THE CANCER LETTER

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NCI Director Broder, Going On 3rd Year, Examines Issues Of Funding, Priorities, For Institute's Future

NCI Director Samuel Broder discussed a variety of issues he has encountered in his first two years and eight months in office in a recent interview with **The Cancer Letter.** Broder addressed the NCI budget, clinical trials funding, cancer centers, cancer statistics, Congress, the National Cancer Act and its special authorities, and NCI's relationship with NIH and FDA, among other topics. The discussion provides insight

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In Brief

Tipping Resigns From ACS; Vaughan Joins UAB BMT Program; PCI Recruits Ball, Finn, Mirro

WILLIAM TIPPING, executive vice president and chief executive officer of the American Cancer Society since 1988, has resigned to "pursue other interests," the society announced this week. Tipping told ACS President Gerald Dodd and Board Chairman John Seffrin of his decision to step down at meeting in Chicago last week, according to ACS spokesman Mike Heron. In a written statement, Tipping said he accomplished his major goals of moving the society to Atlanta, constructing a new headquarters, and reorganizing the ACS national office. "With these goals acheived, I want to step aside and pursue other interests," Tipping said. A search committee to find a successor will be announced at the group's annual meeting in November. **James Bell,** senior vice president for finance, will assume Tipping's duties in the interim. . . . **WILLIAM VAUGHAN,** Univ. of Nebraska, joined the Comprehensive Cancer Center at Univ. of Alabama at Birmingham as professor of medicine and associate director for clinical research. He heads the reactivated bone marrow transplant program, which had been stopped in 1983. The new program will concentrate on autologous BMT and peripheral stem cell transplants for patients with breast cancer and the malignant lymphomas. . . . **PITTSBURGH CANCER** Institute recruited three cancer experts: **Edward Ball,** Dartmouth Medical School and program director for clinical immunology at Norris Cotton Cancer Center, was appointed program leader of hematologic malignancies and bone marrow transplantation. He will coordinate the BMT program at Montefiore Univ. Hospital and will serve as prof. of medicine and hematology div. chief at Univ. of Pittsburgh School of Medicine. **Olivera Finn,** Duke Univ. Medical School, joined PCI to lead the immunology program in the div. of basic research. **Joseph Mirro,** St. Jude Children's Research Hospital, was named associate director for PCI's new div. of pediatric oncology, where he will begin a pediatric BMT program and a pediatric cancer research program.

Broder Discusses Concerns, Priorities For NCI And National Cancer Program

(Continued from page 1)
into Broder's priorities for the Institute and the National Cancer Program in coming years.

Following is the first part of the interview, held by **Cancer Letter** Editor Kirsten Goldberg and founder and Contributing Editor Jerry Boyd. The second part will be published next week.

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CL: When Vincent DeVita came into office [in 1980] he started out immediately by getting into confrontations with the Organ Sites people, [activist] Rose Kushner, with the community docs, with the cancer centers people, with Sen. Orin Hatch. How do your first nearly three years compare?

Broder: It depends on what you mean. I think it's impossible to do anything important, and in particular it's impossible to do anything in the National Cancer Program, without making somebody mad. If nobody is mad, then you're not doing your job. It means you're not doing anything. So I think that you have to keep things focused on the issues as much as you can. I think that it's important to understand which set of priorities is at stake. I think we have different kinds of agendas than we may have had in the early '80s. I think there's a lot of attention to quality of life, to speed of translation of laboratory to clinical endpoints. There's a lot more focus on public health impact of the program. From the Congress there's a much more specific interest in what really has been accomplished. More bottom line type issues than there probably were in the early '80s.

I think there's also a stronger sense of limitations of resources. I think the country as a whole, not only in biomedical research but across the board, has more of a sense of limits as to what it can do. I think as the '80s were starting off, there was still the residual feeling that we weren't going to have the kinds of limitations that have become real now.

CL: There were some severe restrictions being put in that everybody thought, "It's just this year, maybe we'll get a better budget next year."

