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NCI Panel Considers Plan To Centralize Clinical Trial Review And Prioritization

By Kirsten Boyd Goldberg

An NCI working group is considering a proposal to transfigure the existing clinical trials system by creating a central coordinating committee of "senior leaders in oncology" to review and prioritize all Institute-supported trials.

The plan was recently discussed in the Blueprint Group, a subcommittee of the Clinical Trials Working Group, established by NCI earlier this year to review the clinical trials system. Discussions are preliminary, and the plan could be altered or abandoned as the group continues its work over the next year, members said.

The prospect of centralization of clinical trials is certain to mobilize

(Continued to page 2)

In Brief:

Lipscomb Leaves NCI For Emory University; Moore Honored; Holden Names Administrator

JOSEPH LIPSCOMB, chief of the Outcomes Research Branch in the NCI Division of Cancer Control and Population Sciences, was appointed professor of public health in the Department of Health Policy and Management at the Rollins School of Public Health at Emory University. He has faculty appointments at Emory's Winship Cancer Institute and School of Medicine. He also was appointed director for cancer economics and outcomes research at the Emory Center for Health Outcomes and Quality, and named a Distinguished Cancer Scientists by the Georgia Cancer Coalition. **Steven Clauser** will serve as acting branch chief. **Molla Donaldson** will take Lipscomb's place on the NCI-wide committee on the potential research uses for medical records data available from clinical practice information systems. . . . **PEARL MOORE**, CEO of the Oncology Nursing Society, received the Women of Spirit Awards from Carlow College. The awards are presented to Pittsburgh-area women who are leaders in their professions. . . . **TINA DEVERY**, of Children's Mercy Hospital in Kansas City, Mo., and Mayo Clinic in Rochester, Minn., and Scottsdale, Ariz., was named associate director for administration at Holden Comprehensive Cancer Center, said center director **George Weiner**. She succeeds **Ted Yank**, now cancer center administrator at Baylor University. **Martha Hedberg**, administrator for the Division of Hematology, Oncology, and Blood and Marrow Transplantation at the University of Iowa Department of Internal Medicine, was interim associate director following the departure of Yank.

NCI Director: "Many Trials Produce Equivocal Results"

(Continued from page 1)

opposition from the 12 independently governed cooperative groups, which conduct the majority of NCI-sponsored phase II and phase III trials, collect tissues, and control the intellectual property generated by the studies. It is unclear how the plan would affect the cancer centers, the Specialized Programs of Research Excellence, and the NCI intramural program.

Since his appointment as NCI director in 2002, Andrew von Eschenbach has criticized the cooperative groups in his speeches, and privately, has faulted them for conducting trivial studies he described as "Coke vs. Pepsi" (**The Cancer Letter**, July 11, 2003).

Last year, von Eschenbach's NCI launched two apparent efforts to exert control over collection of tumor tissue, an enormously valuable resource held by the cooperative groups and cancer centers. The Institute paid for the development of a proposal for the National Biospecimen Network, a multi-billion-dollar repository (**The Cancer Letter**, Aug. 8 and Dec. 12, 2003). Also, while withholding grant money for the cooperative groups' tissue banks, NCI offered a modest increase, provided that the groups would act as contractors. The groups rejected the proposal, in part because the change would lead to loss of control of the intellectual property (**The Cancer Letter**, Jan. 2, 2004).

"Obvious Centralization of Authority"

The centralization proposal was first described late last month in conference calls of the Clinical Trials Working Group. NCI asked the group to review the clinical trials system, recommend immediate improvements, and develop a "blueprint" for configuring a system for the future.

After hearing the proposal, group member Colin Begg summarized his objections to the plan in an e-mail he sent to CTWG members.

"My immediate reaction to the system is its very obvious centralization of authority," wrote Begg, chairman of the Department of Epidemiology and Biostatistics at Memorial Sloan-Kettering Cancer Center, in a July 24 email to other group members. "I find this a little troubling, because I think one of the great strengths of the NIH system for funding research in this country is its capacity for allowing new investigators to break through any stifling oversight they might experience in their own local programs or departments by seeking funding in an open peer review system."

