LETTER INTERACTIVE

PO Box 9905 Washington DC 20016 Telephone 202-362-1809

Vol. 26 No. 34 Sept. 22, 2000

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CDC Contribution To National Dialogue Raises Questions About Ties With ACS

Earlier this summer, the Centers for Disease Control and Prevention contributed \$100,000 to the National Dialogue on Cancer, an effort by the American Cancer Society to develop an overarching national cancer agenda.

How can a government agency give money to a group that has no legal identity? CDC solved this problem by adding the funds to its ongoing sole-source cooperative agreement with the gigantic non-profit.

As a result, the agency may have violated ethics regulations that prohibit the use of federal funds for lobbying the government, called attention to its close political and financial ties with the Society, and invited scrutiny of the complex structure of the Dialogue and its spin-off, the (Continued to page 2)

In Brief:

Six Scientists Win Lasker Awards; UCLA Opens **Liver Cancer Center; Foundation Honors Murphy**

ALBERT LASKER Medical Research Awards were presented to six scientists for their discoveries. The Lasker Award for Basic Medical Research is shared by Aaron Ciechanover and Avram Hershko of the Technion-Israel Institute of Technology and Alexander Varshavsky of the California Institute of Technology for the discovery and the recognition of the broad significance of the ubiquitin system of regulated protein degradation, a fundamental process that influences vital cellular events, including the cell cycle, malignant transformation, and responses to inflammation and immunity. The Lasker Award for Clinical Medical Research is shared by **Harvey Alter** and **Michael Houghton** for pioneering work leading to the discovery of the virus that causes hepatitis C and the development of screening methods that reduced the risk of blood transfusion-associated hepatitis in the U.S. from 30 percent in 1970 to virtually zero in 2000. The Lasker Award for Special Achievement in Medical Science honors Sydney Brenner of the Molecular Sciences Institute for his work in genetics. . . . JONSSON CANCER CENTER at the University of California, Los Angeles, has opened a liver cancer center. The Dumont-UCLA Liver Cancer Center was made possible through a \$2 million gift from the Dumont Foundation and will conduct basic research and coordinate multidisciplinary treatment. Ronald Busuttil, a surgeon and director of UCLA's liver transplant program, directs the liver cancer center. . . . **DAVID WATERS** was appointed executive director of the Gerald P. Murphy Cancer Foundation (formerly Pacific Northwest Cancer (Continued to page 8)

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CDC Gives \$100,000 To ACS Through A Sole-Source Grant

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National Cancer Legislation Advisory Committee.

The cancer legislation committee is preparing a white paper for the rewriting of the National Cancer Act of 1971. The Dialogue, which was founded two years ago, has about 125 members, who meet to discuss a variety of problems related to cancer.

Documents obtained by **The Cancer Letter** indicate that CDC's contribution pays for Dialogue members' travel to meetings, the organization's phone calls, fees for meeting rooms, and hiring a consultant.

Legal and public health experts raised questions about the propriety of the \$750,000 sole-source cooperative agreement which CDC has increased by \$100,000 to contribute to the Dialogue. Public health experts said projects described in the agreement could have been performed by institutions other than ACS. Attorneys said that the text of the cooperative agreement does not make a strong case for excluding competing bids, therefore creating at least an appearance of patronage.

"As a former prosecutor, I see behavior that makes me pause to wonder why this process was conducted in this manner," said Houston attorney Michael Clark, former chief of the Criminal Division, U.S. Attorney's Office for the Southern District of Texas.



Member, Newsletter and Electronic Publishers Association

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Founded Dec. 21, 1973, by Jerry D. Boyd

The propriety of the CDC contribution to the Dialogue would depend on the ability of the Dialogue leadership to defend their position that the organization does no lobbying and is separate from the legislation committee, observers say.

Though ACS officials state emphatically that the Dialogue is separate from the legislation committee, skeptics point out that: (1) Both entities are funded by ACS; (2) No apparent procedure was followed in forming the legislation committee and naming its leaders; (3) The legislation committee is co-chaired by John Seffrin, the ACS chief executive.

"Is there an actual separation or not?" asks Clark. "There is at least an appearance of impropriety when you have the same individuals wearing several hats that are supposed to be kept separate. How do you have a firewall when you have the same individuals wearing different hats? Human nature being what it is, you cannot divorce yourself from your various interests."

If the alleged firewall separating the Dialogue from the legislation committee fails to withstand scrutiny, it would follow that CDC may have contributed to the effort to write a more prominent role for itself in the new National Cancer Act, legal experts said.

If the firewall withstands scrutiny, CDC would not necessarily be out of the woods. It may have to answer for having contributed public funds to the Dialogue, a group that has a restricted membership and meets behind closed doors. According to Dialogue documents, "all Collaborating Partners are seated at the invitation of President and Mrs. George Bush after consulting with the Vice Chair and the NDC Steering Committee." The Bushes are the group's chairmen, and Sen. Dianne Feinstein (D-CA) is the vice chairman.

ACS officials say the Dialogue and the legislation committee are separate.

"The legislative group has nothing to do with the Dialogue," said Greg Donaldson, ACS national vice president for communications. "They are staffed by separate groups of people. They are funded in separate ways, separate revenue streams. There is absolutely no way to commingle them operationally, funding-wise, or in any other way, and to imply or insinuate that they are even related would impugn the integrity of the American Cancer Society and is absurd."