Broder: What happened operationally was that the restrictions came in across the board and then were selectively lifted for everyone but NCI. We never as an Institute in terms of constant dollars ever recovered from the early '80s, which is interesting. People must know that, but when I show the constant dollar thing, audiences look like they're hearing that for the first time, which I find very astonishing. It's very clear that what happened in the early '80s is that both NIH as a whole and NCI as part of that lost in constant dollars. Then NIH recovered, but NCI never did. NCI is still 6 percent below, approximately, in constant dollars, where we were in 1980. NIH is probably 30 percent above where it was, and that includes the loss for NCI.

Some of the mechanisms have just taken a profound beating, and again, I don't understand why people haven't really been more sensitized to it. The message wasn't really clear. Prevention and control lost a third, cooperative groups lost a third, centers lost about 15 or 16 percent, contracts lost about 50 percent. The research project grant program went up roughly 27 or 28 percent. By that barometer, you can't say there's been a loss. The intramural program would have lost had it not been for AIDS.

CL: That brings up the clinical trials study section issue, and in working on our [soon to be published] index I ran across, in about 1977 or 1978, almost word for word the same type of discussion that we've had in the last year or so: "We can't get grants through the NIH Div. of Research Grants, can we have our own study section, can we get them to do something about it."

Broder: We have to be careful that we're not fighting old battles and assume that the same preordained outcome is going to occur. I'm very optimistic, strangely enough, that we will get the cooperation of DRG. In point of fact, DRG has been very receptive to our concerns, so far. I think that we really have to have a study section that can handle, on a standing basis, important clinical research, clinical treatment related research, R01s that are sent in by the investigator initiated process, by people who have their own ideas, the classical investigator initiated proposals. And that they can expect to receive a fair hearing in the study section.

Ideally, you should have one for treatment related research and you should have one for prevention and control related research. I think that that's the only way to secure the health of a discipline. It is also the only way, operationally, in my opinion, given the realities of how NIH works, to ensure appropriate growth for the discipline. I think we have to come to terms with that.

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People get offended when I say that, but we have to come to terms. It's unwise for us to ignore many decades of realities, very unwise. It's very clear to me that the one mechanism that will enjoy support and will be defended is the research project grant mechanism.

CL: That is great, in talking about clinical research, for studies like Bill Hrushevsky's [in chronobiology]. He's usually gotten his through ET2 without major problems.

Broder: It proves many points. It proves that people who are on the outer envelope of something, who are against the common grain, do not necessarily find themselves completely on the outside. He's been consistently getting support.

CL: But how can you relate that to the needs for the cooperative groups? They're not doing that kind of stuff.

Broder: I think the cooperative groups are an incredibly important mechanism and we need to support them. The cooperative groups per se probably can't realistically go through a standing study section, so that's a second layer of a problem. But I do think that there are innovative ways that certain things that are either done by cooperative groups or are essential to the success of certain types of clinical trials within the cooperative group program, can go in as standard investigator initiated R01 type proposals. I think we need to make more innovative use of the R01 mechanism for clinical trials.

So, there are two different points. One is to try to use the existing study sections as much as possible. And two, even if you can't use them, to still try to use the R01 mechanism as much as possible.

Ironically, other institutes are doing that. In some cases, other institutes are looking at the Cancer Institute with a certain incredulity. They will accept that clinical trials are important, as we say clinical trials are important. In an ironic way, what they have done, shrewdly, is acted on that belief by putting clinical trials in the one mechanism that is ensured to have the most growth.

It's like we at the Cancer Institute have picked certificates of deposit that will lose in value, whereas others have put them in where, over a 10 year period of time, you can expect 30 percent growth.

CL: They're not doing them for large scale phase 3 trials.

Broder: They are doing it for large scale randomized studies, yes indeed. Now, they don't use standard study sections.

CL: Why can't our cooperative groups do the same thing?

Broder: Indeed, why not? That's my question, that's my point. DRG has said, to me personally, that they will extend the flexibility of an R01 to large scale clinical studies, under the appropriate circumstances. They will be flexible now. We have to test them.