A copy of the email was obtained by **The Cancer Letter**. After this reporter learned about the plan and started contacting CTWG members and NCI officials, von Eschenbach issued a statement outlining his view of the problems with the current system and describing the changes he would like to see.

"There is … a significant degree of duplication of effort and fragmentation in the clinical trial system, which wastes resources and slows the clinical trials enterprise," von Eschenbach wrote in the "Director's Update" published in the Aug. 10 NCI Cancer Bulletin. "In addition, many trials take many years and resources to complete, only to produce equivocal results.

"There are also problems with poor patient participation, inadequate reimbursement of trial costs, and complex regulatory requirements," von Eschenbach wrote. "Finally, and perhaps most importantly, there is a lack of a widely accepted bioinformatics platform to support a national clinical trials effort.

"This does not mean jettisoning the entire system," von Eschenbach wrote. "On the contrary, there are many aspects of our clinical trial program that function very well, from our strong biostatistical, data quality, and safety monitoring systems to the

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conduct of trials that are both disease- and modality-oriented."

Von Eschenbach described the working group's agenda: "CTWG will provide guidance to redesign the clinical system. Based on this work, early steps will focus on making infrastructure improvements, with an emphasis on bioinformatics through the cancer Biomedical Informatics Grid (caBIG) and the establishment of biorepositories and laboratories that can support clinical assays for biomarkers," he wrote.

"Longer term, more ambitious areas of discussion will include trial review and prioritization procedures and potential revisions to the classic trial phases (phases I, II, III), with a focus on combination/targeted intervention studies."

The working group is unlike any other at NIH. Usually, advisory committees are comprised entirely of outside experts, while internal working groups are comprised of federal employees. The CTWG is led by an NCI official, James Doroshow, director of the Division of Cancer Treatment and Diagnosis. Including Doroshow, 10 of the committee's 34 members are NCI employees.

In another departure from ordinary procedure, NCI required group members to sign confidentiality agreements that bar discussion of the group's deliberations. Meetings of the working group are not open to the public, but its recommendations would be presented publicly to the National Cancer Advisory Board, Doroshow said.

"We are trying very hard to have a process in which, like a study section, folks feel comfortable to offer a variety of options so that there is free discussion," Doroshow said in an interview last week. "I am very interested in getting as much input as possible. People need to feel free to offer opinions they don't want disseminated. Certainly, discussions we have had to date are preliminary. We are asking them to keep their discussions within the group."

The working group has about a year to develop its recommendations, Doroshow said. However, Doroshow has suggested the formation of a permanent committee to provide oversight of the clinical trials system.

"My hope is that, ultimately, there is constituted a continuing forum for all of the parties involved in clinical trials to get together on a regular basis and look at these issues," Doroshow said. "We are unlikely in the course of a year to solve all the issues and address everything that we want to address.

"Whatever we think the issues are today, it's likely that there will be issues we can't think of," Doroshow said. "If we are successful and can show that we can all work together and make progress for our patients, then we can make case that [the committee] can continued and is worthwhile."

Quest for "The Perfect Peer Review System"

The Blueprint Group, one of three subcommittees of the working group, is trying to devise "the perfect peer review system," said Mark Ratain, associate director for clinical sciences, University of Chicago Cancer Research Center, and co-chairman of the subcommittee. The other co-chairman is James Abbruzzese, chairman and professor of medicine, Department of Gastrointestinal Oncology and Digestive Diseases, University of Texas M.D. Anderson Cancer Center.

Two other subcommittees are considering immediate changes to the system and assessing bioinformatics needs.

Under a plan Ratain and Abbruzzese presented in conference calls with working group members on July 22 and 23, all cancer clinical trial concepts would be submitted to a committee that would review and prioritize ideas and send them on to a group of senior leaders who would coordinate all cancer trials nationwide.

