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Low Budget, Empty Beds, Lack Of Vision Beset Clinical Center, NIH Officials Say

By Kirsten Boyd Goldberg

The NIH Hatfield Clinical Research Center is facing a host of fundamental challenges including under-financing, under-utilization, and the lack of a strong vision for its future, NIH officials told the National Cancer Advisory Board earlier this week.

NCI Director John Niederhuber asked the NCAB to begin thinking about ways to improve the Clinical Research Center, because the NCI intramural research program accounts for about a third of the center's activity.

The institute will contribute $93.4 million to the center's $351.9 million budget in fiscal 2008.

"There is no other place in the world like this unique facility," Niederhuber said at the board meeting June 17. "We need to think creatively

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Capitol Hill:

House Approves Additional Funds For NIH, FDA

The House of Representatives June 19 passed a supplemental appropriations bill that gives NIH and FDA an additional $150 million each.

Both increases are lower than those passed by the Senate May 22. The Senate proposed the boosts of $400 million for NIH and $265 million for FDA.

The President said he would veto any bill that increases domestic spending.

In a related development, the House appropriators proposed a $1.2 billion increase for NIH for fiscal 2009. This would amount to a 4% increase in the institutes' $29.3 billion budget.

The administration has proposed no increase for NIH, continuing a six-year trend of flat funding.

"The $1.2 billion increase proposed for NIH in [the] Labor-HHS markup is a beacon of hope to those suffering from deadly diseases, like cancer, Alzheimer's, and Parkinson's," said Robert Palazzo, president of the Federation of American Societies for Experimental Biology.

"Years of flat funding have been discouraging to researchers and have delayed the progress of life-saving discoveries," Palazzo said. "It is our hope that this markup represents a critical turning point, and we look forward to working with Chairman [David] Obey [(D-Wis.), chairman of the House Appropriations Committee and its subcommittee that funds NIH] and Congress to bring about a sustainable future for NIH."

"Something Has To Change," Clinical Center Director Says

(Continued from page 1)

about how we can strengthen it, how we can support it financially over the years to come, and how we can maximally utilize it."

Despite several advisory committee reviews which made specific recommendations—including three major reports in the last 14 years—the center continues to lack a vision and a distinctive research portfolio, Stephen Katz, director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, said to the NCAB.

"Over the past 10 or 15 years, the recurring theme has been patient census levels and equity in funding among the NIH institutes and centers," said Katz, who heads the Management and Budget Working Group, which recently completed a review of the center's financing.

"These are recurring issues that not only face the NIH director, but face all of the directors, particularly when our budgets are challenged with no increases," Katz said. "There is no single solution that is acceptable to all the institutes and centers."

The center once led the world in innovative clinical research in cancer, heart disease, and other diseases, but has foundered for the past 20 to 25 years, eclipsed by the growth of academic medical centers—most of which receive millions of dollars in research funding from NIH.

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The heyday of the clinical center was probably the height of the Vietnam war. The military draft brought many talented physicians to the Public Health Service, but as the war ended and funding for NIH and NCI increased, much of this talent left the institutes for opportunities to start new programs in academia.

For medical oncology, the center long ago lost its position as the premier training venue in the U.S. The center lacks the size, depth, and breadth of most of the NCI-designated cancer centers, critics say.

Some extramural scientists have advocated sharp reductions in the NCI intramural research program and shifting all clinical research to universities and cancer centers. Others have long recommended that the Clinical Research Center focus exclusively on phase I studies in rare diseases.

In fact, the center's new building, opened just three years ago, was designed specifically to facilitate the conduct of phase I studies, sources said. All patients at the clinical center are supposed to be participating in a clinical trial. The federal government pays for all patient care associated with their treatment at the center, including travel.

