel for first-line treatment of HER2-negative metastatic breast cancer and NCCN guidelines still recommend it for this use," said Charlotte Arnold, a Genentech spokesperson. "We believe insurers should cover Avastin for this use and women with this incurable disease should have the ability to choose Avastin if they, and their doctor, believe it's the right option for them."

Originally, Blue Shield of California said it would flatly deny coverage of the drug in the breast cancer indication, but would consider making exceptions on a case-by-case basis.

However, the company later said that it would rely on expert panels to determine whether such use is appropriate.

"We are pleased that they have since changed that [policy]," Arnold said to The Cancer Letter.

Shivinsky said the company's plan from the outset was to use a panel of oncology experts. However, those details were not a part of the original announcement.

The review panel is "an extra step we put in place that provides an extra level of scrutiny before Avastin is approved or not approved," Shivinsky said to The Cancer Letter.

"We now have in place an expert review panel of three oncologists. We wil be supplementing this panel with additional oncology expertise in the near future."

The Centers for Medicare and Medicaid Services said it would continue to provide coverage for the drug while FDA is deciding whether the indication should remain. CMS has a separate mechanism—called the National Coverage Determination process—to consider removing coverage for medical services.

Three regional Blue Cross/Blue Shield insurers have made policy changes to stop covering Avastin for breast cancer before the FDA hearing last June (The Cancer Letter, July 1).

They are:

• Regence, which has approximately 2.5 million members across Idaho, Oregon, Utah and Washington states. Regence adopted its policy in September 2010.

• Excellus, which has approximately 1.9 million members in Rochester, New York. The insurer adopted its policy in January 2011.

• Dakotacare, of South Dakota, which has approximately 120,000 members, changed its policy in their policy in March 2011.

Two more carriers posted non-coverage policies on their websites, but subsequently removed them. They are: Palmetto GBA, Medicare carrier for South Carolina, West Virginia, Ohio, California, Hawaii and Nevada; and HealthCare Services Corporation, a national health plan with Blue Cross Blue Shield subsidiary plans in Illinois, Texas, New Mexico and Oklahoma.

On Aug. 4, Genentech submitted a post-hearing summary to FDA in support of maintaining accelerated approval of Avastin's breast cancer indication. Genentech's submission included a "middle-ground proposal" with the goal of preserving Avastin plus paclitaxel as an FDA-approved option for women with HER2-negative mBC, while Genentech conducts a new confirmatory phase III trial.

Breast cancer treatment with Avastin costs around $88,000 a year.

Insurer Establishes Coverage For Oncotype DX Colon Cancer Test

Genomic Health Inc. said that Palmetto GBA, the designated national contractor for its Oncotype DX colon cancer test, has established a formal coverage policy for all Medicare patients.

The policy covers men and women with stage II colon cancer.

Palmetto's decision is based on the two QUASAR and CALGB clinical validation studies in addition to clinical utility information. Coverage for the Oncotype DX colon cancer test was posted on the Palmetto GBA website on Sept. 29.

"Palmetto's coverage decision reflects the importance of evidence-based coverage and has the potential to transform care for Medicare colon cancer patients while saving the healthcare system dollars," said Kim Popovits, CEO of Genomic Health.

"This coverage decision allows all appropriate Medicare patients access to Oncotype DX for colon cancer and further recognizes the value our tests are delivering to physicians, payers and patients."

The QUASAR validation study assessed recurrence risk in stage II colon cancer by using the Oncotype DX Recurrence Score, mismatch repair status and T-stage. The paper has been accepted for publication by the Journal of Clinical Oncology, the company said.

Genomic Health said that it plans to expand its Oncotype DX colon cancer offering to include immunohistochemistry testing for MMR status to assess mismatch repair for stage II colon cancer recurrence risk.

Reimbursement for the Oncotype DX colon test was established by Palmetto using a resource-based analysis and an independent pharmacoeconomic analysis, and is consistent with previous decisions by other payers, the company said.

Guideline-based Care Cuts Costs By 30 Percent in Colon Cancer

A study conducted by the US Oncology Network and the Milliman actuarial consulting firm found that colon cancer treatment consistent with evidence-based guidelines has significantly lower cost while demonstrating outcomes similar to those in published literature.

