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# Lame Duck NCI Director: Cancer Centers Should Run Cancer Clinical Trials System

*By Kirsten Boyd Goldberg*

NCI's clinical trials program should be structured around the country's major cancer centers in "a single national program for clinical research" that would replace the existing cooperative group system, lame duck NCI Director John Niederhuber said to the National Cancer Advisory Board.

"We can continue down the road with a 50-year-old structure that we have used for clinical research, or we can become innovative and think about the future and how, if we were given the power and the opportunity, we would redesign the next 50 years in terms of translational and clinical trials structure," Niederhuber said at the board's meeting June 22.

Niederhuber, a Bush administration holdover, has less than three weeks remaining in his post until the arrival of Harold Varmus, who was active

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*FDA News:*

# Pfizer's Withdrawal Of Mylotarg Signals Stronger FDA Resolve To Monitor Confirmatory Studies

*By Paul Goldberg*

A decade after obtaining an accelerated approval, the drug Mylotarg (gemtuzumab ozogamicin) is being withdrawn from the market by its sponsor, Pfizer Inc.

The drug is being withdrawn because a U.S. cooperative group study has failed to demonstrate its efficacy in the approved indication, acute myeloid leukemia. Also, two European studied of the drug have come up negative.

The removal, which was announced June 21, comes at a time when FDA has been given stronger authority to require confirmatory studies for drugs approved based on surrogate endpoints. The agency's powers were enhanced in the 2007 FDA Amendments Act of 2007.

In an interview, Richard Pazdur, director of the agency's Office of Oncology Drug Products, said that the Mylotarg trials predate the FDAAA authorities. However, Pazdur said that sponsors would now be asked to present detailed plans for conducting confirmatory studies as part of the end of phase II meetings with the agency.

Also, the agency is considering using its Oncologic Drugs Advisory Committee to conduct annual reviews of outstanding confirmatory study commitments related to accelerated approval drugs.

At least technically, Mylotarg's removal doesn't constitute a revocation

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## Niederhuber Goes Beyond IOM Recommendations On Groups

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in President Obama's campaign and served on the committee to select the administration's NCI director. Varmus, who served as NIH director during the Clinton administration, has been president of Memorial Sloan-Kettering Cancer Center for the past 10 years.

Niederhuber's remarks, in which he likened the cooperative groups to isolated silos, come two months after an Institute of Medicine report that recommended consolidation of some cooperative group operations and an increase in funding for the program. The report didn't advocate demolition of the entire system (The Cancer Letter, April 16, 2010). Niederhuber repeatedly urged the board to push NCI to make even greater changes.

"It's very difficult to make change, especially in the federal government and the NCI," Niederhuber said in his remarks to the board. "There is a lot of entitlement. But we really need—you, not me; I'm done—you need to make change. I can't imagine that you want to sit at this table three to five years from now and say, 'Gee, we have a problem in our clinical research.'

"If you think about where our science is done, it's not in a hotel room in Chicago or San Francisco," Niederhuber said, in what appeared to be a reference to places where cooperative group members meet to plan trials. "It's done in our cancer centers. We have to recognize that our design of what we want to do should be heavily focused on our cancer centers and our academic researchers, and taking the knowledge that comes out of that rich environment, and taking that forward to create something—instead of siloed cooperative groups—a single national program for clinical research."

The majority of cooperative group investigators work at cancer centers and academic research institutions, although in efforts to increase patient accrual to trials—a goal encouraged by NCI—many private-practice oncologists are also involved in the cooperative group program and the Community Clinical Oncology Program.

There has long been tension over the control of the clinical trials structure. As the NCI-supported cancer centers have grown in financial and institutional power over the past several decades—the majority of NCI grants now are awarded to cancer center investigators—some center directors and investigators have challenged the cooperative group structure and procedures as outmoded.

NCI leadership has been at odds with the cooperative groups over management issues, peer review, and funding, for 20 years. Every few years, there are workshops and urgent reports calling for streamlining the system. The cooperative group chairmen, in turn, have argued that lack of adequate funding and excessive NCI oversight cause as much delay and difficulty as group procedures.