"We've been asked to come up with a starting point for discussion and to refine it based on feedback," Ratain said to **The Cancer Letter**. "It's more than very early. We were asked to get the ball rolling, as a place to start discussions from."

Under the proposal, according to sources who have seen it, anyone who has an idea for a clinical trial would be able submit it to a central office, called the "intake unit," which would be staffed by NCI.

These clinical trial concepts would be reviewed by a peer review group, either a standing committee or a pool of reviewers who would convene to conduct reviews. This entity would be called the Scientific Prioritization Network. That group's recommendation would go to a Coordinating Committee, comprised of senior leaders in oncology. The coordinating committee would make final decisions about protocols and would allocate resources. Another group, called the "implementation unit," would coordinate the further development of a protocol.

"It sounds like someone was reading to you from the slides," Ratain said to a reporter after hearing the description of the proposal. "I'm a little disappointed that brainstorming teleconferences have

been discussed outside the group. It's inappropriate to talk about a discussion that's ongoing."

Ratain declined to discuss the proposal or the subcommittee's deliberations, but was willing to offer his opinions. The clinical trials system is too unorganized, with different avenues for review and funding, and little discussion and planning, Ratain said.

"I would like to see a single system that could do reviews concurrently, with dialogue, rather than things going off in a review process and combing back with a thumbs up or down, with almost no comment," Ratain said.

"Imagine if you were getting some friends together for dinner out," Ratain said. "You suggest going out tonight, but someone else says tomorrow night would be better. You say, 'Thai food.' Someone else says, 'I don't like Thai, how about Mexican.' It's a back-and-forth process.

"The way our review system is structured now, you submit a proposal: 'Dinner tonight, Thai food.' Then you get back the answer: 'No.'"

The cooperative group disease committees "only focus on diseases they are interested in," Ratain said. "No one is doing sarcoma, for example. I would rather see an infrastructure that would permit someone who understands all of GI cancer to oversee other investigators that have more specific focus. We would still have competition, and a process that is fair, and not political."

The Blueprint Group's work has just begun, Ratain said. "We are just throwing some ideas out there and saying, 'Here, attack it,'" he said. "We know what we want it to do, but we don't know how it's going to do that. We want a perfect system that would work for anyone."

The proposed Coordinating Committee would be able to assess ideas quickly and bring in investigators and scientists to improve clinical trial concepts, said David Johnson, a working group member. "It's an interesting idea, but it's too early to say whether it's good, bad, or indifferent," said Johnson, president of the American Society of Clinical Oncology, director of the Division of Hematology-Oncology at Vanderbilt University Medical School, and deputy director of Vanderbilt-Ingram Cancer Center. "It would need to be worked on in more detail. Any proposal of this nature would be potentially threatening to people who are used to the existing system. This is very preliminary."

Cancer centers need more ways of rewarding team science, Johnson said. "Centers tend to be self-contained units," he said. "But no cancer center has it all. So one of the things we are hoping to do is make it easier to cross these artificial boundaries.

"My own view is that, in some ways, science may be outstripping our ability to test concepts in an effective, efficient, and rapid way," Johnson said. "With a lot of new drugs coming along, I don't know whether we can afford to spend two and three years conducting the phase III trials we have had to do in order to determine if a drug does or does not work.

"Congress and the public are asking the question, 'What's happening with the resources?' I think part of answer needs to be, 'We're working a lot harder. Not only are we creating new drugs, but we are creating new ways to test those drugs.' We are trying to come up with novel ideas, not patchworking the whole system.

"We may come back to the realization that the old system is the best," Johnson said. "Change for change's sake is never good in my opinion, but change to improve the system is important."

Competing Visions?

The CTWG is not the only group to propose a plan for improving the clinical trials system. Presenting a competing vision of the future, the Coalition of National Cancer Cooperative Groups earlier this year wrote a report containing 25 ways to improve the clinical research system without major restructuring (**The Cancer Letter**, April 2).