What I'm saying is, first, try to establish an effective mechanism by which clinical investigators can make a reasonable expectation that their proposals will get funded. There's the chicken and the egg phenomenon here. If you don't submit good proposals, then the study section in effect will atrophy. Then, in a strange kind of positive feedback loop that's detrimental to all parties, the study section gets the reputation for being unfriendly to clinical research. It becomes defensive by saying, "Well, we're not getting good proposals." Then the next thing you know what occupies that study section's time are a lot of basic research proposals. In general it's not a good idea to mix basic research proposals with clinical research proposals, in my opinion. What they're going to say is, "But there aren't enough clinical research proposals to occupy the study section's time."

In addition, I think several people in the ET2 [Experimental Therapeutics 2] study section have in good faith, not in any negative way, expressed their feeling of being wronged, that we have accused them of being unfriendly to clinical research. I think they're not totally off the mark on that. I think they have standing to say, "We don't have any proposals." It's circular. Which is why we've obsessively gone out to people and we've said, "Get some proposals, we don't care what your proposals are as long as they are investigator initiated. Get them in to us and encourage your young acolytes to send them in to us. Get the proposals to us so that we have a menu to chose from."

That's the standing study section issue. Within that, however, we still need to explore more innovative ways to use R01s for clinical research, and they may not be suitable for a standing study section. They may be more suitable for special ad hoc reviews, which is done by the Institute, and that's OK. I think we have to use that mechanism, we have to call upon everyone to cooperate with us.

CL: You're telling people, "Trust us."

Broder: I'm telling people, one, trust us. I'm also telling them, "Look at the statement you are making by simply accepting your fate on this." We cannot tolerate a reduction of the Cancer Centers Program, and of the prevention and control program, and of our clinical trials program, by one third. On a piece of paper, Vince DeVita was able to do more clinical trials work through the cooperative group line than we can now, if you correct for inflation. I'm not talking about whether scientific ideas have improved, just in terms of purchasing power. We can't accept that.

CL: You should be doing at least a third more.

Broder: We should be doing more. The bottom line is, we can't get around the reality that NIH reveres, honors, respects, and defends one and only one mechanism. I'm not giving you any editorial comment whether that's good or bad. The research project grant is the most revered mechanism at NIH.

CL: You can't set up your own review group within NCI and channel money from the R01 pool into that?

Broder: You could, but what purpose would that serve? Why would we want to, for ordinary investigator initiated research? I think we should use our standing study section. There's no reason why ET2 can't do a great deal. I'm mixing multiple concepts here. The clinical trials part is a hypertechnical specialized part of this whole equation. But clinical research, in the total sense of the word, certainly, if it's treatment related, could go to ET2. That's primarily a cancer study section.

CL: Relate this now to a specific case. The Southwest Oncology Group isn't now going to come in to ET2 and say, "We need some more money to do all these trials." But if they came in with a strong application to do a specific study with, say, GM-CSF and whatever--

Broder: Why not? Good idea. Absolutely. Why not?

CL: They could get that funded?

Broder: Why not? Why not? Why not, indeed? That's the point I'm raising. Somebody has some new gene therapy they want to do or something. What people are saying is, "We can't send things to ET2, you know how difficult it is." But we've checked ET2, and at least what's in their portfolio now, people may be reacting to a previous era. I don't want to go through a Hatfield and McCoy type feuding that they have had, and I feel that that's a lot of times what we are doing. People are atavistically going back to a previous era and saying, "You know, I went through that." But that's a decade ago. And there might have been insensitivity. I don't even want to know what the issues were then. I only know what the issue is now, and that is that--and I don't want to overly focus on mechanisms, because mechanisms, administrative funding instruments don't cure cancer--but the bottom line is, for whatever reason, we use the RPG mechanism, proportionately, among the lowest of any of the categorical institutes. It's the mechanism that is the most secure and grows the best.

CL: I don't understand how it works. You have your own appropriation, your own amount of money. What difference does it make whether you review it with the study section you set up with the composition you want?

Broder: We have a designated amount for research project grants. When I show the budget tables there's a thing called "Research Project Grants." Then there are other things called "Other Research," other categories of research. For example, the cooperative group line appears a separate line. It is not part of the research project grants. The cancer centers appear as a separate line.