Increasingly, the subject of resources for the center is triggering debates at NIH. Institutes with small intramural research programs don't want to help fund the center, while larger institutes, particularly NCI, find the center an increasing burden, particularly as costs of maintaining the center outpace the intramural research budgets

"Something has to change," Clinical Center Director John Gallin said to the NCAB. "We need to get revenue. We need to pay for escalating costs that are going up at any other hospital probably 6 percent a year. The 3.5 or 2 percent a year that we are living under, we can't continue to live under. We need to get some money, whether it comes from partnerships with industry, whether it comes from third-party recovery, whether it comes from philanthropy, whether it comes from some new costing mechanism. Dr. Zerhouni has even asked me to think about having this like Los Alamos, having this a national research hospital that is contracted out. For the life of me, I can't figure out how that saves money."

Searching For Direction

Over the years, NIH has convened many a committee to study revitalization of the clinical center.

In 1994, a report by the External Advisory Committee of the Director's Advisory Committee, led

by Gail Cassell and Paul Marks noted:

"At least three previous advisory committees have made recommendations for improving the [Intramural Research Program/Clinical Research Center]—some of which have been implemented, but many of which have been ignored."

After the Cassell and Marks report said that the clinical center needed to be rebuilt, Congress provided the money, and the new center opened in 2005.

In the 1990s, the institutes' contributions to the center were pegged to their usage of the facility. In 1997, a review group led by Stephen Straus recommended tapping all institutes in proportion to the size of their intramural research programs. This "school tax" was put in place in 2000 by NIH Director Harold Varmus. Proponents argued that the tax-like structure would increase utilization.

Also, NIH made changes to the intramural program to allocate resources to tenure-track investigators and established "staff physician" status for the physicians who took care of patients on protocols, but were not yet tenured.

When Elias Zerhouni became NIH director, he formed a "Blue Ribbon Panel on the Future of Intramural Clinical Research." This group's report in 2004 said the clinical center represents a "major national investment in clinical research."

The report recommended that NIH define a specific vision for the center to develop a distinctive research portfolio that complements that of the extramural community. "We are still trying," Katz said, characterizing the efforts to develop a new vision for the center.

The 2004 report also recommended that NIH develop novel programs to attract clinical investigators to Bethesda, and establish "streamlined and comprehensive governance" of the intramural clinical research program that would strengthen the role of the director and the clinical leaders in each of the institutes and centers.

"Some of the institutes have, in fact, done [this], and many of the institutes have not," Katz said. "Some of the institutes have clinical directors—such as Lee Helman at NCI, who has a defined role."

In July 2007, at a retreat of the IC directors, Niederhuber asked "a pointed question," Katz said. "'What are we really doing here? What was the clinical research center doing?'"

Zerhouni agreed to a review of ways to enhance research programs at the clinical center and increase usage, Katz said. Katz and Niederhuber convened a meeting at NIH to begin to develop specific initiatives, of which five are in various stages of development:

—A Trans-NIH Center for Human Immunology. "There is a great strength in basic immunology at the NIH, and much of that is with people who have real expertise in clinical immunology, who think about it, but may not actually participate in clinical immunology studies," Katz said. "It was thought there could be sharing and a common goal and a common training ground for people in this area of clinical immunology."

Katz and Niederhuber sought "contributions" from other institutes for space, personnel, and equipment to start this initiative, and have nearly come up with $3 million. "This is going to take off," Katz said.

—The Undiagnosed Diseases Program, which would bring patients with rare or difficult diseases to NIH. Since the program was begun about a month ago, there have been 350 inquiries for consultations, Katz said.

—Identification of "Manhattan-like projects." One project was identified and is in development, a bone marrow stromal cell transplantation center. NCI, NIAMS, and other institues have agreed to support this center, but others are needed. There would be a five-year commitment with milestones, Katz said.

—A major study to identify the barriers to accelerating clinical protocol activation. A report is due next year.

—An increased emphasis on recruitment and retention of clinical investigators. NIH has established a new intramural professional designation of "assistant clinical investigators." These are pre-tenure track physicians who are two to three years from being able to launch their own clinical programs, Katz said.

