THE CANCER LETTER

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Taking Profit Out Of ESAs, Insurer Sending Controversial Drugs Directly To Patients

By Paul Goldberg

Oncologists treating cancer patients insured through the Blue Cross Blue Shield Association of Massachusetts will no longer be able to bill for erythropiesis-stimulating agents.

These controversial drugs will instead be shipped by specialty pharmacies directly to patients who would either inject themselves or use the services of a home care nurse or a nurse at the oncologist's office.

This practice of shipping drugs directly to patients as part of a pharmacy benefit is called "brown bagging." The Massachusetts Blues are apparently the first insurer to take this step toward making administration of ESAs less lucrative to physicians, and industry sources said that other insurers would

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FDA News:

ODAC Votes Against Cell Therapeutics Agent; Requires ChemGenex To Develop Diagnostic

The FDA Oncologic Drugs Advisory Committee March 22 voted against approval of the Cell Therapeutics agent Pixuvri (pixantrone dimaleate) for relapsed or refractory aggressive non-Hodgkin's lymphoma.

In a 9-0 vote, the committee said the single clinical trial of pixantrone was inadequate to support approval.

In another action, ODAC voted 7-1 to require the Australian drug company ChemGenex to develop a well-characterized in vitro diagnostic to select chronic myeloid leukemia patients with T315I mutations.

Such patients would be candidates for treatment with the company's drug Omapro (omacetaxine mepesuccinate).

On April 9, Pixuvri sponsor Cell Therapeutics said it received a Complete Response Letter, in which the agency recommended the company conduct an additional trial to demonstrate the safety and effectiveness of its product. The company said it has decided to pursue a study and an expanded access program for pixantrone.

"On the basis of discussing the PIX 301 clinical trial results with directors of more than 50 of the largest academic and community based lymphoma treatment centers across the U.S., we expect enrollment in a follow-up combination therapy study in a similar population could be rapid and occur predominantly within the U.S.," Jack Singer, Cell Thearpeutics chief medical officer, said in a statement. "We have had preliminary discussions

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Doctors, Hospitals Protest "Brown Bagging" By Insurer

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be expected to follow.

FDA recently made ESAs subject of a Risk Evaluation and Mitigation Strategy because eight studies pointed to their potential to cause strokes, heart attacks, and tumor progression.

REMS require additional training and certification for health care providers as well as distribution of a medication guide for patients who may be receiving these agents. Doctors are cautioned to refrain from prescribing these agents in a setting where a cure is possible, and to administer informed consent at each administration of these drugs (The Cancer Letter, Feb. 19).

Insiders say Massachusetts is a special case in the U.S. healthcare system. The Blues in the state have been particularly tough in negotiating with providers. Also, cancer care in Massachusetts differs from that in other states, because it is provided primarily through academic institutions. Nationwide, for-profit oncology practices take care of a vast majority of cancer patients.

"The issue is actually complicated," said Deborah Schrag, an oncologist and health systems researcher at Dana-Farber Cancer Institute and a member of the board of the American Society of Clinical Oncology. "Oncologists selling drug is not a situation any of us wants to promote. On the other hand, 'brown bagging' is also not a solution. Handling this piecemeal each treatment at a time is going to be cumbersome in the extreme.

"The problem here is more fundamental and deeper. For many years and historically, oncologists were reimbursed for drug delivery and not for the valuable care that we provide our patients. Reimbursement systems have to change and get us out from under that old system."

According to a document distributed to doctors in Massachusetts, the coverage for ESAs would work in the following manner:

• "If the member can self-administer the medication, he/she can fill a prescription for the medication using one of our designated retail specialty pharmacies. The applicable retail pharmacy cost share would apply.

• "If the medication must be administered in your office, you may write a prescription for the medication, and send it to one of our designated retail specialty pharmacies. The specialty pharmacy will ship the medication to your office. The member in this situation will be responsible for both the applicable retail pharmacy cost share and their applicable office copayment or co-insurance."