CL: It can't be called a research project grant if it's reviewed within NCI?

Broder: No, that's not the issue. It can't be called a research project grant if it's not a research project grant. A research project grant is an investigator initiated scholarly research effort.

CL: The issue seemed to me that, OK, it's not getting as high a priority score as it needs at DRG. If you had a committee that you controlled--

Broder: No, if you had a committee that only reviewed clinical investigation, then by definition it will have a percentile payline. That's what the normalization process is. That's why among the most important things to a discipline is to have its own study section. There's no way of getting around it. In that very fundamental way, research priorities have in effect been determined to a significant degree by the name, the quality, and the mission of a study section. OK? If you have your own study section that is supposed to cover clinical research, then when the payline is the 20th percentile, that same payline goes across all standing study sections. It will have to sweep across the clinical ones just as it does anything else, and they'll automatically get funded. No special privileges, no special earmarking, no nothing, it just happens. That's what we have not taken advantage of, in a certain sense.

I don't want to get everybody all offended and all revved up, but the things that we have called unique to the Cancer Institute, that we have used historically to define the character of the Cancer Institute, are the very things that have lost in constant dollars. I urge people to examine what the message is behind that. What we're saying is, these mechanisms are so important that we can't afford to let them fall and be strangled. Think about it.

CL: If the Heart & Lung Institute can get a phase 3 randomized trial funded through ET2, why can't the Cancer Institute?

Broder: Well, again, there are two different issues. One is what you call something, whether it's an R01 or not, and what I'm saying, is in a broad scope, we can call certain clinical trials R01s. We have to do it case by case. That's not the same thing as something going through its own study section. In a parallel way, I think we also have to send clinical research proposals to their own study section and we have to use that mechanism in a stronger way and find innovative ways to use R01s. There are certain things that cooperative groups are doing that can be redesignated as R01s, nevermind the mechanism of review, and within that, some of the things that a cooperative group is doing, or other clinical research that we are doing, can go to existing study sections. So they are parallel problems. There are two different issues.

CL: What sort of reaction do you think this is getting?

Broder: I think people are trying to be supportive, but I think sometimes we're caught in our own rhetoric and we feel that there are certain mechanisms that are unique to the Cancer Institute and are important. We have, by NIH standards, a very large cooperative group program, it's about $60 million, roughly, but it should

be about $90 million roughly.

CL: It was $50 million 10 years ago.

Broder: Right. We've lost ground on it. What people seem to have done is simply accepted that. Now some are going to come back and fly up into high dudgeon and say, "No, we didn't accept that, we fought that, we did this, we did that." We've done everything except be effective. We can't send the message that we love cooperative groups so much that we can afford to have them be strangled by one third of their value. What kind of message is that? By that token, we should use an inverse logic: we shouldn't love them so much and just give them more resources. What are the mechanisms that define NCI? They are centers, prevention and control, and cooperative groups, as a practical matter. Those have been the specific mechanisms that have fallen. I don't make those figures up.

CL: Let's talk about cancer centers.

Broder: I think centers are extremely important. I like centers. I think centers are a very flexible, important mechanism. I think we have to figure out and utilize some more innovative additions to the centers program. I think we need to use other mechanisms besides the P30 [centers core grant].

We will in the next fiscal year be using this P50 mechanism [Specialized Programs of Research Excellence] which I'm very excited about, because it will allow either existing or new centers to really evaluate their own individual strengths, and not necessarily attempt to be all things to all people. We can utilize each unique interest that a group can have, and do it in two ways. One is to encourage institutional commitments to some areas that have been very difficult for us. Breast cancer, prostate and lung cancer have been difficult areas for the Institute. So we need to figure out new ways of doing it.

In addition, we'll probably expand this concept to other things. For example, just off the top of my head, someday maybe we'll have brain tumor P50s, SPORE programs in brain tumors. I could easily see that a center might have a unique interaction between neurosurgeons, radiotherapists, and some molecular biologists, and so on, and might be good in doing research on brain tumors, but they're not a total center in the way we use the term. Why shouldn't they be able to put together a program, capitalize on their unique expertise?

CL: How does that differ from a program project [P01]?