Closed doors are a serious problem, said Peter Eisner, managing director of The Center for Public



Integrity, a Washington-based non-partisan watchdog group. Since the cancer legislation committee has no charter and is not funded by the government, it's exempt from post-Watergate laws that mandate openness.

"It's never appropriate for anything this important—or any government decisions—to be made behind closed doors," Eisner said to **The Cancer Letter.** "Even if it's legally acceptable to do so, it's not ethically acceptable to do so.

"The overriding consideration is that with everything in cancer research, you have to look at the stakes, and the stakes are always that there are millions of people who are standing by every year, suffering and waiting for potential relief," Eisner said. "They can't wait around for short-term bureaucratic or business arrangements being made behind closed doors."

The Hats: Society, Dialogue, Committee

ACS officials acknowledge that the cancer legislation committee is a spin-off of the Dialogue.

Though the Society claims that the two entities are separate, they are not kept in complete isolation from each other. The legislation committee produced the first version of its white paper after surveying the Dialogue members, known in ACS parlance as "Collaborating Partners." At a Dialogue meeting last spring, the partners were asked to comment on the draft.

Moreover, the partners would be expected to advocate for legislation that may arise from the white paper. "It [will be] up to our advocacy groups, the Dialogue, to convince our Congressmen and our new President that [passing the cancer legislation] is the right thing to do," said Vincent DeVita, former NCI Director and co-chairman of the legislation committee.

DeVita spoke before the National Cancer Advisory Board on Sept. 12.

Attorney Clark said he is surprised to encounter an ambiguous structure in a project run by an established organization like ACS. "You would expect that they would have had somebody set this up in such a manner that it wouldn't be questioned," Clark said. "I am sure they must have law firms they seek advice from. This makes you wonder: Has somebody dropped the ball?"

A Washington attorney who specializes in biomedical issues said ambiguity is dangerous in situations that involve lobbying or appearances of lobbying. "Everybody who advises clients in this area advises them to be really, really cautious, to be sure that you don't cross any line," the attorney said. "And it's not clear that ACS officials are exhibiting the caution necessary to protect themselves. They just seem to be going along, doing what they want to do, without recognition that there is a legal framework within which they have to operate.

"This is dangerous for everyone concerned."

The Sole Source Agreement

The cooperative agreement between ACS and CDC argues that the Society is uniquely qualified to perform the work..

"Assistance will be provided only to the American Cancer Society," the agreement states. "No other applications are solicited." According to the agreement, ACS is "uniquely qualified to conduct information and education development and dissemination activities."

The agreement lists three unique characteristics:

- —ACS is the only U.S. grassroots voluntary organization working to prevent and control cancer through research, education, detection, prevention, treatment and control.
- —It has access to "research, prevention, education and treatment programs and to the populations they serve".
- —It has "collaborative relationships with a broad range of national, state, and community-based public, private and not-for-profit organizations to disseminate information related to all aspects of cancer prevention and control; coordinate access to information and services for cancer patients, their families and others; and provide guidance and consultation at the national, state and community level for a coordinated and comprehensive system of cancer activities.

"Therefore, the American Cancer Society is the only organization that can perform these activities," the agreement states.

Experts who reviewed the documents said that all the individual projects described in the agreement could have been carried out by other organizations.

"It is puzzling why CDC would award this as a sole source contract," said a public health expert who regularly takes part in review of cancer prevention and control grants. "There is nothing in the statement of work that indicates why these tasks can only be done by ACS. Indeed, it is questionable whether ACS even has the capacity to perform some of this work with any degree of competence."



Lawyers, too, said that justification for exclusivity seemed insufficient. "In this proposal, I read, 'Assistance will be provided only to the American Cancer Society. No other applications are solicited.' I find that remarkable," said Clark, who specializes in healthcare law.

"What I would expect at a minimum would be more than a conclusory statement," Clark said. "You would at least expect some dialogue to be in there that we have considered other groups and find that they would not be in a position to accomplish the missions for the following reasons...

"As it stands, this agreement spells out a preselection of who is going to get grant funds, and with it, the implication, right or wrong, that there is patronage, and that there is a potential quid pro quo."

The use of sole-source arrangements varies from agency to agency. At NCI, such arrangements are uncommon, sources said.

Projects described in the CDC-ACS cooperative agreement are anything but specialized, agreed a Washington attorney who examined the documents. "To suggest that ACS is the only entity that can do this is naïve," he said. "It's certainly worthwhile to examine what CDC is doing and why are they doing it."

Since the agreement is in its fourth year, it has paid out close to \$3 million. The agreement continues through the spring of 2003.

"It is impossible for CDC grant monies to ACS to be used for anything other than the designated purposes," said ACS spokesman Donaldson. "Every CDC grant that comes to ACS is assigned an account number within the Society. In fact, the amazing thing is that CDC will not reimburse the Society for any grant monies used until we submit a verifiable report documenting how the monies were used, so that the uses of the monies in question accrue to the purpose for which they are intended.

"Additionally, we have an annual audit specifically of our government grants," Donaldson said. "Beyond that, we have a full-time financial staffer whose sole job is to track the CDC grant, to make sure that expenses accrue specifically for the purposes for which the monies were received."

A Persistent Advocate For CDC

ACS has been a persistent advocate for CDC, its Atlanta neighbor. Last year, the Society unsuccessfully sought a \$235 million, 61-percent, increase for the CDC cancer programs.

Recommendations recently presented behind closed doors at the cancer legislation committee's roundtable on cancer prevention and control included proposals that would dramatically upgrade CDC's role in the National Cancer Program.