—Increasing intramural-extramural collaboration, to encourage the extramural community to use the center's resources. NIH is supporting a bench-to-bedside grant award to teams of intramural and extramural investigators. NCI is supporting a study with an extramural PI, Samuel Wells, that will accrue patients at the clinical center.

"Do you think any of these programs, while they are individually very interesting, are going to make a major impact on the utilization of the clinical center, which seems to me to be the central problem here?" asked NCAB member Bruce Chabner, clinical director of the Massachusetts General Hospital Cancer Center.

"No, I don't think they will make a major impact," Katz said.

"The rare diseases, to some extent, and bone marrow stromal could, if it grows into a major new

transplant program, but that's probably years away," Chabner said.

"I do think the Trans-NIH Center for Human Immunology can actually bring in patients if novel approaches are made in the area of multiple sclerosis, in rhumatic diseases, and even in the cancer institute in novel combinations of biologics and chemotherapeutic agents," Katz said. "But it's not going to bring the same avalanche of patients as when treatments for Hodgkin's disease were implemented. These are initiatives to help enhance these programs."

The undiagnosed or rare diseases program could increase utilization somewhat when diseases are identified and physicians begin to refer patients, Katz said. "If we have enough of those investigators, it will make some impact," he said.

"I think that actually raises the corollary question," Chabner said. "I think the secret of this is to really strengthen and revitalize the training programs and bring in a lot of new talent."

"We're trying," Katz said. "We thought the war might help."

"There's no draft, unfortunately," Chabner said.

"Bruce, I think you hit on a key point," said Gallin, the CRC director. "The key point from my perspective is the number of PIs. We have fewer PIs today than we had in 2001. Fewer tenured PIs and tenure-track PIs. To me, that's the problem. If each institute had just three more PIs and each PI had two or three patients in the hospital, we would be over 90 percent occupied."

Another Review of Funding Options

Last December, Zerhouni asked the NIH Management and Budget Working Group, led by Katz, to examine the center's financing.

"We were really getting to a point where the clinical research center, through John's leadership, was saving and saving and saving, there were some costs shifts, but there was very little in the way of flexibility in a flat budget for the past five years," Katz said. "We were charged to recommend how best to allocate the costs of the clinical center—again to address that issue."

The committee wasn't asked to review the quality of science at the center, Katz said.

The committee found that the center's budget as a percentage of the intramural program budget was decreasing, from 14 percent in fiscal 2001 to 13 percent in FY08. However, since 2006, the center has directly billed the institutes for some costs, such as non-clinical blood products and research nurses. When those costs are included, the trend remains unchanged, but the center's budget as a percentage of the intramural program declines to 13.5 percent by 2008.

The committee looked at the long-range implications of a 3.5 percent increase in the clinical center coupled with a flat budget for the intramural research program. The center would begin to require 18 percent of the intramural research budget by 2013.

"Under the current model, there has been steady movement over the past several years to cost-shift expenses to the [institutes and centers]," Katz said. "But we are at a point where there's no more room for cost-shifting, because all the costs that should shift have been shifted, and the clinical center has to assume those other costs, if we are going to have a clinical center." The institutes and centers have difficulty budgeting for these unforeseen costs, and the result is a decrease in clinical center utilization.

The committee considered four financing options:

—Continuing the school tax.

—A direct appropriation to the clinical center, which would require asking Congress for appropriation language authorizing clinical center funding from the total amount for NIH.

—A "hybrid" model in which some costs are assessed by utilization and others assessed by a formula, such as the school tax.

The idea of getting third-party insurance or Medicare payments wasn't considered, because this had been rejected by previous committees, but the committee encouraged the pursuit of supplemental funding from philanthropy, Katz said.

In a report last March, the committee recommended continuing the school-tax financing method for the short term, but said NIH should undertake a fundamental review of the mission of, and opportunities for the clinical center. This review should be conducted by an outside panel with expertise both in clinical research and hospital administration, or by the soon-to-be formed Strategic Management Review Board, authorized by the NIH reauthorization, the report said. This review should be started "as quickly as possible," the committee said.