Each of the 10 cooperative groups, funded through a patchwork of grants, has its own administrative offices and data management staff. NCI's budget for the program has been about $160 million a year. Under financial pressure from NCI in the mid-1990s, four pediatric cooperative groups merged to form a single Children's Oncology Group.

In 2005, an NCAB Clinical Trials Working Group submitted a report to NCI recommended a variety of administrative changes in the clinical trials system. Apparently, the report didn't go far enough for Niederhuber. The NCI director, as a member of the IOM's Cancer Policy Forum, asked the IOM about three years ago to conduct a study of cooperative group system. NCI provided financial support for the report as well.

**"Push And Pull NCI" To Give More To Centers**

In his remarks to the NCAB, Niederhuber advocated more funding for the cancer centers to conduct clinical trials and correlative science, and said NCI support for "patient characterization centers" to provide molecular characterization of tumors will help

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support a new clinical trials program.

"I would like to propose to you that you think long and hard in your future meetings about how you can push and pull the NCI towards putting more resources at the level of the cancer centers in terms of translational trials, that is, taking our science forward, and correlative science," Niederhuber said. "Again, that's where I think most of the correlative science would be performed, associated with the clinical trials.

"We have the Clinical Center here on campus that can back up that program as well," he said. "Hopefully, we will have patient characterization centers to help support this program, and also I believe the [NCI] Community Cancer Centers Program will be an important part of this."

The NCCCP, Niederhuber's signature program, provides funding to small community hospitals to improve the quality of cancer care and provide access to clinical trials.

"I think the future is in your opportunity and ability to create that patient cohort that sits ready to be tapped to answer a specific clinical trial question," Niederhuber said.

"I don't think that in the new era that it will be the patient walking through the door with colon cancer and the doctor saying, 'We have a clinical trial that might work for you, and you can go on arm A, and here's what arm A is, or you can go on arm B, or arm C.' I just don't see that as the future of clinical research," Niederhuber said. "Maybe I will be wrong, but I think that in the future, you will need the large characterized cohort and the question will go into the database, and you will find the patients wherever they are, that are appropriately matched to the target question that you are asking."

In the board's discussion with the NCI director, NCAB member Bruce Chabner, clinical director of the Massachusetts General Hospital Cancer Center, said he was "impressed and heartened and will be very supportive" of Niederhuber's idea for restructuring the clinical trials system.

NIEDERHUBER: "You have to be supportive of Dr. [James] Doroshow [director of the NCI Division of Cancer Therapy and Diagnosis]. He is the one who will need to use a mirror to look under his car every night."

CHABNER: "There are two problems in this. One is designing a new system. We were talking about this last night. It's like running with an old Model T trying to polish its mirrors and put chrome on its bumpers, but what we need is a new automobile for the 21st century. The second is getting buy-in from people who are so invested in the current system. I think that's an even bigger question. We need to convince them."

NIEDERHUBER: "That's a huge problem. I can tell when I am talking to them, and their heads go down and they don't want to look at me. I think to a person they recognize the problems. They just aren't sure how they want it to change or what they are willing to accept, because they built these infrastructures and empires. Jim and I estimated that if we had a bucket of $150 million, we could incentivize this change much more rapidly. We know that if we put the money, people will figure out how they are going to go after it. That's how we all grew up in the academic world."

CHABNER: "That's sort of a sad thing to recognize, that it takes financial inducement to get people to do what's obviously the right thing to do."

**Mendelsohn: Groups At A Critical Juncture**

John Mendelsohn, president of the University of Texas MD Anderson Cancer Center and chairman of the IOM committee that wrote the report on the cooperative group system, gave the board an overview of the report's recommendations. He noted that the cooperative group system involves 14,000 investigators and accrues 25,000 patients to trials each year. "You can do some math on these numbers and draw some conclusions," he said.

"We believe the cooperative group program is at a critical juncture," Mendelsohn said. "The clinical trials infrastructure has not evolved to adequately incorporate the rapid pace of biomedical discovery."