"A common theme of the recommendations involves correcting misalignments in the incentives, review processes, and review criteria so that they support, not undermine, the mission of the system," the report states.

NCI's efforts to exert greater authority over the groups is damaging to the system, the report states. "The autonomy of individual investigators, the driving force for innovation in the groups, appears constrained as the scientific agenda is controlled, rather than facilitated, by NCI…. One result is that the system's most important professional constituency, clinical researchers, is questioning the value of continuing to participate in group studies."

The report said the following changes would speed up the opening of trials:

—The Cancer Therapy Evaluation Program shouldn't review every cooperative group protocol, a process that duplicates FDA review. CTEP review is needed only when CTEP holds the IND for an agent. When a company or group holds the IND, only

FDA review is necessary.

—CTEP should be held accountable, as FDA is under law, for providing a timely review. "If after 60 days, a group has not heard back from CTEP, the protocol should be deemed approved," the report states.

—NCI should eliminate its requirement that all phase III trials be approved by the Central IRB, which has added another six to 12 weeks to trial development. This pilot project should be scaled back "until it has proven that it can reduce the time to protocol activation," the report said.

—The groups should establish targets for time to protocol activation and rate of accrual.

The report's recommendations also include:

—Duplication of trials could be avoided if NCI rewarded cooperation between the groups, centers, and SPOREs. Groups have little incentive to participate in trials with other groups, or in Intergroup trials, because they don't receive credit for that participation. Peer review should reward scientific leadership and group trial participation, the report states.

—Intergroup trials would move faster if the process were more accountable. The Coalition should oversee this mechanism and appoint project managers to design, implement, and coordinate Intergroup activities. With proper incentives for participation in Intergroup trials, this change "should result in a tighter focus on the most promising scientific ideas and trials," the report states.

—NCI should improve funding for the groups and help provide access to core laboratories and resources available in the cancer centers and SPOREs.

The report, which von Eschenbach requested from the cooperative group chairmen, has received no attention from NCI or the Clinical Trials Working Group since it was presented to the NCI director on March 17, sources said.

In a letter to the group chairmen, von Eschenbach thanked them for their efforts, but offered no substantive discussion of the recommendations, sources said.

Several CTWG members said the report was never presented to them. Disagreeing, Doroshow said the report was, in fact, distributed to the working group. "There are issues raised in the white paper that over time we will be hoping to address," he said.

The report, "Harnessing the Science-Advancing Care: A Proposal to Improve the Publicly Funded Cancer Clinical Trials System," is available at www.cancertrialshelp.org/static_binary/1434-9.pdf.

Concept Evaluation Panels

Peer review of clinical trials has been a contentious issue for many years.

In 1999, NCI began a pilot study to determine whether outside review of trials would be faster or better than CTEP review. The three-year pilot project enlisted external experts rather than Institute staff to review concepts for phase III trials for lung cancer and genitourinary cancers.

According to a review of the Concept Evaluation Panels presented to the NCI Board of Scientific Advisors in 2002, the panels were no faster than the traditional NCI concept review, and cost about $180,000 more a year to run for the two diseases.

Also, the panels were no more rigorous than CTEP, approving about the same proportion of phase III trial protocols as NCI over the three years.

After the pilot project was complete, cooperative group chairmen recommended against extending the panels to other diseases. "The CEP process is expensive, time consuming for the reviewers, and prone to conflicts of interest that are less likely to pervade the CTEP review process," Richard Schilsky, chairman of Cancer and Leukemia Group B and chairman of the group chairs advisory committee, wrote in a letter to NCI.

The quality of the CEP review "is not clearly superior to the concept reviews provided by the traditional CTEP process," wrote Schilsky, professor of medicine and associate dean for clinical research, University of Chicago Division of the Biological Sciences.

CTEP concurred with the group chairmen (**The Cancer Letter**, Nov. 22, 2002).

Critics of the pilot project noted that CTEP staff made up a third of the CEP reviewers, so the trials did not undergo unadulterated peer review, but continued to be filtered through NCI.