In addition to ESAs, the Massachusetts Blues are classifying Lupron and the interferon products as drugs obtainable through the pharmacy benefit. A document that includes a complete list is posted at http://cancerletter.com/special-reports.

The changes started taking place on Jan. 1, but reclassification of ESAs started on April 1, documents show.

The change is being protested by the American Society of Clinical Oncology, the Massachusetts Division of the American Cancer Society and the Massachusetts Hospital Association. ASCO is also challenging several provisions of the REMS (The Cancer Letter, March 5).

Opposing the new policy, the Massachusetts Hospital Association said that many hospitals have policies that prohibit receiving drugs from any source other than hospital pharmacies.

MHA Letter Opposing Policy

An excerpt from the MHA letter, dated March 3 and addressed to a an official of the Massachusetts Division of Insurance, follows:

A recent survey of hospitals revealed that eleven out of eighteen respondents have policies that expressly prohibit receipt, storage, handling, or dispensing of any medications received from outside sources rather than from the hospital pharmacy. This list includes

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both teaching and community hospitals from across Massachusetts that currently provide oncology services. The other hospitals that responded have policies that restrict acceptance and administration of drugs from outside sources to certain limited circumstances. Many of these hospitals are currently providing ESAs to cancer patients and will no longer be able to after April 1, 2010. This will result in network disruption and patients will have to find alternative sources to have the medication administered. As we have repeatedly stressed, disaggregating care for this population compromises patient safety, disrupts continuity of care, and inconveniences vulnerable patients. Blue Cross has claimed that this is a cost issue, but has been unable to demonstrate any reduction in costs that would accrue to its employer accounts when all of et patient risks, network disruption, medication wastage, and other additional costs are taken into consideration.

On behalf of our hospital and health system members and the patients they care for, we again urge the Division of Insurance to require that Blue Cross exempt these ESAs (and octeotride) from its new specialty pharmacy coverage policy when used for oncology patients, as it has for use of these drugs in other clinically integrated settings, such as dialysis clinics and ambulatory surgery centers. These drugs should be covered as a medical benefit in clinically integrated infusion centers in physician offices and hospital out-patient departments.

ASCO Letter To Massachusetts Blues

An excerpt from ASCO's letter to the medical director of the Massachusetts Blues follows:

Providing supportive care drugs directly to patients requires the pre-ordering of drugs in advance of care. This may not present a problem for patients with medical conditions other than cancer who are on stable, generally chronic, medication regimens, but in the setting of chemotherapy treatment, the pre-ordering of drugs seems potentially detrimental to the high quality care we are trying to mutually support.

For example, entirely new classes or different forms of supportive care medications may become necessary from one treatment session to the next, and it is difficult to predict which of those might be necessary in advance of the patient visit.

If a new supportive care drug becomes necessary on a given day of treatment, planned chemotherapy could be delayed due to a lack of availability of supportive care drugs. The probable drug waste inherent in such a system is obvious and yet another concern. Increased awareness of the risks of these drugs, particularly erythropoietins, and the need for concurrent laboratory and patient physical assessment with each dose of these medications also necessitates greater and not less physician supervision of dosing.

At a minimum, this will create yet another burden for cancer patients as they will, in this circumstance, be required to first visit the physician office to undergo the appropriate laboratory tests, wait for the results, take the prescription to a pharmacy, get the prescription filled, and then take the drug home for self-administration.

ASCO is concerned about this policy's impact on patients who will be required to pick up, store, and then administer their own supportive care drugs, without health professional oversight. Patients will need to be taught not only how to correctly self-administer the drug, but will now be expected to monitor their own clinical situation for toxicity and appropriateness before each dose. Moreover, patients will now be expected to know how to appropriately transfer and store drugs that may be easily compromised if not handled correctly, and how to correctly dispose of unused drug and drug administration supplies.

In cases where it is determined that the patient is unable to self-administer the drug and that the drug should be administered in the physician's office, the patient must return on a separate visit to the physician's office to have the drug administered, after the drug has been delivered to the office from a pharmacy. All of these requirements introduce needless delays into treatment and unnecessary inconvenience to patients suffering from the serious diseases that necessitate these treatments.