Though it is too early to say what the final recommendations would be, the list presented to the panel included the following:

- —Provide the CDC with authority to give grants for studying prevention and medical and behavioral interventions,
- —Expand the CDC Network of Prevention Research Centers,
- —Assist states in developing comprehensive cancer prevention, control, and surveillance plans through the CDC National Comprehensive Cancer Control Program,
- —Expand CDC and other federal agencies' antismoking funding, and work with state legislatures, governors and state attorneys-general on model use of tobacco settlement money to fund anti-smoking and cancer prevention strategies,
- —Expand the CDC Breast and Cervical Cancer Program to provide screening and diagnosis to underserved populations and provide federal qualification for Medicaid at an enhanced matching rate and work with states to link cancer diagnosis with Medicaid or other insurance programs to cover the cost of treatment for individuals diagnosed with cancer under the CDC program.

Ironically, the quality of at least a portion of the work performed by ACS under the CDC cooperative agreement is unlikely to be held up as an example of scientific rigor.

The cooperative agreement gives ACS \$300,000 for development of "coordinated school health programs," including development of information campaigns.

Experts who were asked by **The Cancer Letter** to review the Society's "deliverable" report to CDC said the health campaign project ignored the substantial knowledge base on design and assessment of the effectiveness of health messages. The increasingly accepted concept of evidence-based interventions was simply ignored.

In the report to CDC, the Society describes the project as an experiment in development of health messages on the grassroots level. "In order to fully understand the current capacity and future potential which exists in ACS Divisions, the National Home Office believed it to be essential for each Division to



'try their hand' at all phases of local campaign development," the report states.

The divisions composed the following slogans and tested them in electronic and print media:

- —"What They Don't Know Can Hurt Them."
- —"It's a Jungle Out There."
- —"Healthy Kids Make Better Students."
- —"A Healthy Child Learns, Achieves and Conquers!"
 - —"Healthy Kids... How Sweet the Sound."
- —"H.O.P.E.," which stands for "<u>H</u>ealth, <u>O</u>utreach, <u>Prayer and E</u>ducation."

The Society declared the project a success:

"We are more certain than ever that involvement in this and future cooperative agreements... has offered and will continue to offer rich opportunities for growth that are vital not only to the ever-changing culture of the American Cancer Society, but to school health overall," the report states.

Experts said the slogan project would have been unlikely to survive even the least rigorous peer review. "There is a whole discipline of developing messages that was simply ignored here," said one expert. "It's like they don't appreciate that the discipline exists! I can't even tell what their target populations are. I assume they sort of wanted to reach Americans. It's the definition of ignorance. They don't know what they don't know."

Has the public benefited from this use of tax dollars?

Consider the experience of the ACS Mid-Atlantic Division, which composed and tested "It's a Jungle Out There." A brochure was mailed to 10,500 households, and a radio spot was aired 105 times on two local stations. Public funds paid for 70 radio spots; the remaining 35 were aired free of charge.

"ACS now has an active role in school health councils," the division concludes. "The Norfolk, [VA], ACS office received 59 calls from persons expressing an interest in school health, with 15 actively wanting to volunteer in some capacity. Additionally, 166 persons answered 'yes' in response to a post-campaign survey question about requesting more information about school health."

Is this a triumph?

"They spent all this money on brochures and radio spots, and all they have is evidence that they got 59 people to call and say, 'I support school health education,' only 15 of whom might want to volunteer," said a public health expert. "If you spend all that money on a public health ad campaign, you have to have an

evaluation component, and the proper way to do an evaluation is with a large survey.

"This is not research. This is amateurish."

"National Cancer Authority" and "National Cancer Control Act"

Skeptical observers marvel at how much the cancer legislation committee co-chairmen DeVita and Seffrin knew about the features of the potential legislation before the legislation advisory committee held its first meeting.

In his address to the President's Cancer Panel last December, Seffrin made repeated referred to the "National Cancer Control Act." (**The Cancer Letter**, Jan. 21). Thus, before the committee decided whether a new law was needed, the chief executive of the organization that bankrolls the committee happened to know the title of the new cancer act.

"The issue has come up of establishing a National Cancer Authority of some sort," DeVita, former NCI Director who now heads the Yale Cancer Center, said in an interview published in the Feb. 4 issue of Yale Bulletin and Calendar. "For example, the Centers for Disease Control would handle a lot of the cancer control part of the cancer plan.

"You could see a scenario where the CDC could receive a great deal of money and let the states apply for grants to support cancer control programs. If this turned out to be \$400 million a year, it wouldn't go into the NCI at all. It would go into the CDC.

"So, the NCI wouldn't be thrown out of balance with the other components of the NIH. If you created some sort of a national fund for support of clinical trials, which is desperately needed, and you funded it outside of the NCI, then that money wouldn't go into the NIH budget either.

"That would take some of the anxiety away that people usually have about putting a lot of money into one basket. We're starting to hear that.

"One of the criticisms came at the peak of funding for the original Cancer Act. The NCI was 33% of the NIH budget. There were 14 institutes at NIH. There was this concern that if you add a lot of money you upset the balance of a very delicate kind of institution.

"If you had a National Cancer Authority, then you would be able to distribute the funds to places other than the NIH."

Asked by an interviewer to describe the potential downside of creating a National Cancer Authority, DeVita came to the defense of the Authority.

"There are all the old images of someone telling



everyone what to do," he said. "The worry is that if you create this kind of a National Cancer Authority, that you come into your office in the morning and you wait for the telephone to ring, and it does, and it's the head of the National Cancer Authority who says, 'Dr. DeVita, today I'd like you to do the following things.'