The pilot project was developed after a four-year process in which two advisory committees and the group chairmen studied ways to improve the clinical trials system. The process resulted in two reports, the Armitage report, named after Clinical Trials Program Review Group Chairman James Armitage, the Henry J. Lehnhoff Professor and chairman of the Department of Internal Medicine, University of Nebraska Medical Center, and subsequent report by an Implementation Committee.

The CEP and other pilot projects created as a result of the reports made the protocol development process more arduous, according to a 2002 report of the NCI Director's Consumer Liaison Group and the Coalition's Patient Advisory Board. The projects resulted in additional layers of review, the report said.

Does Centralization Mean Faster Review?

Working group member Begg, who indicated his unease with the proposal to centralize the trials system, said his email reflected his concerns about making changes of unknown consequence to the existing system.

"I'm not exactly sure what is wrong with the system," Begg said to **The Cancer Letter**. "You hear complaints that it takes a while getting studies going, and people come up with ideas and its hard to get them into trials. And that studies that get set up in the groups are ho-hum.

"I went to this committee open minded, hearing these ideas," Begg said. "Hopefully, after a period of discussion, the committee will come up with a plan—if we need a plan—that has a chance of streamlining the system."

Begg said he did not intend his comments to be made public. "These were my immediate reactions," he said. "Next time I will be more careful before I hit 'reply all' in an e-mail."

Following is the text of Begg's e-mail:

These are some general observations and concerns I have after thinking about the conference call yesterday. I have to say I thought it was an illuminating discussion, in large part because the thoughtful ideas for the new system were presented with conceptual clarity, allowing for an informative open debate.

Narrowing of Authority

My immediate reaction to the system is its very obvious centralization of authority. I find this a little troubling because I think one of the great strengths of the NIH system for funding research in this country is its capacity for allowing new investigators to break through any stifling oversight they might experience in their own local programs or departments by seeking funding in an open peer review system. While I think your goal is to make the system more open to new ideas, in fact, there is a danger of the opposite effect, in that great power will reside in the leaders of the Coordinating Committee, and there will be no alternative system to which an investigator can turn if the prevailing wisdom on the Coordinating Committee is unfavorable to his/her ideas.

This speaks to the issue of "competition" of ideas that was raised in the conference call. In the current environment, the various cooperative groups provide alternative venues for competing ideas. It might be worth reflecting on the experience of the combining of the two pediatric cooperative groups into the COG a few years back. Has this been viewed with hindsight as a generally positive development?

The Future of the Cooperative Groups

The incentive or impetus for the continuation of the existing cooperative groups is a pivotal concern. What role can they be expected to play in the proposed system? It should be noted that the committees of the cooperative groups have served an important function as generators of ideas for new trials. If the cooperative groups in essence transfer their authority for mounting new trials to these national committees, it is not clear that they would continue to exercise their role as idea generators. The center of gravity for developing new trials would presumably move to a more "individualized" focus, and presumably, some of those who feel disenfranchised at the present time would have greater ability to be heard. However, the mounting of a successful national trial involves a lot of teamwork, and the cooperative groups do possess a kind of generalized collective experience that I suspect is quite important to the ultimate success of individual trials. Is that something that would be easily replaced by these central committees, given the large volume of reviews that they would have to undertake?

Also, the cooperative groups have existing infrastructures for conducting the studies. If those were to gradually disintegrate, we would want to be confident that something better will fill the vacuum.

Speed of Review

The slow development of clinical trials has been a mantra of critics of the existing system ever since I can remember. It is also an endless complaint of in-house studies at my own institution. But while slow speed of development is frustrating, it may be that this is an inevitable feature of any system of review that takes its job seriously. Figuring out if a proposed clinical trial will be "successful" is a complex, and somewhat subjective task, that brings together such intangibles as the willingness of doctors to put their patients on the study, the responsiveness of the investigator to criticisms in the review system, and numerous logistical issues in addition to the pure scientific merit of the intervention under evaluation.