Broder: It differs in several ways. One, there's an institutional commitment that is part of it. In other words, the institution really has to make strong efforts for recruiting staff, and use of space, and so on. Second, there are additional factors in this: a strong emphasis, not only on a core, but on developmental funds, on career development and training issues, which program project grants may have, but not in the depth that we're talking about. So this P50 mechanism as we intend to use it will be an amalgam of several different mechanisms, but heavy on developmental things and heavy on career development. In a certain sense it's a mixture between centers, program projects, R01s, and Ks [education/training grants], as we hope to use it. We hope it will be a way of getting around some of the impediments people have and will encourage them to take risks, intellectual risks, to get things done.

Each center that does this will obviously come in with its own research proposals, and probably will get some program project grants. If you want to look at it that way, it is a logical extension of the Organ Systems Program. For people who were afraid the Organ Systems Program was dead, I submit that it is not dead. It's in a form now that is effective, in my opinion. It is in a form now in which institutions are allowed to tap their own inherent genius and capabilities, but will also have a duty to other sister institutions and also to the total program. There will have to be a conference once a year for the SPOREs to get together. There is a duty in this SPORE program to at least in part serve as a resource to other institutions. For example, if you set up a tissue or serum bank or something, you will have to share that with other interested investigators, both within your own institution and outside. We hope to create national institutions that way, national referral centers.

CL: Is the SPORE going to have any relation to or impact on the core grant?

Broder: SPOREs will have their own core as part of it. However, we've constructed it so that a center that has a P30 can, if it so chooses, set up a chain of authority so the institution's PI for a P30, a center director, could run the new SPORE also. It doesn't have to be that way. An institution could decide it doesn't want to do it that way. We don't tell institutions what they can do. They could decide that they don't want the same PI to run both. But we've set it up so that they're welcome to do that. We're also permitting the institutions that aren't full centers to compete on a level playing field. The other advantage of a SPORE, which is not the primary reason for doing it, but is in my opinion not a trivial consideration, is that we will be allowing institutions that have, either directly or indirectly felt restrained as to the growth they can have, to have an opportunity to do some growing, but on a level playing field.

CL: Does that touch on this issue that, you have two centers that have huge core grants and other centers are down lower, and everyone else is at the bottom?

Broder: It's not completely removed from that. I'm not comfortable with the idea of putting caps on core grants. I'm not saying we won't do that someday. But I'm not comfortable with it, because, at one level it's anti-intellectual. If Institution X can cure cancer, then they ought to be able to make their best case and we should go with that. Not arbitrarily saying, "Well, you can cure

cancer, but I'm sorry, we have to cap you at $70 million, that's the way life is." I don't like that principle. I like the principle of people showing their best, doing their best demonstration possible of what their capabilities are, and getting a good review and getting funding on that basis.

If you look at the way the SPOREs are organized, they are for breast, prostate, and lung cancer. If a center cannot come in with good ideas for breast, prostate, and lung, and feels that's too limiting for an established center, then I'd like to talk to the center director. Those are pretty important diseases. If we don't make progress against breast, prostate, or lung, then we're not really going to make a lot of progress against our national cancer statistics.

I'm not satisfied with the level of progress that we've made in those diseases. I don't think anybody should be. People get very nervous when I do the cancer statistics, and I've learned that I've tapped into some deeply rooted feelings which I don't know exactly how to get around. The bottom line is we have some very courageous people in the National Cancer Program, very dedicated people, who are doing a heroic job, at both the basic research level and the clinical level, no question about it. But that doesn't absolve us of the duty to look at the statistics, and to understand what's going on with them.

By no definition can we say that we've made progress in breast, prostate, or lung. I'm sorry. That's the way it is. We have to accept that on a national level. I'm not talking about progress in the sense of new basic science observations, where we've made phenomenal progress. I'm not talking about progress in terms of certain types of innovative clinical trials, which are also asking interesting questions. We have to accept the principle that we can and should be judged by what's happening to the national public health statistics. A lot of people are very defensive about that. I think that's inappropriate. I think we need to take a look at it and understand what we need to do better. We may need to have better outreach activities, we may need to have better prevention and control activities, we may need to have better patient education activities, better training. There are a lot of different things that we can do. But we can't ignore the statistics.