"That, of course, is an illusion," DeVita pledged. "It can't happen. It wouldn't happen."

In a recent presentation to NCAB, DeVita said NCI needn't fear efforts to put more money into cancer control. "One of the things that came up very early was the fear that comments I made, like that the CDC needs to have additional support, meant that what we would do might drain money away from the research programs, especially those at NCI," he said.

"Nothing could be further from the truth, in terms of our intentions, obviously."

In his NCAB appearance, DeVita said that he has had complete independence from ACS.

"I was asked to co-chair, and from my point of view, my co-chairing meant that I could do whatever the hell I please, and the American Cancer Society did not tell me what to do," he said. "They have been very good about that. We have picked the members of the committee. We have not really had any conflicts amongst ourselves. I have not been told to do anything specific that would favor the American Cancer Society."

If one were to accept DeVita's assurances that he has not been influenced by ACS, his co-chairman Seffrin, the Society's CEO, would have a more difficult time supporting such a claim.

"[Seffrin] doesn't hold any office with the National Dialogue, and I understand he has a role in the [legislation] advisory group," said Donaldson. "The American Cancer Society obviously has an interest in cancer policy matters. The American Cancer Society has an interest in the Dialogue. That's no secret. They are two entirely different projects that address two entirely different sets of issues."

Genesis: Version 1 vs. Version 2

The idea that the DeVita-Seffrin committee is developing proposals that are widely expected to boost the significance of CDC does not play well at NCI, the agency currently in control of the National Cancer Program.

On Sept. 12, when DeVita appeared before the NCAB, the board of advisors to the Institute Director, the tone of the discussion was less than collegial.

"Recently [DeVita] has been co-chair of a group called NCLAC that was asked to be brought into existence, I believe, by Senator Feinstein," said NCI Director Richard Klausner as DeVita stood at the lectern. "He has come to give us an update on what they are doing and where they are going."

The caveat "I believe" suggested that there is more than one version of the committee's genesis. The first, official version advanced by ACS, holds that the committee was founded at Feinstein's initiative, and that it was Feinstein who chose its two cochairmen and asked them to appoint the rest of the committee.

An alternative version holds that the committee was created as part of a plan by ACS to change the National Cancer Act by writing in a more prominent role for itself and CDC. Though ACS acknowledges that the legislation committee is a spin-off of the Dialogue, the Dialogue's Collaborating Partners and its governing steering committee were never consulted about the formation of the legislation committee and the appointment of DeVita and ACS chief executive John Seffrin as committee co-chairs (**The Cancer Letter**, Jan. 21).

After Klausner's loaded introduction, DeVita returned fire:

"One of the marks I left [at NCI] was my initials carved on the corner of the desk," he said to Klausner. "Are they still there?"

"I seem to trip on it," Klausner shot back.

The exchange was anything but friendly verbal horseplay. Both men seemed to be having so much difficulty controlling their hostility toward each other that at one point in the debate, DeVita said that 48-year-old Klausner is too young to be able to put the National Cancer Act of 1971 in proper historical perspective.

"You have to keep in mind, Rick, that you were probably in knee pants when the Cancer Act was passed," said 65-year-old DeVita, who ran the Institute between 1980 and 1988.

"Vince, I am still in knee pants," Klausner retorted. "That's one of my goals in life."

Personal digs notwithstanding, the disagreement between Klausner and DeVita boils down to a fundamental issue of science and policy: Has science reached the point where the emphasis of the cancer program can be shifted, at least partially, from research to public health? Klausner says No; DeVita says Yes.

The new version of the Cancer Act is needed because science has reached "critical mass" by creating



an "embarrassment of riches" of knowledge that needs to be further developed and applied, DeVita said.

Modern-Day Yarborough Commission?

In his NCAB presentation, DeVita made persistent references to his committee as the modern-day equivalent of the Panel of Consultants to the Senate Labor and Public Welfare Committee. Established in 1970 by Sen. Ralph Yarborough (R-TX) and chaired by the financier Benno Schmidt, the panel framed the National Cancer Act.

"The closest analogy to NCLAC is that you would look at it as the modern-day Yarborough commission," DeVita said. Describing his committee's mandate, he said, "We are commissioned by the Congress to do this."

Unlike the DeVita-Seffrin committee, the Yarborough panel was formed as a result of a Senate resolution. The panel was funded with public money and staffed by government employees. The DeVita-Seffrin committee is funded by ACS and is advisory to Sen. Feinstein.

"It seems that a hidden-away little offshoot of a committee shouldn't be allowed to make major changes without Congressional leadership weighing in," said Eisner, of The Center for Public Integrity. "The greatest thing I am concerned about is all the elements of a closed-door operation, with ego taking the place of prudent policy considerations."

Though the cancer legislation committee meets behind closed doors, in his remarks at NCAB, DeVita attempted to create an illusion of sunshine.

Describing a series of workshops sponsored by the committee, DeVita appeared to invite everyone to attend.

"By the way, you are all welcome to attend these workshops," he said. "They are not closed. The more the merrier. We are trying to at least have people have the opportunity to give some off-the-top-of-their-heads kind of thoughts about what would you do in the ideal world."

Are the workshops indeed open?

That appears to depend on your definition of "open."

"They are open to the people who can contribute to the discussion," said Rebecca Kirch, project director for the committee.

Similarly, at NCAB, DeVita implied that the materials generated by his committee are openly available.