At a budget retreat for the institute and center directors last month, Niederhuber "brought up the idea that we have had enough of these panels, we should just get on with it, and I got the sense that was the sense of the IC directors, but I have been told that is not going to be the case," Katz said.

Also at that meeting, Niederhuber argued that the school tax doesn't give the institutes an incentive

to use the center. Katz said Niederhuber asked several questions:

—Is the CRC to remain as the singular unique asset that sets NIH apart as an exceptional federal research enterprise?

—What is the NIH commitment for a CRC within tight budget constraints?

—Is there, or should there be, a direct tie to the overall NIH budget level?

—Is it necessary to tie CRC budget growth to either intramural research or Research Management and Services budget lines?

—Would another review useful?

—Have the prior reviews resulted in any lasting constructive change?

"I think the last was not meant to be a cynical comment by John Niederhuber, but meant to help facilitate this issue and move it along in a rapid way," Katz said.

If the CRC didn't exist, NIH would lack the ability to attract outstanding clinical scientists, the study of rare diseases would be compromised at NIH, and translational research would not be done at NIH, Niederhuber said to the IC directors. The center is conducting about 400 phase I and phase II trials.

The clinical center spends 1.2 percent of the total NIH budget. Niederhuber suggested increasing that proportion to 1.35 percent of the budget, for a $45 million increase. By comparison, the NIH Roadmap initiatives take 1.7 percent of the NIH budget. He also suggested engaging a professional consultant to advise on the most appropriate management structure for the center.

Niederhuber also recommended setting up a consortium of the six institutes that account for about 80 percent of the patient census, to be financially and programmatically responsible for the center. NIH would have to commit to adequate growth of the center.

Katz said he disagreed with that proposal. "To me, it's six of one, half a dozen of the other," he said.

For now, NIH is continuing the school tax, and Zerhouni is establishing the Scientific Management Review Board, made up of nine institue and center directors and 10 or 12 advisors from outside NIH. The board will review the mission of the CRC.

NCAB Discussion

At the NCAB meeting, Niederhuber said his goal in the presentation to the institute and center directors was to "try to get some motion on this."

NIEDERHUBER: "I was hoping to not have another committee look at this."

KATZ: "In fact, that was embraced."

NIEDERHUBER: "I thought that we as institute directors understand probably better than anyone what the meaning of the clinical center is. I think it's hard for anyone from the university environment to come to this unique environment and understand it in a short period of time. I thought it was our problem to solve, and we ought to step up to the plate and get the job done. That's the surgeon in me, I guess."

KATZ: "Or the dermatologist in me."

NIEDERHUBER: "The proposal I made was to just try to get something different out on the table. I don't have a strong bias to that. I do think it's a complicated management structure. John [Gallin] is working diligently toward information systems that would better help the leader of the facility manage that in real time much more effectively. He has been very responsive to my asking for a cost accounting of the pharmacy so I could share that with leaders of the major pharmaceutical companies so they could be informed about what that cost was to us and to see whether or not they would feel this is an important enough activity that they might wish to support that in kind or with dollars."

NCAB member Jean deKernion, chairman of urology and senior associate dean for clinical operations at the University of California, Los Angeles, said Congress should provide a specific appropriation for the clinical center. "This doesn't fit in the budgets of the institutes," he said.

"I disagree a little bit, Jean. It really is a research laboratory," Niederhuber said. "It is just a different kind of laboratory."

Niederhuber said that while it might be attractive to have Congress fund the center as a line item, it would raise the potential issue of mandates. "I don't think we want them at that level of detail," he said. "I could see how a particular word or paragraph in the appropriation to say, 'we want the clinical center to do such-and-such. There's a lot of opportunity in that for meddling.

"This really is an NIH enterprise," Niederhuber said. "It would seem to make more sense to me if it was right up at the top of the NIH budget with a budget line with a formula attached to it."