ASCO also has numerous concerns related to "brown bagging" programs. It is fairly common for a patient's chemotherapy treatment regimen to need adjustments on the planned day of treatment, and the reasons for this are multifold: patient response and tolerance to specific drugs, idiosyncratic reactions, drug-drug interactions, symptoms and complications from comorbidities, adverse events, and patient preference.

In these situations, chemotherapy would be delayed while the physician and patient either await delivery of the appropriate drugs or wait while the patient obtains the appropriate drug and brings it to the physician's office. Overall, within the context of ongoing chemotherapy treatments, it is unclear what the arrangements are for drug delivery and storage, and what provisions have been made regarding the waste that will result from changing treatments or drug expiration.

Finally, in contrast to physicians maintaining

practice based inventories of supportive care and antineoplastic drugs for immediate administration and treatment as necessary for their patients, there is no assurance that a needed drug will be available in a timely fashion through the payer-directed distribution channels.

FDA News:

In Unanimous Voted, ODAC Rejects Pixantrone For NHL

(Continued from page 1)

on the subsequent trial design with a leading statistician, and potential lead investigators who believe the study will be positively received by the lymphoma treatment community on the basis of the PIX 301 clinical trial results and the lack of satisfactory alternative therapies for their patients with multiple relapsed aggressive non-Hodgkin's lymphoma."

Cell Therapeutics said that later this month it expects to submit a Marketing Authorization Application to the European Medicines Agency in the third quarter of 2010.

The Australian company ChemGenex similarly said it would work with the agency to develop a T315I test. ChemGenex is seeking FDA approval for Omapro for the treatment of adults with CML who have previously not benefited from treatment with Gleevec (imatinib) and have the Bcr-Abl T315I mutation.

"The [FDA] Office of Oncology Drug Products would like to underscore the importance of having a well-defined companion diagnostic test available at the time of approval of any drug that claims to identify a subset of patients that will have a differential response to therapy," Richard Pazdur, director agency's oncology unit, said at the March 22 meeting. "This is an integral part of the development of any drug making such claims."

The text of Pazdur's opening remarks on the two applications follows:

Pixantrone Trial Stopped For Poor Enrollment

This morning's session of ODAC will focus on the drug, pixantrone, submitted for the indication of single-agent treatment of patients with relapsed or refractory aggressive non-Hodgkin's lymphoma who received two or more prior lines of therapy.

This application is based on a single incomplete trial of single-agent pixantrone for the treatment of patients with relapsed or refractory aggressive non-Hodgkin's lymphoma who have received two or more prior lines of therapy. Patients were required to have demonstrated prior response to anthracyclines/anthracenediones, to have an EF > 50%, and to have received < 450 mg/M^2 of doxorubicin or its equivalent.

Patients were randomized to either pixantrone or a choice of 8 comparator therapies. The primary endpoint was complete response and complete response unconfirmed (CR/CRu) by independent review. Patients were also followed for PFS and OS.

Accrual to this trial was stopped early due to poor enrollment. Only 44% of planned enrollment was accrued. The planned enrollment to the trial was 320 patients in 36 months; however, at termination of enrollment only 140 patients were enrolled in 45 months. FDA was not consulted prior to decision of terminating enrollment.

The timing of this trial's termination of accrual was not pre-specified in the original statistical analysis plan. Poor accrual occurred worldwide, but was most evident in the United States, where only 8 patients were enrolled, despite the opening of 28 US sites.

The applicant considered this poor accrual to be related to a number of factors, including a preference for combination regimens in the US and Western Europe, a preference for palliative care in late-stage disease, the wide-spread adoption of front-line rituximab during the course of the study, and the limited availability of a patient population meeting their eligibility criteria.

The primary analysis was a comparison of CR/CRu in the intent to treat population. Twenty percent (14/70, 20%) of patients in the pixantrone arm and 5.7% (4/70) of patients in the comparator arm achieved CR/CRu. However, 5/14 patients with CR/CRu in the pixantrone arm had ineligible, generally low-grade, disease by retrospective central histologic review. If only patients with centrally confirmed aggressive histology are included, the CR/Cru rate is 16.7% versus 6% for pixantrone and the comparator arm, respectively.