"There is a web site posted on

CancerSource.com, by a member of the committee, so you could get access to the information," he said.

That is correct, sort of. All you need is a password.

Keeping the doors closed at the committeesponsored workshops makes the process operate smoothly, Kirsh said.

- —**Discussion Remains Focused.** "What we are trying to do is keep the dynamic of the group to a manageable number," Kirsh said. "We are trying to assemble a group of 15 experts who perhaps wear different hats and may represent a bunch of different groups at the same time. For example, [committee member] Amy Langer, in addition to being at [National Alliance of Breast Cancer Organizations] is also a cancer survivor. So we have the patient element."
- —**People say what they really think.** "The point is to pull in these people and come in with a broad base of information, but also expert information that they can present in a small group, where people can be frank, and say, `Here is what it's really like, and here are the solutions I thought of, or policies that I think may accelerate our progress. So that's the dynamic we want to keep, so people feel open to talk," Kirsh said.
- —**Distractions are avoided.** "It's like a dinner party," Kirsh said. "You don't want to invite too many, or nobody can talk. Nothing gets done if the group gets too large... We don't want to get this town meeting atmosphere, where there are so many distractions that they can't get down to the work at hand."

The time for openness will come, Kirsh promised.

"Once we get the stuff so it's in a usable form, then we are going to have as many people as are willing to take a look at what the policy paper recommendations are evolving into, and then we will continue working on them, based on the comments we get back," she said.

The white paper will be posted on CancerSource.com, Kirsh said.

Will there be a password-protected section as well?

"It's not decided," said Kirsh. "I will have to talk with Drs. DeVita and Seffrin."

DeVita is chairman of the medical advisory board of CancerSource.com., a web site launched by Jones & Bartlett, a Sudbury, MA, company that publishes the American Cancer Society's Consumers Guide to Cancer Drugs, which is a part of the site's editorial



content.

Altogether, three members of the DeVita-Seffrin committee serve on the CancerSource.com medical advisory board, as does LaSalle Leffall, chairman of the Dialogue Steering Committee. Kirsh said CancerSource.com is not paid for designing and maintaining the legislation committee's web site.

The fact that the materials from the cancer legislation committee will appear on the web site with which DeVita is connected is potentially troubling, said Eisner. "If it's determined that DeVita is privately developing his business goals in a publicly-funded forum, I would be very concerned," he said.

How Much Support?

DeVita said cancer research and cancer care are popular issues in Congress, and the level of support for the new Cancer Act would be high.

"I don't want to predict, but I think the political climate is pretty good," said DeVita. "I don't sense either party being opposed to doing something like this. So I don't think we are fighting one political party or another. I think Rick [Klausner] is in very good standing in the Senate."

DeVita said his sense of the level of support was based on information from "two ex-officio [NCLAC] members from Sen. Connie Mack's staff and Sen. Feinstein's staff."

"They have gone around and looked at the level of support they see from members of Congress," DeVita said. "I think it will come as no surprise to you that there is a great deal of support in Congress for the whole issue of supporting cancer research, cancer care, and translational research in the cancer area.

"We have a lot of friends in Congress," DeVita continued. "And I think they need an instrument that they can comfortably put forward,"

The Cancer Letter obtained the minutes of five meetings of the legislation advisory committee. These documents show that all the meetings were attended by two members of Feinstein's staff. Mack's senior policy advisor Mark Smith stopped showing up after the first two meetings, documents show.

At the first meeting, on Feb. 8, Smith said Mack (R-FL) preferred a step-by-step, as opposed to a global, approach to cancer policy. The minutes state: "Mark Smith, legislative assistant [sic.] to Sen. Connie Mack, indicated that Sen. Mack is deeply committed to improving cancer research and policy, but believes the most effective strategy at this point is to move

forward with incremental steps that have broad-based support."

The minutes also reflect Smith's advice that the committee should not rush into proposing broad, overarching social legislation. According to the minutes, "Smith concluded his comments by noting that NCLAC should take the time it needs to deliver a quality product that answers the tough questions about what is appropriate and practical for national legislation."

Smith didn't show up for the committee's third, fourth and fifth meetings. At about the same time, NCI stopped attending the meetings of the National Dialogue on Cancer.

Minutes demonstrate that the committee is something of a work in progress. Recruitment of members continued through the most recent meeting on June 28. "Dr. Seffrin indicated that since the April meeting, the committee has considered adding three new members in order to broaden representation from the cancer community and to maximize face validity of NCLAC. With this final round of additions, he said, virtually all of the major cancer constituencies are represented," the minutes said.

The support of patient advocacy groups would be crucial for the committee's work to "maximize face validity." Yet, minutes show that the most prominent patient advocate on the panel, Nancy Brinker, the founder of the Susan G. Komen Foundation, did not attend any of the meetings. Patient groups represented include the National Alliance of Breast Cancer Organizations, the Pancreatic Cancer Action Network and the Kidney Cancer Association.

Prominently absent are the National Breast Cancer Coalition, the National Coalition for Cancer Survivorship, and the National Prostate Cancer Coalition. Many of the patient groups critical of the National Dialogue on Cancer are opposed to being amalgamated into complex, overarching political structures and express skepticism about the ability of ACS to set its institutional interests aside (**The Cancer Letter**, Jan 21).

What Do We Know?

Addressing NCAB, DeVita painted a rosy picture of the state of cancer research.

"I think it's an appropriate time for us to be going to the next level of the National Cancer Program," he said. "I personally believe that we are at critical mass. We will be astonished at what's going to happen in the cancer area.