DEKERNION: "Fine. So it's research. But you still have the problem. It's not thriving. You aren't filling the beds and you are having trouble paying for it. If you don't have the money, then why not try to make it part business and part research? Have an outpatient business you run with pharmaceutical companies and the help you pay for protocols and the drugs. The inpatient—why

aren't you billing third parties for services?"

GALLIN: "Your comment about a line item has been a question that every director of the clinical center has raised since it opened, starting with Jack Masur. It has never happened. I happen to feel there might be some virtue in a line item, either as a direct appropriation to the clinical center, or a direct appropriation to the director of NIH. It could enable some things to happen that don't happen now, for example, really making it a national hospital with ready access to the extramural community to utilize the hospital and to pay for those services that they utilize, which is not possible today. If a grantee wanted to do phenotyping of a patient cohort at the clinical center, it would be very difficult to use grant dollars to pay for it.

"In terms of third party recovery, the appropriation language allows NIH to do third party recovery, and to keep the money—even more amazing. It's never been done. We have had at three very intense studies evaluating whether this would be a good idea. And in each case, they concluded that it wouldn't be worth it. The reason it wouldn't be worth it is that we wouldn't collect much money, if you look at the patient population, both because of their socioeconomic status and because of the very heavy load of research. We can't collect from Medicare and Medicaid, because you can't move money from one part of the department to another.

"When you really look at how much money we would collect and the burden of dealing with every third party payer in the country, we wouldn't collect that much. The patients have told us they wouldn't come here and volunteer for research if they were close to their lifetime insurance cap and we said we were going to some of the cap while they are here.

"Our investigators say, you underpay us but we come here because we like research, and if you put us in a position of having to fill out all the paperwork for third-party recovery, we'll go somewhere else and double our salaries. For those reasons, it's never been done."

CHABNER: "Some of the trends you are showing, decreased bed utilization, we've seen that at the same time outside, virtually all of cancer care and experimental care is given in an outpatient setting. I have a feeling that this new hospital that was built really created a facility that is going to be difficult to really use for inpatients. I don't know how much of your costs are related to that."

KATZ: "Can we erase the tape?"

CHABNER: "The second point is, we have faced this problem of paying for drugs on clinical trials and we made the decision that we don't start clinical trials unless there is a financial backing for that trial. We don't pay for Avastin because some young faculty member wants to do a combination trial in some disease. If he can get the drug company to pay for it, if he can get a grant for it, then we will do it. I would suggest that you look very carefully at any trial people want to open that are going to require you to pay literally millions of dollars for drugs you have to purchase.

"The third thing is that I think you need to actively engage with drug companies to pay the costs of trials. If the trial is good enough and interesting enough, they ought to be willing to pay just like they do for us outside. We have 400 protocols; you have 400 protocols. We collect about $35 million a year from drug companies to support those trials. That would make a hell of a difference."

KATZ: "John is taking the lead with drug companies. That is a real issue and that would attenuate a lot of the burden."

CHABNER: "They could pay some of the other costs, the radiology, the lab costs, if they think the trial is compelling enough, they will do that. If it isn't compelling enough, maybe you shouldn't be doing the trial."

KATZ: "Good point."

NIEDERHUBER: "That is a good point, but it's not quite that simple. There are a lot of other pharmacy costs. The second point is that we're often driven by scientific opportunity, that we want to do something unique that isn't going to be done elsewhere, because we see a potential use for a given agent, and that agent an awful lot of the time already has a label. Industry is very reluctant. They will stall and do anything they can to not have that go forward, because they don't want the risk of finding there could be side effect that wasn't picked up before, they aren't sure whether we are using this in a different fashion, with a different combination of drugs, what might be the downfall for them financially. So that puts us in a bind, either you don't do it or you pay for it."

CHABNER: "We are in the very same bind."