Inefficient processes, excessive delays, lack of stringent prioritization, stagnant funding, and extensive government oversight are some of the problems, he said.

The report recommended four goals:

I. Improve the speed and efficiency of the design, launch, and conduct of clinical trials.

II. Incorporate innovative science and trial design into cancer clinical trials.

III. Improve the means of prioritization, selection, support, and completion of cancer clinical trials.

IV. Incentivize the participation of patients and physicians in clinical trials.

Goal I includes the recommendation for "some consolidation, not into one cooperative group, but not 10, either," Mendelsohn said.

• The front office operations of the groups should be consolidated by "reviewing and ranking the groups with defined metrics" and linking funding to review scores.

• The number of disease-site committees among

the groups should be reduced through consolidation or elimination by peer review.

• NCI should require the consolidation of back-office operations, including patient registration, audit functions, submission of case report forms, data collection, image storage, training of clinical research associates, drug distribution, credentialing of sites, and funding and reimbursement for accrual.

• NCI should coordinate and streamline protocol development as recommended by the Operational Efficiency Working Group. A manager should be assigned to each protocol, and phase III trials should be launched in 300 days, while phase II trials should begin in 250 days. Conflicts should be resolved by prompt conference or arbitration. Trials should be rigorously prioritized by the newly established Scientific Steering Committee.

Investigators should resist the temptation to constantly "tweak" trials, but federal oversight should be more flexible for minor amendments, Mendelsohn said.

Under Goal II, the committee recommended that NCI mandate the submission of annotated biospecimens to high-quality, standardized central biorepositories when samples are collected from patients in the course of cooperative group trials. All data should be considered precompetitive, unencumbered by intellectual property restrictions, and made widely available.

NCI should establish a national inventory of samples in central repositories. NCI should have a defined process for access by researchers that includes a single scientific peer review linked to funding; currently there are two peer reviews, one for access and one for funding.

Mendelsohn emphasized that NCI doesn't need to physically establish one single biorepository. The samples can be stored in multiple sites.

Another recommendation is that NCI should allocate a larger portion of its research portfolio to the cooperative group program. The per case reimbursement rate should be increased to adequately fund high ranked trials.

External advisory boards such as the NCAB and the NCI Board of Scientific Advisors shoud have a greater role on advising NCI on funding allocation for trials.

To assure sufficient funding for high-priority trials, the total number of NCI-funded trials undertaken by the groups should be reduced if adequate funding is not available. However, this is not to preferred solution, Mendelsohn said.

The report, "A National Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program," is available at www.nap.edu.

**Reducing Oversight By NCI, Increasing Funding**

In a question-and-answer session with Mendelsohn, NCAB member Chabner noted the report's focus on reducing excessive oversight by NCI staff.

There is a 120-day period for NCI review of a phase III trial, he said. "This is a protocol that has been reviewed and prioritized by the scientific community and overseen by biostatistical centers funded by NCI, yet is has to go through another level of extended review. This is the biggest time element in the timeline. It's unnecessary to do that. If we trust these investigators as the best people to do this, why do you need that?"

"We certainly agree," Mendelsohn said. "If you get money to do a trial and you are an expert and you have been peer-reviewed, you still have to be doubly reviewed again, every step of the way. This is when NCI does not hold the IND, and this is a somewhat controversial recommendation. We believe that the NCI should facilitate, but not be a participant, in the oversight of that."

"I think a lot of changes have to be made all up and down the line," Chabner said. "To get change, you need buy-in from the groups and their leadership. Do you think we have that?"

"We heard from a number of group leaders," Mendelsohn said.

Richard Schilsky, former chairman of the Cancer and Leukemia Group B, served on the IOM committee, and other group chairmen spoke to the committee.

"I am hearing from underground that some of the group leaders are already beginning to talk about joining together," Mendelsohn said.

IOM committee vice-chairman Harold Moses said that when groups see that peer review is coming, they might voluntarily consolidate their disease-site committees.