The mortality statistics suggest that we really are not having an impact on breast cancer, from a mortality point of view. I don't think we can credibly sustain the argument that the incidence is going up, but the mortality is flat, and somehow, by a convoluted form of reasoning, that's a form of progress. I understand when people make that point, but that's just pure esoteric. The bottom line is the curve looks flat. Actually it's gone up 0.2 percent per year for much of the decade.

Prostate cancer is the same thing. I don't think any of us can be satisfied with the level of progress we are making. What we're doing is saying, the most common, the most frequent tumor in women, breast cancer, the most frequent major tumor in men, prostate cancer, and the most frequent tumor of both, lung cancer, is where we want to really encourage people to come in. If that isn't Organ Systems, at least in spirit, then what is? That's what we're trying to do. But we're trying to make it in a way that's meaningful, effective, and that can make an impact on people, and I'm optimistic.

CL: I think one of the reasons for some of the negative reaction when you talk about the statistics is that people feel that at least to some extent, it's really not within NCI's capability or mission, because the biggest impact probably is going to be made in the socioeconomic area and not in science.

Broder: I don't agree with that. I understand what you said, I agree that that may be a sentiment, but I don't agree with that. I think that our job is to cure cancer and not make excuses. The mission of the Cancer Institute is to prevent, diagnose, treat, and cure cancer. That's our job. I didn't say it's an easy job. I didn't say that we're going to do it overnight. I think it is going to require a long term commitment from the Congress and the public. If we don't acknowledge that it's our responsibility, then whose responsibility is it? I feel that the most effective and intellectually appropriate thing we can do is to accept the mission that we have, not claim it is easier than it is, be very careful about promissory notes that we can't deliver, and to be the first to identify problem areas.

CL: Identifying them is one thing, maybe even figuring out what ought to be done about it, but actually doing it, like changing the economic level, better education, upgrading the whole health care system. Now, where do you think NCI's responsibility lies?

Broder: I think NCI's primary responsibility is a scientific one. We have to generate the knowledge at both the basic science and the clinical level that is necessary for the society as whole to respond to the problem of cancer. If poverty is an important problem, which it is, then we should identify it. Poverty and its relationship to cancer is open to scientific discussion and scholarly interaction. The relationship between poverty and cancer is amenable to certain things, is amenable to innovative programs in prevention and control, is amenable to programs within the Div. of Cancer Etiology, is amenable to important innovations in cancer treatment.

It is far better for us to say that and to accept our responsibilities than to convey the impression that we are giving excuses. I think that comes off as being arrogant. I think it comes off as being detached, in a way that doesn't keep faith with the public. I think there's also the aspect of blaming the public, which is not intended but is received. We have to be careful about that. It is not our job to blame the public that supports the Institute. It's like going to a doctor and he

blames you. Well, at a certain point in time you may stop going to that doctor.

I think there's a certain amount of honest feedback that we need to give to the public. If we say that smoking is a problem, then we can't blame the public, we can't say something like, "If only people would stop smoking, we wouldn't have lung cancer." That's not an appropriate response for an agency that depends on the public and the trust of the public. Our response should be that, if we have adequate resources, we will stop smoking, we will develop innovative programs to assist people with stopping smoking. We can't give a variant of, "It's your fault." Which in fact I think people do without realizing it.

I would say that one of the most challenging things that I had to worry about was the level of concern that the Congress expressed in my appropriations hearings. They're asking very specific and appropriate questions, which they have every right to ask. We have to respond, not defensively. Not with a, "You don't understand how hard my job is" kind of thing. I think we have an obligation to describe the problem. By the same token, Congress has the standing to say, "Look, for the last 20 years, perhaps you've misled us." I'm not saying that's a valid thing. They've said, "We've heard about all sorts of breakthroughs coming through. How can you have breakthroughs if the incidence and death rate are going up?"