The study shows mean-per-patient cost differences of more than 30 percent: $53,000 for the treatment of adjuvant colon cancer and $60,000 for the treatment of metastatic colon cancer.

The study, which compared patients treated through Level I Pathways to patients who were not, was published in a special joint peer-reviewed issue of the Journal of Oncology Practice and the American Journal of Managed Care.

The study utilized Level I Pathways treatment guidelines, as developed by physicians in the US Oncology Network.

The study titled "Pathways, Outcomes, and Costs in Colon Cancer: Retrospective Evaluations in Two Distinct Databases" is the second study of the guidelines conducted by US Oncology-affiliated investigators and published in the JOP.

Last year, US Oncology and Aetna published a study suggesting that adherence to these pathways in treating non-small cell lung cancer showed outpatient cost savings of 35 percent while demonstrating equivalent health outcomes.

"Once again, a study has indicated that the use of Level I Pathways could reduce costs significantly without sacrificing outcomes or compromising the survival of the patient," said Russell Hoverman of Texas Oncology, an affiliate of the US Oncology Network, and principal investigator in the colon cancer study. "We have now shown for both lung and colon cancer that on-pathway treatment decisions are more cost effective and have similar results to off-pathway."

For this most recent study, Milliman consultants analyzed claims data for colon cancer patients, providing key cost comparisons, while the iKnowMed EHR System was used to compare outcomes for patients treated on-pathway with those treated off-pathway.

Study results suggest that the on-pathway treatment of patients with colon cancer costs less, and the use of these pathways demonstrated clinical outcomes consistent with published outcomes, the company said.

In particular, the study supports the idea that using

these pathways in patients with colon cancer results in lower costs for chemotherapy and overall cancer care and may result in fewer hospitalizations for patients.

"These are significant results," said Roy Beveridge, co-author of the study and chief medical officer of the US Oncology Network and McKesson Specialty Health. "The US Oncology Network physicians have been dedicated to developing evidence-based Level I Pathways in order to better provide high-quality, cost-effective cancer care. Being able to demonstrate once again that evidence-based treatment could save patients and the nation's health care system millions of dollars while producing equally effective, if not better, results is exciting and encouraging."

Two independent studies of separate databases were performed.

The first study used clinical records from an electronic health record database to evaluate survival according to pathway status in patients with colon cancer.

Disease-free survival in patients receiving adjuvant treatment and overall survival in patients receiving first-line therapy for metastatic disease was calculated using the Kaplan Meier method.

The second study used claims data from a national administrative claims database to examine direct medical costs including the cost of chemotherapy and of chemotherapy-related hospitalizations according to pathway status as surmised from treatment patterns observed in the claims data.

Overall costs from the national claims database, including total cost per case and chemotherapy costs, were lower for patients that appear to be treated on-pathway, compared with other patients.

Use of pathways was also associated with a shorter duration of therapy and lower rate of chemotherapy-related hospital admissions.

Survival for patients on-pathway in the EHR database was comparable with those in the published literature.

The study is posted at www.usoncology.com.

FDA News

FDA Grants Accelerated Approval To Ferriprox for Iron Overload

FDA last week gave an accelerated approval to Ferriprox (deferiprone) for iron overload due to blood transfusions in patients with thalassemia, a genetic blood disorder that causes anemia, who had an inadequate response to prior chelation therapy.

The approval sets a precedent, as the agency for the first time approves an application based on a retrospective review of data.

Last month, the FDA Oncologic Drugs Advisory Committee accepted this lower level of evidence, voting 10-2 to recommend approval, departing from its usual insistence of prospective clinical trials.

The advisory committee—and the agency—also accepted extensive international experience with the drug as evidence supporting its safety and efficacy (The Cancer Letter, Sept. 30).

Patients with thalassemia have excess iron in the body from the frequent blood transfusions (transfusional iron overload), a condition that is serious and can be fatal. These patients also have a risk of developing liver disease, diabetes, arthritis, heart failure or an abnormal heart rhythm.