"Diseases that we thought were totally intractable are going to become treatable. They are going to become treatable easily.

"We are learning how to prevent diseases. We are only resources away from making it happen soon. It's going to happen. What we would hope to do would be to be able to provide resources at a nationwide level to make it happen sooner.

"It's already unstoppable, quite frankly," DeVita said.

Much of DeVita's optimism is based on the work of Brian Druker, an associate professor at Oregon Health Science University, who is developing an agent called STI-571 for CML. "We have a specific target and a specific compound," DeVita said. "It's just embarrassment of riches for us to be very proud of."

Pride and optimism notwithstanding, do Druker's early stage findings, as well as similar efforts by other scientists warrant new legislation restructuring the National Cancer Act?

"I am wondering if you could explain why you think we have [reached] that critical mass," said Klausner. "I am not sure what you mean."

DEVITA: "I think that information on controlled cell division and the molecular control of cells to me are major steps in the direction of ways of controlling cancer. If you look at treatment of metastatic cancer with drugs, a major roadblock to going from 20-percent cure rate to 100-percent cure rate has been the ability to understand drug resistance.

"I think for the first time we are not aiming at targets that we don't even know. We are aiming at specific targets that have a very good chance of payoffs. I think, personally, that with sequencing of the genome, with the DNA micro-arrays and tissue arrays; tools like that, we are going to be able to find the genes responsible for making the current therapies less effective than they are, and you are going to see a paradigm shift. If you accept the fact that we might wind up doubling the cure rates with existing tools as a result of this as critical mass, that's what I mean by critical mass.

KLAUSNER: "As a proponent of all the..."

DEVITA: "You have to keep in mind, Rick, that you were probably in knee pants when the cancer act was passed. We were shooting in the dark."

KLAUSNER: "Vince, I am still in knee pants. That's one of my goals in life.

"The issue with this paradigm shift, just to put it in historic perspective, you know, we often at each time think we are at a paradigm shift, we've reached the critical mass. My own strong feeling as one of the pushers of the paradigm shift is that we are not at that critical mass. Yes, we know how to speak about the language of our genes, but there is so much more about targets we need to know. I do want to discern that as we build this, whether there are real inflection points of the profound change when we know enough and now it's just application... I think we should carry on.

DEVITA: "I will give you an answer. First of all, we have cured many diseases, including many cancers, without knowing what caused them or anything about their biology.

"If the definition of critical mass is you have to know everything about cancer before you can cure it, I don't buy into that definition.

"I think you were talking about targets that you will have to identify. You are measuring things you don't even know exist, and it's still going to be useful. You will eventually find out what they are. I think we can be at a critical mass.

"The difference between now and 20 years ago, in terms of specific targets can be highlighted by Brian Druker. It's a proof of principle. If you have a specific target as the cause of the disease, and you can aim a drug at it, you can control the disease. That to me is a huge difference from what we had before.

"We were just basically shooting at DNA, and saying that if we damage DNA, it would be okay."

KLAUSNER: "I don't think we should give anyone, the public or Congress, the sense that we did what we needed to do in basic research, and now it's just a question of application."

DEVITA: "I get your point. People said that about the mortality rates declines as well."

LARRY NORTON [Member of NCAB and breast cancer specialist at Memorial Sloan-Kettering Cancer Center]: "You are both right, of course. In studying history of science, there is in most periods a discrepancy between the definition of problems and the availability of interventions. And usually you get slow, progressive change, either in the area of better definitions, or interventions in search of a target.

"Decades are spent for that. What makes this [time] unique in biology, is the availability both of improved methods of characterization in biology and improved methods of intervention.

"That really is a special confluence. In history of science, that's where you get paradigm shifts. I would side with those who say this really is a critical moment.



"Not to slow down, obviously, but to run harder than ever."

KLAUSNER: "That's my point. There is a lot more to do."

DEVITA [interrupts]: "Can I respond to that, Rick? I think the fear is that if you say that, then there is no need to put more money into basic research. That's an old argument. There is some merit to it.

"When I first became Director, we used to report the annual statistic: we had one line for mortality and one line for incidence. And mortality was going up and incidence was going up. And we changed that to reporting by individual disease.

"The big argument that went on at that time was when you show that the news is bad, Congress will keep giving you money. My argument was that if you show that it's a mixture of bad news and good news, then you will get more money because you are making progress.

"I think it's a delicate balance between saying we are all there already, which is not what I said, and that you invested in something that paid off handsomely. Keep it coming. Now the American people deserve to get the payoff for what they invested in.

"They put \$40 billion into this, and they deserve it."

Applying What We Know?

Harold Freeman, chairman of the President's Cancer Panel, head of the newly formed NCI Center to Reduce Cancer Health Disparities, a member of the ACS board, and a participant in the Dialogue, suggested a different way of asking the question.

"I don't think the question is, 'Are we at the high point?" said Freeman. "Like Larry says, we have been at the high point many times. I suspect, 10 years from now we will be at a different high point, and we will look back on 2000 and say we were pretty primitive. The question to me is, 'Are we applying all we know to the American public in an appropriate manner, at whatever point we are?"

"The answer is 'No,'" said DeVita. "And that's an emphatic 'No.' And that's not necessarily the mission of the Cancer Institute. I can tell you that what I had and what Rick has basically is a bully pulpit, and it works to some degree, but it's not the most effective way of doing it.