We need to make sure that when we issue a promissory note, it's redeemable. If the problem is very difficult, we say, "This is a difficult problem. We have to keep working on it." Both extremes are wrong: the extreme of not accepting responsibility, directly or indirectly, or the extreme of making a declaration of a problem solved when it isn't solved. I think that could be a very significant problem for us. As a community of scholars we have to be cautious that we do not create the impression that we give promises that can't be delivered.

I think I know as much about laboratory research as the average person. I've done some investigator initiated basic lab research in my time. I think it's important, the beauty of the things that we do in the laboratory is very strong, and people should have pride in their own sense about that, but we also have to be careful to express the limitations of basic research in terms of what we know as to practical application. I do get uncomfortable when people talk about the basic research advances having immediate applications. The basic research we do certainly will have applications across the whole waterfront, and they are important as a societal value in their own right. But we have to be very cautious when we say we've learned so much about this aspect or that aspect of the cancer cell, that's going to have an immediate impact. You have to be extremely cautious about that, unless we know.

That's been the philosophy that I think we've tried to do in the last two to three years. When you promise something, deliver. If you can't promise, warn people that you can't promise. I think the whole scientific community can do that. The public and Congress do understand that and might be more willing to actually work with us. If you think about it, both the progress that we make and areas where we're having difficulty both call for a redoubling of a commitment. Where we're making progress, we need to capitalize on that. Where we're not making progress, we need to make sure that resources are there to overcome the problems.

We have to be the first to identify problems, and that's why I've driven the SEER data people crazy. There was a time when I knew the SEER database better than most of the SEER people. Numbers fade quickly. It's important for every NCI director to know the statistics very well, and intimately.

CL: It seemed that every year survival was going up; it is now over 50 percent.

Broder: Yes, I think that's an important contribution. I think we've made progress. I don't think I've ever given a presentation that didn't focus on the areas of progress. I have given presentations where people at the end were shaking their heads about the areas where we're not making progress and somehow felt that I'd done them wrong.

CL: You mentioned you're involvement in lab research. When you took this job you were going to continue a little lab work in the AIDS area.

Broder: Boy, it's hard. It's hard.

CL: You haven't been able to do it.

Broder: I wouldn't say I haven't been able to do it, but it's hard. It's harder than I thought. Sometimes you can, some times of the year you can't. Realistically it's very difficult to do this job and expect that you will be able to maintain the kind of laboratory momentum that people normally associate. I'm not saying I'm completely out of it, but you need to recognize there are limitations to what you can do.

CL: Are you keeping up with what's going on in AIDS research?

Broder: I think so, I think I'm keeping up. But I think that the specific monitoring, the specific aspects of research that you need to do if you really want to have a high grade lab effort is very hard to do. I'm not saying it can't be done, but basically, I'm here till 8 o'clock every night, and, you know, there's not a lot of time left.

Next week: Broder discusses NCI's responsibilities for AIDS research, the Institute's special authorities under the National Cancer Act and the "chain of authority" within NIH, the importance of being "effective" in Washington, NCI's relationship with FDA, and personnel changes within NCI.

RFPs Available

Requests for proposals described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs, citing the RFP number, to the individual named, the Executive Plaza South room number shown, National Cancer Institute, Bethesda MD 20892. Proposals may be hand delivered to the Executive Plaza South Building, 6130 Executive Blvd., Rockville MD. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CM-27724-71

Title: Development and production of parenteral dosage forms for clinical studies

Deadline: Approximately Oct. 18

The primary objective of this project is to develop and produce pharmaceutically acceptable parenteral dosage forms of promising new agents with activity against cancer or the HIV virus. Certain agents selected by NCI's Div. of Cancer Treatment, Cancer and AIDS operating committees will be assigned for development and production as parenteral products (primarily sterile freeze dried products). Batch sizes will range from small developmental batches (less than 100) to intermediate size batches to be used in phase 1 and 2 trials; however, escalation to large batch size (10-30,000 or more) for phase 3/4 trials and Group C distribution is possible.

It is estimated that the successful offerors must be prepared to supply more than five hundred thousand parenteral dosage units each year. The capability to develop and manufacture other pharmaceutical dosage form (e.g., large volume parenterals, sterile emulsions, sterile micro-dispersions) is desirable but not essential.