The standard of care to treat transfusional iron overload is chelation therapy – chemical agents that are used to remove heavy metals from the body. Ferriprox is intended for use when chelation therapy is inadequate.

Ferriprox is marketed by ApoPharma Inc. of Toronto.

ApoPharma has agreed to several post-marketing requirement and commitments. One commitment includes further study of the use of Ferriprox in patients with sickle cell disease who have transfusional iron overload.

"Ferriprox represents the first new FDA-approved treatment for this disorder since 2005," said Richard Pazdur, director of the Office of Hematology and Oncology Products in the FDA Center for Drug Evaluation and Research

Earlier this year, HHS launched the Sickle Cell Disease Initiative bringing together HHS agencies to enhance the quality and quantity of SCD data, develop best practice guidelines and quality of care metrics, improve health care delivery and coordination of care for patients with SCD, facilitate approval of new medical products, and expand research on SCD. The post-marketing requirement for further study of Ferriprox

aligns with the goals of the SCD Initiative.

The safety and effectiveness of Ferriprox is based on an analysis of data from twelve clinical studies in 236 patients. Patients participating in the study did not respond to prior iron chelation therapy. Ferriprox was considered a successful treatment for patients who experienced at least a 20 percent decrease in serum ferritin, a protein that stores iron in the body for later use. Half of the patients in the study experienced at least a 20 percent decrease in ferritin levels.

The most common side effects seen in patients who received Ferriprox included nausea, vomiting, abdominal and joint pain, urine chromaturia, neutropenia, and an increase in the level of a liver enzyme that may be indicative of tissue or liver damage at unsafe amounts.

The most serious side effect seen in about two percent of patients treated with Ferriprox was the development of agranulocytosis, a serious and potentially life-threatening reduction in the number of granulocytes (a type of white blood cell that fights infection).

USPSTF, ACS Publish Guidelines On Screening for Cervical Cancer

The U.S. Preventive Services Task Force published a draft guideline for screening for cervical cancer last week.

The task force advises that women reduce the number of tests they get over their lifetime to better ensure that they receive the benefits of testing while minimizing the risks.

The task force advises screening for cervical cancer with cytology (Papanicolaou smear) every three years for women between 21 to 65 years of age who have had vaginal intercourse and have a cervix. This is an ”A” recommendation, the highest grade.

Also in the draft guideline:

• The USPSTF recommends against screening for cervical cancer in women younger than age 21 years, regardless of sexual history. This is a D recommendation, which means such screening shouldn’t be done.

• The USPSTF recommends against screening for cervical cancer in women older than age 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer. This received a D recommendation.

• The USPSTF recommends against screening for cervical cancer in women who have had a total hysterectomy for benign disease. This is a D as well.

• The USPSTF recommends against screening for cervical cancer using human papillomavirus testing, alone or in combination with cytology, in women younger than age 30 years. This gets a D.

• The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of HPV testing, alone or in combination with cytology, for screening for cervical cancer in women ages 30 years and older. This is an “I” rating, which stands for insufficient evidence.

Under new procedures, USPSTF releases its draft guidelines for a public comment period that runs for a month, before the guidelines become final.

The American Cancer Society, the American Society for Colposcopy and Cervical Pathology, and the American Society for Clinical Pathology mimicked these procedures and similarly proposed new guidelines for the prevention and early detection of cervical cancer.

The joint guidelines, which ACS and the professional societies released on Oct. 19, are posted for public comment.

The proposed recommendations from the USPSTF are posted at http://www.uspreventiveservicestaskforce.org/tfcomment.htm.

The proposed recommendations by ACS and the professional societies are posted at www.asccp.org/practice-management/molecular-screening-symposium.

The proposed ACS guidelines also include a preference for co-testing using the Pap test and HPV test for women age 30 and over.

After a public comment period that begins immediately and a multi-stakeholder symposium in November to discuss the proposed recommendations among a broad group of experts, the recommendations will be revised and incorporated into a final guideline from the American Cancer Society, anticipated in mid-2012.

The proposed guidelines were released on the same day that the U.S. Preventive Services Task Force formally released its proposed guidelines update for cervical cancer screening.