"I would say some of the group leaders are as frustrated as you are, and in a way, this provides cover," Mendelsohn said. "It is very hard for a group leader to discontinue a disease site committee that is working under their leadership, but when it is mandated from above, it may help."

"How can the NCAB help you?" asked NCAB Chairman Carolyn Runowicz, director of the Neag Comprehensive Cancer Center at University of Connecticut Health Center, who has completed her term on the board. "Here is what I think we should charge

the NCAB to do over the next year—mind you, I am getting off the committee. The NCAB should have an increased role in advising NCI regarding funding allocation on national clinical trials. We need to advise on a system that eliminates duplication. So we heard that cooperative groups have multiple GI groups, multiple breast groups, and maybe we want to begin to consolidate that. We want to begin to look at NCI oversight. When NCI does not own the IND then they should look to a facilitator and move away from that 120-day gap. Is it time to move to one or two or three cooperative groups and share front end and back end business? I think the NCAB could really dig down and begin to make these recommendations."

CHABNER: "I was going to reinforce what you said by suggesting that we have a regular report on the implementation of the IOM report. We need to monitor progress on these very good recommendations. Maybe every other meeting until we see real progress."

MENDELSOHN: "I appreciate your list, but let me make a comment since we discussed this thoroughly. We would not recommend collapsing to one GI group for the whole country, or one breast group for the whole country. We don't think there should be six, either. Some competition always makes things better. So collapsing the infrastructure a great deal, but not collapsing all of these disease sites into one."

MOSES: "Remember that you have a volunteer army in the cooperative groups. So anything that's done, be sure it does not cause them to drop out of the clinical trials process."

RUNOWICZ: "That's a good point, Harold. I think the point would be made to improve efficiencies and to make clinical trials faster, and not end up where people left the volunteer army."

NIEDERHUBER: "Also recognizing it costs money for individual physicians [to take part in trials]. We need to work on the per-case reimbursement."

RUNOWICZ: "The NCI budget for the cooperative groups is small. To get this done and move into targeted therapies, we may need a more efficient system, but we may need to fund it with more money."

MENDELSOHN: "The last thing we want to do is reduce the number of trials."

NIEDERHUBER: "I certainly agree, but it is very hard in the NCI budget to move resources from one line to another, because there is a hue and cry if you take it away from R01s, if you take it away from cancer centers. You have to find a place to take it. When there's an increase of 2 percent or 3 percent, every one of those constituencies expects the same increase. So you have very little flexibility to really do something, to move $100 million into making a difference. I don't see that changing in the future, unless the appropriations come through with a big increase, unless it is targeted. But an across-the-board increase, everyone is going to want their share."

MENDELSOHN: "I can sympathize, because at a cancer center, we see the same thing. But, this board could give you the cover. Mandates tend to happen, and people who have to take a cut will find other ways."

CHABNER: "I would suggest that until these changes are made or at least underway, we don't increase the funding for something that's not working well. I think it's a valuable thing, but let's fix it first and then think about how to fund the new cooperative group system."

**NCAB Members Complete Terms**

In addition to NCAB Chairman Runowicz, the following NCAB members completed their terms at the June 22 meeting: Lloyd Everson, vice chairman of US Oncology; Kathryn Giusti, CEO of the Multiple Myeloma Research Foundation; David Koch, executive vice president of Koch Industries; and Diana Lopez, professor of microbiology and immunology at University of Miami.

**NCI Deputy Director Anna Barker To Leave**

In his remarks to the NCAB, Niederhuber noted that "NCI will miss" Deputy Director Anna Barker.

Barker confirmed to The Cancer Letter that she has long planned to retire from the institute.

Barker, who was an executive at a small biotech company, rose through the leadership of the American Association for Cancer Research to become a national figure in oncology politics.

She came to NCI in 2002 to serve as a scientific advisor to then-NCI Director Andrew von Eschenbach. She was appointed deputy director for strategic scientific initiatives under von Eschenbach's reorganization that established four deputy directors at the institute.