Data obtained from the contract will: 1) be used to support IND applications submitted by NCI to FDA, 2) be provided to other NCI contractors engaged in manufacture and analytical evaluation of these dosage forms, and 3) be provided to physicians, pharmacists, nurses, and other medical personnel handling these products in a clinical setting. It is anticipated that an incrementally funded, cost plus fixed fee type contract will be awarded for five years beginning on or about March 15, 1992.

Contract specialist: Joseph Bowe
RCB Executive Plaza South Rm 603
301/496-8620

RFA Available

RFA CA-91-23

Title: Cancer center outreach education programs

Letter of Intent Receipt Date: Nov. 1

Application Receipt Date: Dec. 6

NCI invites grant applications for support of community outreach education programs from recipients of NCI center core grants (P30). It is anticipated that these education programs will result in increased community efforts related to cancer prevention, to expansion of programs for screening, to earlier detection of cancer, and to the systematic application of the best available methods for the treatment and care of cancer patients. The underserved, elderly, and minority populations must receive high priority in carrying out these objectives.

Only organizations that have a currently active Cancer Center Support Grant (P30) are eligible to apply for this grant since its primary purpose is to encourage cancer centers to expand their role in technology transfer by providing state of the art information about cancer prevention, detection, diagnosis, and treatment to community professionals and relevant community organizations.

Support will be through the NCI Cancer Education Grant mechanism (R25). For FY 1992, $1 million in total costs per year for three years will be committed. Awards will be limited to a maximum of $100,000 in direct costs plus 8 percent indirect costs, and only one award will be made to a given cancer center. Ten to 15 awards will be made. Project period may not exceed three years; earliest award date is July 1, 1992.

Reports have indicated that if state of the art approaches to the prevention, detection, diagnosis, treatment, and care of cancer patients used at major cancer centers were widely implemented at the local community level, there would be a significant reduction in cancer incidence, morbidity, and mortality. A key step in the dissemination of this knowledge is the establishment of educational programs that will transmit state of the art cancer information to community health professionals who are primarily responsible for providing the majority of cancer care. These educational programs must also include community leaders.

The NCI designated cancer centers are a logical location for these outreach education programs since an essential element of the cancer centers is their role as a focal point for clinical and research training and for continuing education programs designed for local and regional health care professionals.

These education programs must provide state of the art knowledge related to the prevention, screening, detection, diagnosis, and treatment of cancer to local and regional health care professionals, community leaders, and staff of relevant community organizations. Topics must be selected on the basis of their relevance to the day to day activities and problems of the community health care professionals and to the welfare of cancer patients and their families.

These outreach programs are intended to be of particular benefit to underserved communities and to groups with disproportionate cancer incidence and death rates (e.g., minorities, people over age 65). High priority local and regional needs for specific types of cancer education programs must be addressed by the proposed programs and described in the application.

The type of programs, their subject content and duration will depend upon local priorities, the availability of appropriate resources, and the nature of the target professional and lay populations to be addressed.

The application must describe examples of specific topics and approaches that might be included in the cancer education programs if an award were to be made. Emphasis must be given to outreach education topics that would have the greatest impact on reducing cancer incidence and mortality and on improving the quality of life of cancer patients in general.

An area of special interest to NCI, for example, would be educational programs designed to improve the quality of mammography and the accuracy of its interpretation. Other high priority topics include: improved procedures for prevention, detection, diagnosis, and treatment of cancer among elderly, ethnic, minority, low socioeconomic, and other underserved populations that have an elevated incidence of cancer.

The application must include a detailed budget describing and justifying each category of costs requested, and it must indicate the nature and extent of any institutional contribution to the activities supported by a grant awarded as a result of this RFA.

Inquiries may be directed to Dr. Robert Adams, Cancer Training Branch, NCI, Executive Plaza North Rm 232, Bethesda, MD 20892, phone 301/496-8580; fax 301/402-0181. Inquiries regarding grants management may be directed to Robert Hawkins, Grants Administration Branch, NCI, Executive Plaza South Rm 242, Bethesda, MD 20892, phone 301/496-7800.