ACS, ASCCP and ASCP worked independently of the USPSTF to review existing evidence and develop these draft recommendations. The groups coordinated the release with the USPSTF, to enable stakeholders to consider both sets of recommendations concurrently with the goal of creating consistent guidance that will lead to less confusion for providers and the public.

The ACS-ASCCP-ASCP proposed guidelines would include the following changes from the current ACS guidelines:

• They would recommend that all women start screening at age 21, and drop the recommendation that women under 21 begin screening three years after starting vaginal intercourse.

• They propose that for women 21 to 29, Pap tests (conventional or liquid-based) be done every three years, and recommends against annual Pap testing. Current guidelines call for a conventional Pap test every year, or a liquid-based Pap test every two years for this age group.

• For women 30 and over, the guidelines propose that Pap tests be done every three years, recommending against annual or more frequent Pap testing. Current guidelines say women 30 and over who have had three normal Pap tests in a row may be tested less often, every two to three years.

• The guidelines propose that Pap test plus HPV testing every 3-5 years be the preferred strategy for women aged 30 and older, and recommend against screening with any test or combination of tests more often than every three years. Current ACS guidelines call for testing no more frequently than every three years with a Pap test plus the HPV DNA test 'an option' for women over 30 who have normal immune systems and no abnormal Pap results.

• The proposed recommendations also say screening is not recommended for women 65 or older who have had three or more normal Pap tests in a row and no abnormal Pap test results in the last 10 years, or who had two or more negative HPV tests in the last 10 years. Current guidelines say women may choose to stop being tested at age 70 when they've had three or more normal Pap tests in a row and no abnormal Pap test results in the last 10 years.

"These draft recommendations are being presented for review by interested individuals and stakeholders, primarily clinicians and researchers, who are invited to provide feedback through a web-based open comment period," said Debbie Saslow, director of breast and gynecologic cancer for the American Cancer Society. "The six working groups that developed these recommendations will then consider the submitted comments, and make revisions to these proposed recommendations based on that input and available evidence."

Other new recommendations included in the proposed guideline include:

• Women who have a normal Pap result and a positive HPV test result should receive genotyping for HPV 16 and 18 or repeat both the Pap and HPV tests in one year. The proposed guideline recommends against immediate colposcopy.

• Women having a mildly abnormal Pap result (called ASC-US) and a negative HPV test result should be followed by either HPV testing plus Pap or HPV testing alone at intervals of three years or longer.

• At this time there is insufficient evidence to recommend for or against a comprehensive program for primary screening with HPV testing alone (with defined follow-up testing) in the US.

• Women who have been vaccinated against HPV should begin cervical cancer screening at the same age as unvaccinated women, i.e. at age 21.

The working groups who drafted the proposed guidelines will meet along with delegates from 25 organizations at a symposium in November 2011 to further discuss and finalize the recommendations, which will then be adapted into a final guideline from the American Cancer Society, anticipated in mid-2012.

Capitol Hill News

Legislators Urge Supercommittee To Not Cut Payments for Cancer Care

A group of legislators sent a letter Oct. 14 to members of the Joint Select Committee on Deficit Reduction, from more than 60 members of Congress, urging the committee to reject a proposed $3 billion cut to cancer drugs—a cut that, if enacted, according to the letter, would adversely affect cancer care in the U.S.

The proposed payment cut—offered to the committee as a potential offset, or "payfor," within federal debt reduction efforts—would slash reimbursement for cancer-fighting drugs under Medicare Part B from the current rate of Average Sales Price plus six percent to ASP plus three percent.

This lowered payment would amount to a $3 billion funding cut to cancer care, as projected by the Congressional Budget Office.

The bipartisan letter, led by Reps. Leonard Lance (R) and Bill Pascrell (D), both of New Jersey, states:

Enacting cuts to ASP could also worsen an already troubling access problem, as community oncology practices are already struggling even as demand for cancer care is now starting to exceed the supply of oncologists. According to one report, in the last 3-and-a-half years alone, 199 cancer clinics have closed and 369 practices, with multiple clinic locations, are struggling financially. And it is predicted that over the next ten years there will be an oncologist shortage for one in four cancer patients, and enacting $3 billion in cancer cuts will only exacerbate this problem.