Her role at NCI has been to lead programs in nanotechnology, genomics, and biospecimens. Some of her initiatives resulted in controversy over the institute's role in technology development. An early proposal to develop a single national specimen biorepository drew so much controversy and objection for its huge cost and was withdrawn.

Prior to joining NCI, Barker was involved in a start-up that planned to sell nutraceuticals over the Internet (The Cancer Letter, April 30, 2003).

*FDA News:*

## FDA May Ask ODAC To Review Accelerated Approvals Annually

(Continued from page 1)

of an accelerated approval indication by FDA.

So far, only one drug has lost an indication under this approval mechanism. This occurred in 2005, when the drug Ethyol (amifostine), marketed by MedImmune, lost one of its indications, reducing the cumulative renal toxicity from cisplatin in non-small cell lung cancer. The indication was withdrawn because of emergence of better treatment options for non-small cell lung cancer. The drug retains its other indications and remains on the market.

Another drug, Iressa (gefitinib), sponsored by AstraZeneca, was placed in a restricted access program that barred physicians from prescribing it to new patients. This action was caused by failure of confirmatory trials to demonstrate a survival advantage.

Mylotarg was approved in 2000, under the accelerated approval regulations (21 CFR 314 subpart H). The drug's initial sponsor was Wyeth Pharmaceuticals Inc. The company has since been acquired by Pfizer.

The drug was approved for "treatment of patients with CD33 positive acute myeloid leukemia (AML) in first relapse who are 60 years of age and older and who are not considered candidates for other cytotoxic chemotherapy."

The Subpart H approval was based on evidence of response rates, which were thought reasonably likely to predict clinical benefit. Data were pooled from 3 single-arm, single-agent, Phase II trials in a total of 142 patients with AML in first relapse.

The original labeling noted that "there are no controlled trials demonstrating a clinical benefit, such as improvement in disease-related symptoms or increased survival, compared to any other treatment."

The Cancer Letter asked Pazdur to respond to a series of questions about the Mylotarg withdrawal and the agency's thinking on accelerated approval.

The text of the interview follows:

THE CANCER LETTER: *What was the recent action and reason for withdrawal of Mylotarg from the US market? When will removal occur? Will patients continue to have access?*

PAZDUR: On June 21, 2010, Pfizer Inc., in agreement with the FDA, announced that the commercial marketing of Mylotarg will be voluntarily discontinued, and the new drug application (NDA) for Mylotarg will be withdrawn as of Oct. 15, 2010.

Mylotarg will remain available commercially now for a short time to allow patients currently receiving the drug the option to complete their planned course of therapy. Patients may complete their therapy following consultation with their physicians.

New patients should not be prescribed Mylotarg. The drug will be available for investigational use as provided through the investigational new drug (IND) application process. Ongoing trials in the U.S. should be conducted under IND.

Accelerated approval includes a requirement to conduct further study to verify clinical benefit such as improved survival. The trial, designed to demonstrate clinical benefit (SWOG S0106), was conducted but failed to verify that the addition of Mylotarg to standard chemotherapy achieved clinical benefit.

The pre-planned interim analysis disclosed increased deaths on the Mylotarg plus chemotherapy arm compared to the chemotherapy alone arm. At the time of accelerated approval, Mylotarg was associated with an estimated 1% incidence of veno-occlusive disease (VOD). However, in 2006 the labeling was changed to indicate an overall VOD incidence of 10.2%. Given Mylotarg's lack of efficacy and additional safety concerns, the potential benefits no longer outweigh the potential risks.

TCL: *How was the SWOG study designed and what were the results of the SWOG study that led to the action? What was the mortality of the patients treated on the SWOG study? Did the Agency have access to the data or top-line results?*

PAZDUR: Following several meetings with Wyeth and discussions at a 2003 Oncologic Drugs Advisory Committee, Wyeth proposed a trial to fulfill the Subpart H requirement.

Trial S0106 began in 2004. The design tested (1) the addition of Mylotarg to standard induction chemotherapy to improve the complete response (CR) rate and (2) the effect of Mylotarg as maintenance therapy for those achieving a complete response to the induction therapy, measured by prolongation of disease-free survival (DFS). The primary objective was to show a survival benefit with the addition of Mylotarg.