Furthermore, FDA-initiated radiologic review of all panel-assessed CR/CRus determined that 4 of the patients on the pixantrone arm and 1 on the comparator arm had responses that did not qualify as CR/CRu.

The p-value for the comparison of CR/CRu was 0.021. This value should not be compared to the conventional nominal value of .05. The required p-value with 44% of patients accrued would be 0.0096. Based on statistical methods that would have been appropriate for an interim analysis at 140 patients, the primary endpoint (CR/CRu) did not achieve the required level of statistical significance, leaving no alpha for evaluation of secondary endpoints, including progression-free

survival and overall survival. These secondary endpoints cannot provide the required proof for drug approval and such analyses should be considered exploratory and hypothesis-generating.

Major safety concerns included adverse events leading to death (17.6% of patients in the pixantrone arm and 7.5% of patients in the comparator arm) and adverse events leading to discontinuation (36.8% of patients in the pixantrone arm and 31.3% of patients in the comparator arm). Grade 3-4 adverse events (> 10%) included neutropenia, leukopenia, and thrombocytopenia. On the pixantrone arm, 7.4% of patient experienced grade 3-4 febrile neutropenia compared to 3.0% of patients in the comparator arm. In addition, 25% of patients on the pixantrone arm (4.4% Grade 3-4) and 11.9% of patients on the comparator arm (1.5% grade 3-4) developed cardiac dysfunction.

The major concerns regarding this application which is supported by a single, incomplete trial are the following—

1) Whether the application provides necessary evidence of efficacy;

2) Whether these results are generalizable to the US population; and

3) Safety of pixantrone in light of increased rates of cardiotoxicity and febrile neutropenia on the pixantrone-treated arm.

Other therapeutic areas in the FDA require two trials to support marketing applications. In oncology we have frequently accepted a single trial to support a marketing application, due in part to the small number of patients for specific indications, the lack of reliable pre-clinical predictive markers, and the corroboration of secondary endpoints.

Unfortunately, in this morning's ODAC session we have less than a single completed trial submitted with this application since less than half of the planned patients were accrued. Please note that this is the initial submission of this drug and we have no past regulatory approval to provide any supportive evidence of efficacy.

In our meetings with this sponsor—as with other sponsors contemplating using a single trial for drug approval—clear advice has been given regarding the requisite evidence required for a single trial to support a marketing application: "For a single randomized trial to support an NDA, the trial must be well-designed, flawlessly executed, and internally consistent and provide persuasive efficacy so that a second trial would be ethically or practically impossible to perform." This statement is adapted from the FDA's Clinical Evidence of Effectiveness Guidance. When a single, incomplete trial is used to support an application for a new molecular entity with no prior approval history, this evidence should be especially persuasive.

In discussing this application we ask you to address three questions required for a single trial to support an NDA. First, is this single trial well-executed and complete? Second, are the results of this single randomized trial consistent across patient subsets? And lastly, does this trial include statistically persuasive findings? The FDA has problems answering any of these questions in the affirmative.

An additional concern is whether this trial's results are generalizable to the US population, as only eight US patients were enrolled. The prior treatment characteristics of these eight US patients were different from those of the population as a whole, and none achieved complete response or unconfirmed complete response.

In a risk-benefit analysis several safety concerns will be raised in the FDA presentation. Patients treated with pixantrone experienced increased rates of febrile neutropenia and cardiotoxicity. 9% of pixantrone treated patients discontinued therapy secondary to febrile neutropenia or neutropenia, while no patients on the comparator arm discontinued for either of these reasons.

At the conclusion of this morning's ODAC we are asking you to consider if this single incomplete trial meets the criteria necessary for a single randomized trial to support approval. The following issues need to be addressed in your decision-making.

• For a single randomized trial to support an application for drug approval, it should be well-executed, internally consistent, and include statistically persuasive efficacy findings.