If a goal of the new system is to speed implementation, there needs to be a very critical evaluation of whether this is truly a realistic claim. Simply making the review process more centralized does not, in itself, ensure a faster turnaround.

Clinical Trials Working Group Membership

Chairman, James Doroshow, director, NCI Division of Cancer Treatment and Diagnosis.

Committee members (non-NCI): James Abbruzzese, chairman and professor of medicine, Department of Gastrointestinal Oncology and Digestive Diseases, University of Texas MD Anderson Cancer Center; Martin Abeloff, director, Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins; Peter Adamson, chief, Division of Clinical Pharmacology and Therapeutics, The Children's Hospital of Philadelphia; David Alberts, director, Cancer Prevention and Control, Arizona Cancer Center; Fred Appelbaum, director, Clinical Research Division, Fred Hutchinson Cancer Research Center; Steven Averbuch, executive director, clinical research & oncology, Merck Research Laboratories; Colin Begg, chairman, Department of Epidemiology and Biostatistics, Memorial Sloan-Kettering Cancer Center; Michael Carome, associate director for regulatory affairs, Office of Human Research Protection, HHS; Jean deKernion, associate dean, clinical research, University of California, Los Angeles; Gershon Locker, head, Division of Hematology Oncology, Evanston Northwestern Health Care, professor of medicine, Northwestern University; David Johnson, director, Division of Hematology/Oncology and deputy director, Vanderbilt Ingram Cancer Center; Richard Kaplan, professor of clinical cancer studies, University of Leeds, and associate director, National Cancer Research Network; Michael Katz, vice president, Board of Directors, International Myeloma Foundation; Amy Langer, executive director, National Alliance of Breast Cancer Organizations; Eberhard Mack, professor of surgery, University of Wisconsin; John Niederhuber, professor, Division of General Surgery, University of Wisconsin-Madison; David Parkinson, vice president and head, Clinical Oncology Therapeutic Area, Amgen; Richard Pazdur, director, Division of Oncology Drug Products, FDA; Edith Perez, professor of medicine, director, Cancer Clinical Study Unit, Mayo Medical School; Mark Ratain, Leon O. Jacobson Professor of Medicine and associate director for clinical sciences, University of Chicago Cancer Research Center; Mack Roach, professor, Department of Radiation Oncology, University of California, San Francisco; Richard Schilsky, professor of medicine, associate dean for clinical research, University of Chicago; Mitchell Schnall, associate professor, Department of Radiology, Hospital of the University of Pennsylvania; and Sean Tunis, chief medical officer, Centers for Medicare and Medicaid Services, and director, Office of Clinical Standards Quality, HHS.

Committee members, NCI staff: Jeffrey Abrams, senior investigator, Clinical Investigations Branch, CTEP; Karen Antman, deputy director for clinical and translational science; Kenneth Buetow, director, Center for Bioinformatics; Michaele Christian, associate director, CTEP; Howard Fine, chief, Neuro-Oncology Branch; Leslie Ford, associate director for clinical research Division of Cancer Prevention; Louise Grochow, chief, Investigational Drug Branch, CTEP; Lori Minasian, chief, Community Oncology and Prevention Trial Research Group; and Sheila Taube, associate director, Cancer Diagnosis Program.

Executive Director: Margaret Holmes, chief, NCI Office of Grant Program Coordination.

Funding Opportunities:

RFA Available

RFA-CA-05-019: Patient Navigation Research Program

NCI Center to Reduce Cancer Health Disparitie, invites cooperative agreement grant applications to develop operationally effective and cost-effective patient navigation interventions. The purpose of the PNRP is to develop interventions to reduce the time to delivery of standard cancer care services—non-cancer resolution or cancer diagnosis and treatment—after identifying an abnormal finding from a cancer detection procedure.

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The full RFA text is available at http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-05-019.html.

Inquiries: A. Roland Garcia, NCI, Center to Reduce Cancer Health Disparities, phone 301-496-8589; fax 301-435-9225; e-mail Garciaar@mail.nih.gov.

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