
What is the National Dialogue on Cancer?

With its complicated organizational structure that brings together many influential players, and its goal to set the national cancer agenda, the Dialogue can hardly be anything but controversial. Its supporters—many of whom hold the purse strings of cancer research—often express surprise when questioned, repeating the Dialogue’s stated objective of fostering cooperation and coordination in the cancer field.

As of this writing, in August 2003, it is clear that the Dialogue is acting as something other than a hatchery of ideas for the organizational structure that supports cancer research in the U.S. Together with NCI, the Dialogue is proposing fundamental changes while bypassing open review and discussion.

What follows in this Special Report are 11 stories that appeared in The Cancer Letter from 2000 through 2002, in chronological order. The Dialogue set the stage for NCI Director Andrew von Eschenbach’s controversial policies based on his “challenge goal” to end suffering and death from cancer by the year 2015.

The emergence of that plan is the subject of another Special Report.

ACS-Led National Cancer Dialogue Beset By Patient Mistrust, Lack of Openness

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The American Cancer Society is constructing a political structure called the National Dialogue on Cancer and undertaking a related effort to rewrite the fundamental document of the cancer program, the National Cancer Act of 1971.

According to ACS officials, the Dialogue’s goal is to bring together the major cancer groups in an effort to foster better coordination of cancer research and cancer control.

“We can almost guarantee no harm, but also the synergy that comes out of this could have a positive impact that could not be gained in the near term in any other way,” ACS Chief Executive Officer John Seffrin said to The Cancer Letter.

If the Dialogue succeeds, ACS could be in a position to enhance its role among cancer groups and in the National Cancer Program.

If the Dialogue fails, the Society’s national leadership will have to face the consequences of spending about $1.2 million and wasting the time of some very prominent people. These include former President George Bush and Barbara Bush, co-chairmen of the Dialogue, and Sen. Dianne Feinstein (D-CA), the vice-chairman, and Governors Tom Ridge of Pennsylvania and Tommy Thompson of Wisconsin, “Collaborating Partners” in the process.

The outcome will depend on the Society’s ability to build trust with advocacy groups as well as its ability to reverse the trend of puzzling strategic decisions and administrative missteps.

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Shandwick Subsidiary Represented R.J. Reynolds
(Continued from page 1)

—Last August, ACS stunned the Dialogue participants by announcing the formation of a committee that would advise Feinstein in the rewriting of the National Cancer Act.

Critics say that the decision to form the committee and selection of its co-chairmen—Seffrin and former NCI Director Vincent DeVita—were made behind closed doors, without participation of Dialogue Collaborating Partners or the Steering Committee.

In a statement to The Cancer Letter, Andrew von Eschenbach, one of the founders of the Dialogue and a member of its Steering Committee, noted the “lack of input by the Dialogue partners into the formation of Sen. Feinstein’s advisory committee.”

“It is our responsibility and that of the leadership of the cancer community to resolve such problems,” said von Eschenbach, director of the M.D. Anderson Cancer Center’s Center for Genitourinary Cancers, who is in line to become ACS president in 2002.

—The Cancer Letter learned that Shandwick International, a public relations firm involved in running the Dialogue as well as the Cancer Act rewrite, also represents tobacco interests.

John Fish, vice president for federal government affairs at R.J. Reynolds Tobacco Holdings Inc., said the tobacco company is represented by Decision Management Inc., a Shandwick subsidiary. Shandwick purchased Decision Management last year.

The parent company said it’s not involved in marketing tobacco products. “Other types of work, including public information campaigns on the terms of the [tobacco] settlement, anti-youth smoking campaigns, and some work on policy issues has been done in some offices,” Shandwick officials acknowledged in a statement to The Cancer Letter. The company said “recent events have caused the company to take this policy under review.”

ACS officials said they asked appropriate questions before hiring Shandwick, but were not aware of the company’s work with R.J. Reynolds. “The Society does not make it a practice of monitoring the mergers and acquisitions of its vendors,” Greg Donaldson, ACS national vice president, communications, said to The Cancer Letter. “However, if what is being reported is true, then obviously the Society would want to talk further about the matter with Shandwick.”

ACS may want to consider finding a new contractor, said John Durant, executive vice president of the American Society for Clinical Oncology and a member of the Dialogue Steering Committee. “As a personal opinion, it would be unwise for a company that represents tobacco to be involved in the rewriting of the National Cancer Act,” Durant said.

—According to documents obtained by The Cancer Letter, Allan Erickson, the staff coordinator of the Dialogue who serves as a senior consultant to Seffrin, was pursuing a dual agenda in his dealings with NCI.

While trying to keep the Institute collaborating with the process, he aggressively sought reinstatement of $25,000 in Institute funds for development of tobacco control programs in Latin America, a project that NCI officials described as inappropriate for the research institute.

Erickson said his dual relationship with NCI did not harm the Dialogue. “You’d have to use a million-mile yard stick to try to figure out that that has any connection to the National Dialogue on Cancer,” Erickson said to The Cancer Letter. “I don’t think [NCI Director] Rick Klausner even knew that I had any kind of a relationship.”

As a retired ACS official who serves as a consultant to the Society, Erickson can have multiple clients. Still, trying to convince NCI to cooperate with an undertaking that threatens to diminish its role in the National Cancer Program, while at the same time trying to obtain Institute funds for activities inconsistent with its mission may not be the most pragmatic strategy.