• Robust effects on primary endpoints must be demonstrated for either regular or accelerated approval. Accelerated approval is not a salvage mechanism for failed trials or marginal drugs. The level of evidence should be the same as for regular approval and accelerated approval. However, in accelerated approval the effect is observed on a surrogate endpoint reasonably likely to predict clinical benefit.

• In this application, the phase 3 trial stopped at 44% of planned enrollment due to poor accrual.

• The primary endpoint (CR/CRu rate) did not meet the critical significance level.

• Secondary endpoint analyses should be considered exploratory, with no alpha remaining for statistical interpretation.

• Five of the 14 CR/CRus on the pixantrone arm occurred in patients with ineligible, generally non-aggressive, histologies by central review suggesting that the response rate reflects a combined indolent and aggressive NHL population rather than in the proposed population of patients with aggressive NHL only.

• Grade 3-4 neutropenia, febrile neutropenia, and cardiotoxicity were increased on pixantrone-treated arm.

• Only 8 US patients at 28 sites were enrolled, bringing generalizability of results to US population into question. The applicant has speculated that the failure to accrue to this single-agent therapy trial likely demonstrates that, for patients with multiply relapsed or refractory aggressive non-Hodgkin's lymphoma, combination regiments are usually the treatment of choice among treating physicians. This notion is further supported by the fact that the majority of patients who went on to receive post-study therapy did in fact receive additional combination therapy, rather than single-agent therapy, as their next line of treatment. This apparent preference for combination therapy in conjunction with a total absence of CRs/Crus in the few patients receiving single-agent pixantrone, leads us to ask whether the applicant should consider rationale development of this drug as part of a combination regimen prior to its approval.

Frequently, a drug has biological activity as evidenced by a response rate, yet requires further study to demonstrate the required evidence for drug approval. The mere demonstration of biological activity is usually a signal to further develop the drug. FDA realizes that patients, especially those with life threatening diseases who have exhausted available drugs, may desire drugs that are being investigated. FDA published the Final Expanded Access Regulations in August of 2009 that subsequently became effective in October, 2009. Recent regulations provide charging for investigational drugs under an IND for clinical trials and expanded access.

Omapro Trial Incomplete, Lacks Companion Diagnostic

This afternoon's session will focus on Omapro. The proposed indication is the treatment of adults with chronic myeloid leukemia who have had failure on prior therapy with imatinib and have the bcr-Abl T3151 mutation.

Patients who have the T315I mutation are not believed to respond to approved tyrosine kinase inhibitors—dasatinib or nilotinib—that are approved for the treatment of CML patients who have failure or intolerance to imatinib.

The efficacy claim for this NDA is based on the findings from a single, incomplete, single-arm trial, CML 202, in 66 patients with CML who had failure on or intolerance of imatinib and who had the T315I Bcr-Abl mutation.

The primary efficacy endpoints for chronic phase patients were major cytogenetic response (complete cytogenetic response + partial cytogenetic response) and complete hematologic response. The primary efficacy endpoints for accelerated phase and blast phase patients were major cytogenetic response and major hematologic response (including complete hematologic response, no evidence of leukemia and return to chronic phase). An independent Data Monitoring Committee adjudicated all responses for the primary efficacy analysis.

FDA's review found that for the chronic phase cohort of 40 patients, the major cytogenetic response rate was 15% (including 10% complete cytogenetic response + 5% partial cytogenetic response) with a median response duration of 7.7 months. The accelerated phase cohort of only 16 patients had a 6.3% major cytogenetic response rate and a 31.3% complete hematologic response with a median response duration of 5.1 months. There were no responders in the blast phase cohort.

The toxicity profile was similar to that of a conventional chemotherapeutic agent, with hematologic toxicities such as neutropenia, thrombocytopenia and anemia occurring most frequently. Additionally, 20% of patients had a cardiac-related adverse event, the vast majority of which were arrhythmias. Laboratory abnormalities included 49% of patients with hyperglycemia and 36% of patients with hyperbilirubinemia.