KENNETH COWAN, director of the Eppley Cancer Center at University of Nebraska Medical Center and an NCAB member: "Who says you have to be at 95 percent [of bed usage]? Our businesses have to be at 95 percent because our universities lose money if we don't. I understand there are cost efficiencies if you are at a higher utilization, but a lot of hospitals have closed beds and you might be in the same situation. Not necessarily a fixation on usage, but what is the proper size to fulfill

your mission of being either unique or strategic. It's the same thing in terms of the pharmacy budget. If that trial is worthwhile for NCI, then they ought to pick up the budget to do it. It ought to be budgeted that way. Which trials fulfill the need for the uniqueness or strategic mission, so scientific review of the science and also the budget. Maybe that has to be built into the some of the budgets of the institutes….

"Your clinical research is going to be dependent on the clinical investigators that you bring in here and train. So the place has to be exciting to make sure you attract the best trainees. Somehow building that into the model for financing is critical, too."

NCAB member Lydia Ryan, clinical director for hematology, oncology and stem cell transplantation at Children's Healthcare of Atlanta, suggested the center should get data on the portion of research versus non-research costs and apply the research costs to the ICs and find another funding source for non-research costs. She said NIH could use advice from hospital administrators on business tactics that could be applied to the center.

Gallin said the center engaged the consulting firm Price Waterhouse to help transform its accounting system from an "activity-based costing system" to more of a retrospective cost accounting and billing system. About a third of the center's costs are research and two-thirds are standard of care. Improving these information systems may make it worthwhile to consider billing third parties for some care in specific instances, he said.

"This is such a valuable resource, and you are at a point now where you could lose it," deKernion said. "I would just say that, if you get outside consultants, get ones you don't have to pay, because they are all going to tell you the same thing. After $20 million, I can tell you what they are going to tell you. I would say you might want to separate the outpatient from the inpatient and try to set a budget. Bruce is right, you can support a lot of clinical trial programs with industry funds. At least do that part."

For the inpatient costs, perhaps NIH could cut some fixed costs by downsizing, deKernion said.

Lee Helman, NCI scientific director for clinical research, said the institute's patient census isn't decreasing, but is slowing increasing, growing at about 1 percent a year.

Helman said he has challenged NCI investigators to only propose phase I and phase II studies that will make a significant impact. "Our job is to do a pilot study or a phase I study, that if it is positive, it will be taken by the extramural community to be further explored in larger studies," he said.

"Are We Really Getting Unique Studies?"

Richard Pazdur, director of the FDA Office of Oncology Drug Products, who represents the agency on the NCAB, asked Gallin about the clinical centers portfolio of trials. "Do you really think that the trials being done at the clinical center really represent trials that are not being done at the major cancer centers?" Pazdur said. "I see all of the protocols. I have an opinion which I won't voice. The issue here is that when the clinical center was designed, medical oncology practice was a lot different. There weren't a lot of medical oncology programs at the universities, there were a handful of cancer centers.

"When I see company sponsored trials adding three or four drugs together—these trials can really be done in the universities," Pazdur said. "Are we really getting the unique studies here? There are some unique advantages the clinical center has. Your patients are getting all their transportation provided and lodging provided. That should be for very unique trials."

"We can do things that can't be done in a university environment," Niederhuber said. "We can monitor patients, with imaging, we can sample tissues more easily and more often. There are a lot of things we can do in this environment."

"I think this is an issue that I've pushed," Helman said. "I think five years ago, this was a problem." He said NCI is doing studies with imaging and genetic profiling that are unique, and early phase small studies, intensively monitoring patients to try to identify response biomarkers.

"This is one of the most interesting and important topics the NCAB has addressed since I've been on it," said Donald Coffey, professor of urology at Johns Hopkins University. "What I see, as man who has never taken care of a patient, is that it is not being done right. It's not being done right, because what's being done is a collage. It should be put together with strategic planning. I was not convinced by any of the arguments that anything could be done here better than it could be done in the university. It is true for rare diseases, it could be done better here. This is so unique and important, that it should be refocused and done right."