At a planned interim analysis in August 2009, the trial's Data Safety Monitoring Board recommended that the trial be halted. SWOG agreed, and the trial was terminated early due to lack of efficacy and the observation of more induction phase deaths on the Mylotarg plus chemotherapy study arm compared to the chemotherapy alone arm.

FDA does not have access to the primary data for

this trial. However, the interim analysis, performed by the SWOG statistical center, reported the following results:

No improvement in CR rate with the addition of Mylotarg to induction chemotherapy (66% CR rate on the Mylotarg plus chemotherapy arm versus 69% on the chemotherapy alone study arm).

In total, deaths during the induction phase were increased on the Mylotarg-containing arm, 8.8% versus 1.6% on the chemotherapy alone arm. Considering deaths that were judged as at least possibly treatment-related, the results were similar with 5.7% on the Mylotarg containing arm versus 1.4% on the chemotherapy alone arm.

No improvement in DFS with Mylotarg versus observation without therapy in the maintenance phase.

TCL: *Was other data available than the SWOG trial?*

PAZDUR: Although Wyeth and Pfizer have not identified any other trials that they are conducting to fulfill the post-marketing requirement to demonstrate clinical benefit, FDA is aware of reports of additional randomized controlled trials, conducted by other cooperative groups.

The British Medical Research Council AML15 trial was reported in abstract form to the American Society of Hematology in 2006 and 2009. Approximately 1,115 patients with newly diagnosed AML age $\leq$ 70 years were enrolled. A randomization to include Mylotarg was part of the induction treatment and also was provided in the consolidation treatment.

No improvement in any outcome (response rate, relapse-free survival, or overall survival) was reported for the addition of Mylotarg to the induction treatment or to the consolidation therapy.

Another European trial, HOVON-43, tested the effect of Mylotarg as a maintenance treatment. Patients age 61 and greater with newly diagnosed AML, who had had complete responses to induction therapy, were randomized to receive either Mylotarg or no additional therapy as maintenance. The authors reported no significant differences between the two groups in relapse probabilities, non-relapse mortality, overall survival, or disease-free survival, and that "post remission treatment with Mylotarg in older AML patients does not provide benefits regarding any clinical endpoints." (BLOOD 2010; 115: 2586-2591)

TCL: *Can you explain why the approval of Mylotarg was in a different indication than the studies used to confirm clinical benefit?*

PAZDUR: Studies for accelerated approval in oncology are generally performed in refractory disease settings where there is no available therapy or the drug has demonstrated an improvement over available therapy. Hence, it would be very difficult to study the approved indication. FDA believes that investigating the drug in an earlier disease setting (usually less refractory patients) promotes drug development and provides the necessary evidence that the drug has clinical benefit (usually an improvement in survival or disease-related symptoms).

TCL: *Under accelerated approval provisions, is there a new interpretation of "due diligence" in the completion of confirmatory trials? Has FDAA legislation a factor in this decision? Why did it take 10 years?*

PAZDUR: FDA's regulations for accelerated approval (21 CFR 314.510) require the applicant to study the drug further, to verify and describe its clinical benefit, by conducting post-marketing studies that are adequate and well-controlled, and to conduct such studies with "due diligence." The interpretation of "due diligence" is open to interpretation; however, the extended time period in this NDA is of obvious concern. Some time was needed to conduct an initial pilot study to determine if Mylotarg could be added to other agents to treat AML. FDA concerns of this ongoing regulatory obligation led to public discussion at both 2003 and 2005 ODAC meetings called to discuss specific accelerated approval commitments.

FDAAA, passed in September 2007, has provided FDA additional authorities. Under FDAAA, failure to conduct studies under accelerated approval provisions could result in civil (e.g., monetary) penalties. However, at the time of FDA's public announcement, FDAAA legislation was not a factor in the decision to withdraw Mylotarg.