Major deficiencies of this application include the following:

1. A single, small and incomplete efficacy study CML-202

Study CML-202 planned to enroll 100 patients; however, the NDA submission only included the efficacy data from 66 patients. The applicant continued to enroll 31 additional patients after the data cut-off for these 66 patients with a current enrollment of 97 patients. Thus, data from approximately one-third of the patients enrolled on this efficacy trial are missing from the current submission. In addition, FDA believes that any regulatory efficacy claims for the accelerated and blast cohorts are insufficiently demonstrated due to the small sample sizes.

2. One-third of CML-202 patients are ineligible per protocol-defined criteria

The regulations governing the content of an NDA submission state that for a trial to be considered adequate and well-controlled, "the method of selection of subjects provides adequate assurance that they have the disease or condition being studied." FDA believes that the applicant has not met this criterion. Please note that 35% of trial CML-202 patients did not have a confirmation of their Bcr-Abl T315I mutation status by the central laboratories at the time of enrollment, a required study entry criterion.

In addition, perhaps more importantly, false positive test results for the presence of the T315I mutation would deny patients an opportunity to receive effective therapies for their imiatinib-resistant or intolerant disease. Please note that 10 of the 66 patients were deemed to have mutational status at an outside laboratory but had negative results at a central laboratory required to confirm their T315I mutational status as the key eligibility criterion. Dasatinib and nilotinib have considerably greater efficacy and tolerability than omacetaxine in the patients with CML who have intolerance or failure on imatinib.

In addition, among the 11 responders, 5 did not have confirmation of the T315I mutational at enrollment raising concerns as to whether these responders were truly eligible for this trial.

3. Assays with different performance characteristics were used at the two central laboratories to detect the T315I mutation

The applicant used two different assays at the two central laboratories for the confirmation of T315I mutation status prior to patient enrollment. There were no bridging studies performed to support assumptions about the similarity of the enrolled patient population tested at each site.

Performance characteristics of an assay should be known prior to widespread use of the assay and drug use based on this assay. These characteristics include sensitivity, specificity, limit of detection and reproducibility of the assay and the ability of the test to identify differences in drug efficacy for test "positive" and test "negative" cases. No information for the assays to detect the T315I has been submitted to FDA's Center for Devices and Radiological Health (CDRH).

The lack of having a uniform in vitro diagnostic assaycreates uncertainty about patient selection both in this trial and, more importantly, in a post-approval setting. I would like to reiterate that if a patient does not harbor the T315I mutation but is falsely identified as having such a mutation by these un-reviewed assay methods, the patient may not receive more effective, less toxic therapy such as dasatinib or nilotinib. FDA would like to remind the members of ODAC that the efficacy of both dasatinib and nilotinib are considerably higher in CML patients after imatinib resistance or intolerance. Hence, it is essential to have a well-defined assay to identify patients with this mutation.

4. Low response rates observed in the efficacy study

Due to the single-arm trial design and lack of historical control to compare the efficacy results, the clinical meaningfulness of the observed low response rates unclear. Due to the sample size, the results can not be considered robust.

5. Safety concerns regarding the overfilled vial size

The applicant has presented an overfilled vial size that contains more than twice the average dose of omacetaxine used in the efficacy and safety studies (CML-202 and CML-203). FDA has concerns about the potential for overdose as well as the environmental impact of drug disposal.

The development of a companion diagnostic should preferentially occur before or in the pivotal efficacy trial for which the indication is being sought. If the companion diagnostic test that will be marketed after approval is not identical to that used in the registration trial for the drug, then there needs to be information bridging the test used in the clinical trial to that used in the post-approval setting. This bridging information is necessary to put the clinical results of the registration trial in the context of the post-approval setting. Additional clinical trials may be necessary if this bridging is not possible.

The Office of Oncology Drug Products would like to underscore the importance of having a well-defined companion diagnostic test available at the time of approval of any drug that claims to identify a subset of patients that will have a differential response to therapy. This is an integral part of the development of any drug making such claims.

NCI News:

Report Urges Steps To Shorten Phase III Trial Activation Times

An NCI working group has recommended a series of changes to cut in half the time to activate new phase III trials conducted by the cooperative groups.