"What is the most effective way? I haven't the foggiest notion at the moment. Maybe it will spring eternal from the reports, but I don't know that."

Funding Opportunities

Program Announcements:

PA 00-127: Quality of Life for Individuals at the End-of-Life

The National Institute of Nursing Research and 6 other ICs seek research grant applications that include basic, clinical or care delivery studies focused on management of physical and psychological symptoms, patient-provider and patient-family communication, ethics and clinical decision-making, caregiver support, or the context of care delivery for those facing lifelimiting illnesses. In a broad sense the purpose of this program announcement is to enhance the quality of life remaining for individuals who are nearing the end of their lives. The PA will use the NIH research project grant R01 award mechanism.

Inquiries: For NCI—Claudette Varricchio, Division of Cancer Prevention, NCI, 6130 Executive Boulevard, EPN 300, Bethesda, MD 20892, 301-496-8541; fax 301-496-8667; e-mail varricce@mail.nih.gov

PA-00-131: NIH National Research Service Awards for Senior Fellows F33

NIH awards NRSA senior fellowships to experienced scientists to make major changes in the direction of their research careers or to broaden their scientific background by acquiring new research capabilities. The awards, whose mechanism of support is the Senior Fellowship Award F33, will enable individuals with at least seven years of research experience beyond the doctorate, and who have progressed to the stage of independent investigator, to take time from regular professional responsibilities for the purpose of receiving training to increase their scientific capabilities. In most cases, this award is used to support sabbatical experiences for established independent scientists.

Inquiries: For NCI— Lisa Begg, NCI, phone 301-496-8580; e-mail beggl@mail.nih.gov

RFP Available

RFP N02-CM-17001-28: Collection, Storage, Advertisement and Distribution of Biological Response Modifiers

Proposals Due Date: Nov 1, 2000

Biological Resources Branch of NCI is soliciting sources capable to support its effort in providing high quality biological response modifiers and biological standards to qualified investigators for preclinical and laboratory studies. The contractor would provide the facilities and personnel to operate a computerized inventory system and repository for the acquisition, receipt, storage and distribution of biological reagents, standards and tumor cell lines. A single-cost reimbursement term type contract award will be made for a five-year period of performance with incremental



funding each year.

Inquiries: Carolyn Barker, contracting officer, phone 301-496-8620; fax 301-402-6699; e-mail cb123d@nih.gov; Web site http://www.amb.nci.nih.gov

Other Funding Notices

NCI invites physicians providing alternative medical treatments to patients with cancer to submit data from their best cases for review by conventional research and alternative medicine experts. Successful approaches can receive financial support and recommendations for further research, visibility among the clinical research community and feedback on the strengths and limitations of the approach.

Inquiries: Office of Cancer Complementary and Alternative Medicine, NCI, EPN/Suite 102, Bethesda, MD 20892; phone 301-435-7980; fax 301-480-7980; e-mail ncioccam-r@mail.nih.gov; Web site http://occam.nci.nih.gov and click on Best Case Series Program.

NCI Funding Opportunities Applicable to Breast, Prostate, Ovarian, and Head and Neck Cancers

NCI announces the availability of web-based information and announcements which describe current NCI funding opportunities available to researchers interested in research in all disciplines relevant to cancers of the breast, prostate, ovary, and head and neck. Announcements are available on-line at http://cancer.gov/scienceresources/initiatives.html.

Inquiries: For Disease Specific Research Initiatives Announcements or Progress Review Groups—Progress Review Group Coordinator, Office of Science Planning and Assessment, Office of the Director, NCI, 31 Center Dr., Bldg. 31, Rm. 11A03, MSC 2590, Bethesda, MD 20892-2590; phone 301-496-5515; fax 301-435-3876; e-mail webmasterospa@mail.nih.gov

Supplements to Expand Access to Large Specimen Collections

NCI announces the availability of administrative supplements to encourage investigators collecting human specimens and associated clinical data as part of large studies to make them more available to research. Institutions with an NCI supported study that has accrued at least 2000 cases; is funded at a direct cost of \$1M or more over the life of the grant; and plans to retain specimens for 5 years or more, are eligible to apply. In addition, studies with significant numbers of cases of rare or unique tumor types or specimens and data from unique populations likely to be of long term interest to the scientific community are eligible for supplements. The resource must have both specimens and relevant associated clinical and demographic information. Investigators collecting specimens and data in the NCI Clinical Trials Cooperative Groups and other large

clinical studies are examples of the type of resource we are interested in supplementing.

Inquiries: Roger Aamodt, Division of Cancer Treatment and Diagnosis, NCI, 6130 Executive Boulevard, Rm 6035A, Bethesda, MD 20892, phone 301-496-7147; fax 301-402-7819; e-mail ra32u@nih.gov

Midcareer Investigator Award (PA-00-005): Policies of NCI

This notice informs potential grant applicants of NCI policy in the following two areas:

- 1. The NIH Guide PA(http://grants.nih.gov/grants/guide/pa-files/PA-00-005.html) under Eligibility Requirements says "Candidates must have independent research support at the time of application for this award. The support could include NIH awards or awards from other sources." NCI interprets this to mean that all candidates must have independent research support in patient-oriented research as either NIH awards or awards equivalent to NIH peer-reviewed support and would not include support from industry. This interpretation will be used as a basis for accepting applications for peer review and will be used by the peer reviewers in the evaluation of applications.
- 2. In the same section as above "Recipients of this award are required to hold independent research support, either Federal or private, during the period of this award." Candidates must hold independent patient-oriented research support as defined above for the duration of the award. However, should recipients of this award lose their independent research support, they will be given up to one-year to regain it before NCI takes any action to terminate the K24 grant.