In the States:

Calif. Stem Cell Group Forms Collaboration With Canada

The California stem cell research organization has formed a collaboration with Canadian researchers

The three-year agreement announced June 18 at

the BIO International Convention in San Diego lays out a plan for the California Institute for Regenerative Medicine and the California and Canadian spin-off called the Cancer Stem Cell Consortium to explore collaborative approaches to evaluate, fund and monitor cancer stem cell research projects.

Canadian authorities are contributing over $100 million (Canadian) to the venture. California has committed $3 billion to stem cell research at state-based universities and research institutions.

Consortium members currently include: Canada Foundation for Innovation, Genome Canada, Canadian Institutes of Health Research, Ontario Institute for Cancer Research and the Stem Cell Network.

"California is committed to being a leader in stem cell research, but no one state or nation should do this alone" Governor Schwarzenegger said in a statement. "Entering into collaborations such as this, which bring together leading medical research capabilities, have great potential in improving the lives of not only Californians, but people around the world."

The collaboration leaders said the first potential area for collaboration under consideration is the upcoming CIRM Disease Team grants. These grants will provide an opportunity for researchers in California and Canada to collaborate, broadening the potential pool of expertise.

The Disease Team Awards will support multi-disciplinary teams of scientists in pursuit of therapies for specific diseases. The goal is to fund the work of disease teams that would result in therapy or diagnostics for a particular disease or serious injury. Request for Applications for these grants will be issued by CIRM in October, with grants announced in June 2009. Successful proposals will likely include a description of a path to an Investigational New Drug filing at the end of the four-to-five year grant.

"Canadian researchers have been at the forefront on stem cell research and Drs. James Till and Ernest McCullough received the Lasker Prize for work, which pioneered the field," Tony Clement, Canada's Minister of Health said in a statement. "By working together across borders and bringing together the top scientists from both countries to tackle cancer stem cell research, I believe we will be able to shorten the time to bring great improvements to the lives of those affected by cancer,"

Canada's contributions will fund the Canadian components of cancer stem cell projects and those funds will be available to scientists across Canada, Clement said.

Funding Opportunities:

NCI To Commit $10 Million For SBIR Bridge Awards

In an effort to accelerate the development and commercialization of novel cancer therapies and imaging technologies, NCI has begun a pilot initiative to bridge the funding gap many early stage biomedical companies face.

The new NCI Small Business Innovation Research Phase II Bridge Award is intended to augment previously funded NIH-wide SBIR Phase II projects that require additional funding in order to achieve key technical and regulatory milestones along the path toward commercialization.

This funding opportunity focuses on the continued development of cancer therapies and cancer imaging technologies, which require clinical evaluation and approval by a federal regulatory agency.

NCI intends to commit up to $10 million to fund five to 10 SBIR Phase II Bridge Awards in fiscal year 2009.

To incentivize partnerships with third party investors, the SBIR Program expects the Bridge Award amount to be matched by non-federal funds. By providing half of the resources for these projects, NCI is helping reduce the risks to investors at this critical stage of development, said NCI SBIR Director Michael Weingarten.

Competitive preference and funding priority will be given to applicants that demonstrate the ability to secure substantial independent third-party investor funds (i.e., third-party funds that equal or exceed the requested NCI funds).

Small businesses that have previously received SBIR Phase II funding through NIH's SBIR Program are eligible to apply for up to $3 million over three years through the Bridge Award for projects critical to advancing cancer therapies and cancer imaging technologies.

Budgets up to $1 million in total costs per year for up to three years may be requested from the NCI. Development efforts may include preclinical R&D, which is needed for regulatory filings (e.g., IND or IDE) and/or clinical trials.

Receipt Dates: Sept. 19, 2008; Feb. 27, 2009.

The text of the Request for Applications is posted at http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-08-021.html.

Further information on the program is available at http://sbir.cancer.gov.

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