The current process of activating new phase III trials takes more than two years, while phase I and II studies require more than 500 days, the Operational

Efficiency Working Group group said. The 63-member group was formed under the auspices of the NCI Clinical Trials and Translational Research Advisory Committee.

Each year, about 25,000 to 30,000 patients are accrued to NCI-supported clinical trials.

Many trials, particularly those that take longer to open, never reach their accrual goals and are closed, a recent analysis of NCI trials found. The analysis found that many steps in the trial activation process are unnecessary.

The OEWG began its review in December 2008.

The group's final report outlines 14 initiatives, including target dates and deadlines for the initiation of new clinical trials within the cooperative groups, cancer centers, and institutions conducting early-phase studies. The report was presented March 23 to the CTAC.

Among the recommendations:

• A target of 300 days for the time between submitting a phase III concept to the NCI Cancer Therapy Evaluation Program and the time of trial activation.

• Phase III trials will be terminated if they are not activated in 24 months.

• For phase I and II studies, the target for submission to opening is 210 days, with a drop-dead date for activation of 18 months.

To achieve these timelines, the report recommends:

• Dedicated clinical trial development managers for protocol activation duties.

• Real-time project tracking systems that monitor where a concept or protocol is in the review process and who the responsible party is for that stage of the process.

• More support for protocol development, including dedicated medical writers who may be able to reduce the number of protocol revisions.

• Policies and procedures that coordinate interactions between group members, phase I/II trialists, and CTEP.

NCI is awarding administrative supplements to all of the cooperative groups to fund the development of action plans, hire additional staff, and to purchase and begin using project tracking tools, according to James Doroshow, director of the NCI Division of Cancer Treatment and Diagnosis, who served as chairman of the OEWG.

NCI is reviewing supplement requests for 48 of the NCI-designated cancer centers, Doroshow said.

CTEP has developed an action plan to improve efficiency and speed protocol activation.

The new deadlines for trial termination will become effective on Jan. 1, 2011.

"Implementing these initiatives will require considerable commitment and effort by the extramural clinical trials community and NCI program staff to modify current processes to achieve the agreed upon goals," the report said. "Although most of the work will be in doing things differently rather than undertaking new activities, a modest NCI investment in certain targeted initiatives will be required. Such new commitment and investment will result in a more efficient clinical trials system and is crucial for ensuring that the large, ongoing national investment in cancer clinical trials achieves the goal of bringing effective new therapies to patients as rapidly as possible."

Gabriel Hortobagyi of the University of Texas M. D. Anderson Cancer Center, served as co-chairman of the OEWG.

The OEWG report is available at http://ccct.cancer.gov/files/OEWG-Report.pdf.

NCI Launches Quantitative Imaging Program

NCI is launching a new program to qualify existing NCI designated Cancer Centers as Centers of Quantitative Imaging Excellence.

The goal of the program is to decrease variability in image procedures done while a patient is undergoing treatment as part of a NCI-sponsored clinical trial. The American College of Radiology Imaging Network (ACRIN) and the American College of Radiology will coordinate this program for NCI.

The 58 clinically focused NCI designated Cancer Centers represent the optimal sites to support and promote advanced quantitative imaging for measurement of response, the institute said.

Currently there exist significant delays in the time required to open a clinical trial with advanced imaging as an essential component.

To try to shorten the process, NCI and its partners will develop standard operating procedures and a corresponding guideline for the qualification of a Cancer Center as a Center of Quantitative Imaging Excellence.

The procedures will include both brain and body imaging for volumetric computed tomography (vCT) or MR (vMR), positron emission tomography (PET), and dynamic contrast-enhanced magnetic resonance imaging (DCE-MRI).

Further information about the program is available at http://imaging.cancer.gov.

Professional Societies:

AACR Elects New Officers, Directors, For 2010-2011

American Association for Cancer Research members elected Judy Garber as president-elect. Garber is the director of the Cancer Risk and Prevention Program at the Dana-Farber Cancer Institute, associate professor of Medicine at Harvard Medical School, and associate physician of medicine and attending physician of medical service at Brigham and Women's Hospital.