The U.S. has the best cancer care delivery system in the world... It is imperative that Congress continues to ensure that cancer patients across the nation can continue to have access to lifesaving medical treatments. It is for this reason that we urge you not to sacrifice cancer care while seeking deficit reduction solutions.

The letter was signed by: Lou Barletta (R-Pa.), John Barrow (D-Ga.), Brian Bilbray (R-Calif.), Tim Bishop (D-N.Y.), Madeleine Bordallo (D-Guam), Bruce Braley (D-Iowa), Lois Capps (D-Calif.), John Carney (D-Del.), Andre Carson (D-Ind.), Kathy Castor (D-Fla.), Judy Chu (D-Calif.), Emanuel Cleaver (D-Mo.), Howard Coble (R-N.C.), Joe Courtney (D-Conn.), Joseph Crowley (D-N.Y.), Susan Davis (D-Calif.), Diana DeGette (D-Colo.), Bob Filner (D-Calif.), Bill Flores (R-Texas), Barney Frank (D-Mass), Elton Gallegly (R-Calif.), Charlie Gonzalez (D-Texas), Kay Granger (R-Texas), Gene Green (D-Texas), Nan Hayworth (R-N.Y.), Brian Higgins (D-N.Y.), Rush Holt (D-N.J.), Michael Honda (D-Calif), Jay Inslee (D-Wash.), Hank Johnson (D-Ga.), Bill Keating (D-Mass.), Larry Kissell (D-N.C.), Leonard Lance (R-N.J.), Tom Latham (R-Iowa), Barbara Lee (D-Calif.), Stephen Lynch (D-Mass.), Ed Markey (D-Mass.), Doris Matsui (D-Calif.), Jim McDermott (D-Wash.), Jim McGovern (D-Mass.), David McKinley (R-W.V.), Patrick Meehan (R-Pa.), Gregory Meeks (D-N.Y.), Richard Neal (D-Mass.), Richard Nugent (R-Fla.), John Olver (D-Mass.), Bill Pascrell (D-N.J.), Ed Pastor (D-Ariz.), Ted Poe (R-Texas), Reid Ribble (R-Wis.), Mike Rogers (R-Mich.), Dennis Ross (R-Fla.), Tim Ryan (D-Ohio), Linda Sanchez (D-Calif.), Terri Sewell (D-Ala.), Jackie Speier (D-Calif.), John Tierney (D-Mass.), Paul Tonko (D-N.Y.), Edolphus Towns (D-N.Y.), Niki Tsongas (D-Mass.) and John Yarmuth (D-Ky.).

In Brief

Gruber Named Director At Norris; UAB Receives $27.5 Million from NCI

(Continued from page 1)

center, where he is the associate director for cancer prevention and control, and will succeed Peter Jones, who has led the USC center for the past 18 years.

"Recognizing that research is the foundation of all that we do in cancer care, I've really been looking for ways to optimize our ability to advance the care of patients and families with cancer," Gruber said in a statement. "The Trojan family allows me to do that best, and I'm really looking forward to this transformative opportunity here at the USC Norris Comprehensive Cancer Center to really make a difference in the lives of our patients and families, as well as our research community."

At Michigan, Gruber also holds the H. Marvin Pollard Chair of Medicine and faculty appointments in the Departments of Internal Medicine, Epidemiology and Human Genetics at the University of Michigan Medical School and School of Public Health.

Gruber is a medical oncologist, cancer geneticist and epidemiologist whose research focuses on genetic and environmental contributions to cancer. His particular research interests include the genetic epidemiology of cancer, with emphasis on colorectal cancer; the molecular pathogenesis of cancer, integrated with genetic epidemiology; methods in genetic and molecular epidemiology; and clinical cancer genetics and translational research in cancer prevention.

As director of the Cancer Genetics Clinic at the University of Michigan, Gruber concentrates his clinical practice on the care and management of patients and families with inherited susceptibility to cancer. Since 2005, he has been chair of the NCI Colorectal Family Registries Advisory Panel for the National Cancer Institute. For the past three years, he chaired the Cancer Genetics Education Committee of the American Society of Clinical Oncology.