Inquiries: Lester Gorelic, Cancer Training Branch, Office of Centers, Training and Resources, NCI, 6116 Executive Blvd. Suite 7011, Bethesda, MD 20892-8346, phone 301-496-8580; fax 301-402-4472; e-mail lg2h@nih.gov

Rapid Access to Preventive Intervention Development, Addendum

Investigators are hereby notified that the receipt date for requests for NCI's RAPID resources has been changed to Nov. 21, 2000 and the website has been updated: http://dcp.nci.nih.gov/CB/

Inquiries: RAPID, c/o James Crowell, Division of Cancer Prevention, NCI, Executive Plaza North, Suite 200B, 6130 Executive Blvd., Rockville, MD 20852 (overnight mail), 9000 Rockville Pike, Bethesda, MD 20892 (regular mail), phone 301-496-8563; fax 301-402-0553; e-mail jc94h@nih.gov

Cancer Education and Career Development Program PAR-00-064

This is to inform applicants of a change, which applies retroactively to all submitted applications, in the



level of support permitted under Other Expenses for a postdoctoral candidate/trainee, under PA: PAR-00-064. All other provisions remain unchanged. The complete PA can be found at http://grants.nih.gov/grants/guide/pafiles/PAR-00-064.html

Inquiries: Lisa Begg, Office of Centers, Training and Resources, NCI, 6116 Executive Boulevard, Suite 7011, MSC 8346, Bethesda, MD. 20892-7390; fax 301-402-4472; e-mail beggl@mail.nih.gov

Small Business Innovation Research Program

Contract Proposal Receipt Date: Nov. 3, 2000

The Public Health Service SBIR program provides support for research and development of new or improved technologies and methodologies that have the potential to succeed as commercial products.

Inquiries: For a copy of the contract solicitation proposal form, http://grants.nih.gov/grants/funding/sbir.htm

Competing Supplemental Applications: Innovative Cancer Complementary and Alternative Medicine Initiative in Cancer Centers

The NCI supplemental initiative is intended to assist Cancer Centers in building a research capability in cancer complementary and alternative medicine research through provision of developmental funds for innovative pilot research projects having potential, ultimately, to compete for R01 support. NCI staff will contact current grantees regarding application procedures and format.

Inquiries: Phuong Thi Kim Pham, program director, Office of Cancer Complementary and Alternative Medicine, Office of the Deputy Director for Extramural Science, NCI, NIH, 6130 Executive Blvd., Suite 102, Rockville, MD 20852; phone 301-496-3866; fax 301-480-0075; e-mail pp64n@nih.gov

In Brief:

Bill Promotes Awareness Of Pediatric Cancer Research

(Continued from page 1)

Foundation), the Seattle-based foundation's Board of Directors said. Waters is recognized for his work in comparative medicine and prostate cancer research. He was co-director of Purdue University's Comparative Oncology Program, director of the Drug Development Shared Resource of the Purdue Cancer Center, and associate director of the Purdue Gerontology Program. He joined the Purdue faculty in 1991. At its August meeting, the foundation board voted unanimously to change its corporate name to the Gerald P. Murphy Cancer Foundation, honoring the late founder, who died last January while traveling

in Tel Aviv. The Foundation plans to support and conduct basic, comparative, and clinical research, particularly prostate cancer chemoprevention, novel therapies against skeletal metastases, and exploring the unexplained link between aging and prostate cancer development. . . . **REP. DEBORAH PRYCE** (R-OH) last week introduced the Childhood Cancer Awareness, Research and Treatment Act (H.Res. 576), which expresses the sense of the U.S. House of Representatives that Congress should support public and private efforts to promote awareness of childhood cancer, support public and private investment in childhood cancer research, and support policies that will result in better treatments, including encouraging participation in clinical trials and education about pain management, incentives to encourage medical trainees and investigators to enter the field of pediatric oncology, and incentives to encourage drug development for pediatric cancer. . . . HHS SECRETARY DONNA SHALALA received the Susan G. Komen Foundation Women's Health Advocate Award at the foundation's National Grants Conference in Washington earlier this week. Sen. Connie Mack (R-FL) received the Komen Lifetime Achievement Award for his public policy work to advance screening and treatment for breast cancer. **Rep. John Lewis** (D-GA) received the Champion of Change Award for advancing the interests of minorities and the medically underserved with regard to health care access and quality. . . . LUTHER TERRY Awards presented at the World Tobacco Congress in Chicago last month went to **Kjelle Bjartveit** of Norway and Nigel Gray, formerly of Victorian Anti-Cancer Council in Melbourne and now at the Division of Epidemiology and Biostatistics at the European Institute of Oncology in Milan, Italy. The awards were presented by U.S. Surgeon General David Satcher. . . . FLOSSIE WONG-STAAL was appointed vice president of genomics of Immusol Inc. Wong-Staal and colleagues at NCI cloned the AIDS virus. In 1990, she became the Florence Riford Chair in AIDS Research at University of California, San Diego. She is a cofounder of Immusol. . . . LEONARD COHEN, of the American Health Foundation, of Valhalla, NY, was named editor of Nutrition and Cancer: An International Journal. Published six times a year, Nutrition and Cancer reports and reviews current findings on the effects of nutrition on the etiology, therapy, and prevention of cancer. Further information about the journal is available at http:// www.erlbaum.com.



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