Garber will officially become the president-elect on April 19, at the AACR annual meeting in Washington, D.C.

Elizabeth Blackburn, the Morris Herzstein professor of biology and physiology in the Department of biochemistry and biophysics at the University of California, San Francisco, and Nobel Laureate in Physiology or Medicine, will be sworn in as president of the AACR. Blackburn succeeds Tyler Jacks, director of the David H. Koch Institute for Integrative Cancer Research, the Koch professor of biology at the Massachusetts Institute of Technology, and a Howard Hughes Medical Institute investigator. Jacks served as AACR president for the 2009 to 2010 term and will now fulfill the role of past president. Garber, Blackburn and Jacks will serve in these roles for one year.

Garber's research has focused primarily on breast cancer risk assessment and risk reduction. She has served in many leadership roles with AACR. She was a member of the Board of Directors (2007-2010) and is currently a member of the Stand Up To Cancer Innovative Research Grants Review Committee, Finance and Audit Committee, Special Conferences Committee, Grants Advisory Committee and the Susan Love/Avon Army of Women Scientific Advisory Committee. She was chairperson of the Breast Cancer Research Foundation-AACR Grants for Translational Breast Cancer Research Scientific Review Committee in 2008, and has served on several other grants committees and scientific award selection committees over the years.

Garber is a senior editor of Cancer Prevention Research and a member of the editorial board for Cancer Epidemiology, Biomarkers & Prevention. She has also served as a senior editor for Clinical Cancer Research. All three publications are AACR journals.

A graduate of the University of Virginia, Garber earned her medical degree and her master's degree in public health from Yale University School of Medicine and completed her internship and residency at Brigham and Women's Hospital and the Brockton-West Roxbury Veteran's Administration Medical Center. She completed her fellowship in medical oncology at the Dana-Farber Cancer Institute.

William Hait will serve as AACR treasurer, succeeding Bayard Clarkson, who has served in that position since 1994. Hait is the senior vice president and worldwide therapeutic area head of oncology of Johnson & Johnson Pharmaceuticals Research & Development.

The following were elected to serve on the Board of Directors for the 2010 to 2013 term: Todd Golub, Jennifer Rubin Grandis, Sir David Lane, Kornelia Polyak, and Owen Witte. Golub is founding director of the Cancer Program at the Broad Institute of Harvard and Massachusetts Institute of Technology. Grandis is the vice chair for research and University of Pittsburgh Medical Center Endowed Chair in Head and Neck Cancer Surgical Research. Lane is the chief scientist at the Agency for Science, Technology and Research (A*STAR), Singapore, and chief scientist at Cancer Research UK, London, England. Polyak is associate professor in the department of medical oncology/ molecular and cellular oncology at Dana-Farber Cancer Institute. Witte is director of the Eli and Edythe Broad Center of Regenerative Medicine and Stem Cell Research, the David Saxon Presidential Chair in Developmental Immunology, distinguished professor of microbiology and molecular genetics, and distinguished professor of molecular and medical pharmacology, at the David Geffen School of Medicine, University of California, Los Angeles.

The following scientists have been elected to serve on the Nominating Committee for the 2010 to 2012 term: Nancy Davidson, Ronald Evans, Peter Jones, and Carol Prives. Davidson is director of the University of Pittsburgh Cancer Institute. Evans is the March of Dimes chair in molecular and developmental neurobiology and professor of the Gene Expression Laboratory at The Salk Institute for Biological Studies. Jones is director of the University of Southern California/Norris Comprehensive Cancer Center. Prives is the Da Costa professor of biology in the department of biological sciences at Columbia University.

THE SOCIETY OF GYNECOLOGIC ONCOLOGISTS elected **Daniel Clarke-Pearson** as president at the organization's annual meeting last month in San Francisco. Clarke-Pearson is chairman of the Department of Obstetrics and Gynecology and the Robert A. Ross Professor at the University of North Carolina at Chapel Hill School of Medicine.