TCL: *What lessons from this action may be applicable to the future? Does the FDA plan to hold an additional ODAC regarding commitments under accelerated approval?*

PAZDUR: As we have obtained more experience working with accelerated approval, some lessons and recommendations follow. These recommendations take on greater importance since we now have the new authorities under FDAAA.

Sponsors should have a comprehensive drug development program formulated that spells out not only their plans for accelerated approval studies, but also their plans for confirmatory studies in early discussions with FDA. This should occur definitely before or

at the end of Phase 2 meetings. These plans should include populations to be studied, planned enrollment, and estimated completion dates and any anticipated effect that the accelerated approval would have on the completion of confirmatory trials.

We will be asking all sponsors of accelerated approval applications to present their subpart H confirmatory studies and anticipated completion dates to ODAC. Since these trials are anticipated to be on-going at the time of approval, we would expect sponsors to provide reasons for any delays and new anticipated start dates. ODAC would be expected to comment on these trials and completion dates in their deliberations.

A single trial to confirm clinical benefit is extremely risky and trials fail for a variety of reasons. We strongly encourage sponsors to have more than a single study to serve as their subpart H requirement to confirm clinical benefit. As noted above, FDA has exercised regulatory flexibility in allowing these confirmatory trials to be conducted in a different setting than the approved indication. Hence, if these trials are positive, they will not only satisfy their subpart H (or subpart E for biologics) requirement, but also serve as new marketing applications for supplemental NDAs/BLAs.

Since failure to conduct trials under subpart H may carry penalties, sponsors should retain control of their trials and have the ability to increase accrual by adding sites and additional resources to meet their original accrual dates specified in their approval letter.

We plan on holding ODAC meetings to discuss subpart H commitments. A yearly meeting to discuss accrual to these confirmatory trials is being discussed.

*Capitol Hill:*

## House Rescues Physicians From Cut In Medicare Claims

The House of Representatives late June 24 temporarily rescued physicians from the 21.3 percent cut in Medicare spending.

The bill—H.R. 3962—slaps a six-month patch on the Medicare system, which means that the problem will recur in late November.

The Centers for Medicare and Medicaid Services have been paying Medicare claims at reduced rates since June 18. The law also affected the TRICARE system for the military. These payments would now be supplemented.

To solve the problem permanently, Congress would have to alter the Sustained Growth Rate law that was enacted in 1997 to control health care costs.

While doctors have been spared SGR's cuts year-to-year, the impact of the law has accumulated, creating a $247 billion budgetary illusion, which Congress seems to have no political will to abandon.

Washington observers noted that the decision to pass a six-month patch doesn't appear to be arbitrary. This deadline pushes the issue beyond the mid-term elections.

The Senate passed its version of the bill earlier, and President Obama is expected to sign it.

The Obama administration also supports repealing the SGR law. "Kicking these cuts down the road just isn't an adequate solution to the problem," Obama said in a statement. "The current system of recurring cuts and temporary fixes was passed into law more than 10 years ago. It's untenable.

"I believe we need to permanently reform the Medicare formula in a way that attacks our fiscal problems without punishing our hard-working doctors or endangering the benefits on which so many of our seniors rely."

*Funding Opportunities:*

## New NCI Assay Development Program RFP Available

NCI's Division of Cancer Treatment and Diagnosis has started a program called the Clinical Assay Development Program to facilitate development and validation of clinical assays. These assays are often integral components of phase III and large phase II clinical trials.

NCI has issued a request for proposals (RFP) to find laboratories that can help in the development of these assays.

The laboratories that enroll in this program will need to have expertise in one or more of the following technologies: immunohistochemistry, ELISA, in situ hybridization, quantitative Reverse Transcriptase-Polymerase Chain Reaction, quantitative PCR, and DNA sequencing. Additional technologies may be required in the future.

Using reference sets of specimens, the labs that will comprise the clinical assay development network will assess reproducibility, robustness, inter- and intra-laboratory variability, and other relevant measures of assay performance and utility.

The RFP, which closes on July 23, is available at https://www.fbo.gov/spg/HHS/NIH/FCRF/ST10-1078/listing.html.