He also holds two patents on a mutation associated with familial colorectal cancer.

Gruber was selected after a national search, led by Jon Samet, founding director of the USC Institute for Global Health and chair of the Keck School's Department of Preventive Medicine.

"Dr. Gruber is one of the world's leading investigators studying the molecular epidemiology of cancer," said Max Wicha, distinguished professor of oncology and director of the University of Michigan Comprehensive Cancer Center. "He has been a wonderful leader for our Cancer Center as the associate director for cancer prevention. We will miss Steve at Michigan, but are excited by the opportunities he will have at USC. We hope that we can work together in the future."

CEDARS-SINAI and the **Translational Genomics Research Institute** plan to collaborate on phase I clinical trials of new anticancer therapies aimed at molecular targets in prostate, kidney, bladder and colorectal cancers.

Research also will be conducted on drugs for less common adrenal, neuroendocrine and thyroid cancers.

"Our two organizations share the same goal: to greatly improve cancer treatment with therapies that attack the disease in new and innovative ways," said Steven Piantadosi, Phase One Foundation chair and director of the Samuel Oschin Comprehensive Cancer Institute. "Translating new research into effective therapies will improve the lives of cancer patients, and, ultimately, lead to a time when cancer is a manageable condition not a feared disease."

The collaborative endeavor also will study new approaches to improve patients' quality of life during cancer treatment and create innovative models to deliver supportive care and services to cancer survivors.

The drug development research collaboration will be coordinated by Cedars-Sinai with Clinical Trials, a partnership with TGen and the Virginia G. Piper Cancer Center at Scottsdale Healthcare.

HYAM LEVITSKY was named Head of Cancer Immunology Experimental Medicine for **Roche**.

Levitsky's new role with the Pharma Research and Early Development organization (pRED) will entail guiding research and early development programs focused on immunotherapy of cancer, overseeing experimental medicine studies and projects in collaboration with internal or external partners.

"With his extensive and wide-ranging academic and medical research background, we believe he is uniquely qualified to bring new and different perspectives to the pRED Oncology organization and look forward to utilizing his expertise to develop differentiated cancer medicines that are beneficial for patients and healthcare providers," said Michael Burgess, Global Head, Oncology Discovery and Translational Area.

Levitsky's contributions to oncology include basic discoveries in antigen processing and presentation, T cell tolerance, lymphocyte homeostasis, vaccine development, and novel molecular imaging of anti-tumor immunity.

G. DAVID ROODMAN was named director of the Division of Hematology Oncology at the **Melvin and Bren Simon Cancer Center at Indiana University**.

Roodman's work includes bone and myeloma research, and understanding the role of bone marrow microenvironment in promoting hematologic malignancies. He also has previous experience as vice-chair for research at Pittsburgh. To go along with his new role, Roodman will also be the Kenneth Wiseman Professor of Medicine at the university's School of Medicine.

"His recruitment was only possible with strong support from the IU Simon Cancer Center and the Lilly Physician Scientist Initiative. Dave's contributions will strengthen the School of Medicine team which is dedicated to finding cures and providing exceptional treatment to our patients," said David Crabb, the John B. Hickman Professor of Medicine and Chair of the Indiana University Department of Medicine.

REBECCA NAGY was elected president of the **National Society of Genetic Counselors.** Nagy is a certified genetic counselor and researcher at the Ohio State University Comprehensive Cancer Center—Arthur G. James Cancer Hospital and Richard J. Solove Research Institute.

Nagy's work includes providing comprehensive cancer genetic consultations to individuals and families with a history of cancer.

ERIC PERAKSLIS was named the FDA Chief Information Officer.

Perakslis specializes in IT and drug discovery and development for large and small molecule therapeutics.

"We are enormously fortunate that we have been able to bring Eric on to our FDA team. With Eric's leadership and industry experience, I am confident in his ability to drive the effort within OIM to enhance FDA's IT security, identify advanced technologies for application development, and build a more robust infrastructure," said FDA Commissioner Margaret Hamburg.