—ACS officials and some key volunteers appear to underestimate the reservations of patient advocacy groups about taking part in the Dialogue, and describe critics as a disgruntled minority.

Seffrin said the resistance of advocacy groups surprises him. “It’s amazing to me that we have had difficulty getting some people to participate, in terms of getting them directly involved,” he said to The Cancer Letter.
Dan Smith, ACS vice president for public policy, said the majority of Dialogue participants don’t criticize the process. “I think there are a great many people who feel good about the progress of the Dialogue, and obviously, there will be a number of people who are going to be upset with a number of things there, but I think that’s probably the minority,” said Smith.

Helene Brown, a member of the DeVita-Seffrin committee and an ACS volunteer for the past 50 years, said criticism comes with the territory for a group like ACS. “Any time you have an organization like General Motors, the small automobile maker is going to complain about them,” Brown said. “Any time you have an organization that has the life-long series of accomplishments that the Cancer Society has had, you are going to hear people complaining.

“If there is somebody else out there that wants to take this on their shoulders, and wants to fund it, and wants to organize it, I am sure they are welcome to do it,” Brown said. “But there isn’t anybody else that has that kind of freedom, because of the constituency and the size of the purse.”

The ACS purse is impressive—the Society raised over $600 million last year. However, on Capitol Hill, the Society is just another player with a legislative agenda. In the halls of Congress, shoestring patient groups that possess expertise, grassroots support, and moral authority can be no less effective. Their opposition is not something to court.

“Survivors are extraordinarily important,” said ASCO’s Durant. “The people who have been affected by cancer have the attention of significant decision-makers. Leaving patients out, or making them feel left out is not a very smart idea.”

If the Dialogue fails to earn the support of patient advocacy groups, it will accomplish little on the Hill, agrees Robert Cook-Deegan, director of the National Cancer Policy Board of the Institute of Medicine. “Any national legislation is going to require the support from a broad base of cancer patient advocacy groups,” he said.

**A Matter of Strategy**

Criticism of the Dialogue reaches beyond patient groups. “I don’t think the National Dialogue on Cancer has been designed as a smooth oncopolitical process,” said ASCO’s Durant. “I communicated my confusion over what the governance was and how decisions were made, and nothing happens. It goes right on. I can’t tell you that I have gotten wonderfully satisfying answers to the questions I’ve raised.”

Transparency is essential, agrees Donald Coffey, president-elect of the National Coalition for Cancer Research and former president of the American Association for Cancer Research.

Some critics of the Dialogue say unanimity in cancer politics is a bad strategy. “I have always believed that cancer organizations can work together where there is a shared agenda, but it would not be desirable for all of us to speak in the same voice on every issue,” said Fran Visco, president of the National Breast Cancer Coalition and a member of President’s Cancer Panel. “What that does is keep in place the status quo, and the same people who have been in power remain in power.”

Advocates involved in the Dialogue do not dispute the need for an overarching cancer agenda, but question the ACS claim that the Dialogue is operated independently from the Society and are disappointed by what they describe as the absence of openness.

“I am trying to give them every benefit of the doubt, because I believe so strongly in the need for collaboration,” said Carl Dixon, president and executive director of the Chicago-based Kidney Cancer Association.

“I think there is confusion as to whether the Dialogue has its own charter or whether it’s simply an adjunct to ACS, and I think that tension is troubling to many people. When I hear people from ACS speaking on behalf of the Dialogue and using ‘we,’ I don’t know if they mean ‘we the Dialogue,’ of which I am a member, or ‘we the American Cancer Society’ of which I am not.”

Dixon is a Collaborating Partner in the Dialogue and a member of its Public Policy Roundtable.

**Patients Demand “Transparency”**

Whatever support the Dialogue enjoys is extremely fragile. For one thing, not all the prominent people whose names figure on the list of Collaborating Partners actually show up at meetings.

NBCC President Visco, whose name appears on the list, does not regard herself as such. “We did send someone to the first meeting, and then decided not to participate” Visco said to The Cancer Letter. “I don’t know how they are using my name as a Collaborating Partner. NBCC didn’t give them permission to use my name or any other as a representative. We chose not to participate.”

ACS officials say the names of Collaborating Partners are included after they are invited by the Bushes. Typically, the most senior official of an organization is invited to join.

“If Fran Visco’s name is still listed, it means that clerically [NBCC has] not designated the exact person they want to be listed or asked to be taken off the list,” said Harmon Eyre, executive vice president for research and cancer control.

FDA Commissioner Jane Henney appears to fall into the same category as Visco. “She has received a letter
from President Bush, and has not attended a Dialogue meeting, and the only issue would be, does she ever want to come, or does she want to designate someone as her replacement, or does FDA not want to be involved,” Eyre said.

For those who attend, attendance does not necessarily equal support.

“I am watching, and I think that’s probably the attitude of a fair number of folks, who are watching to see if anything comes of it,” said ASCO’s Durant. Some of what Durant sees worries him. “It has always seemed to me that this was an issue of control by the ACS over the cancer agenda,” he said. “They are protecting their fundraising capacity.”

Several participants said they would quit the minute they feel that nothing is being accomplished. For advocates, who typically have limited resources and crowded schedules, this threshold is especially low, said Ilene Penn Miller, executive director of the New York-based Cure For Lymphoma Foundation.

To represent lymphoma policy issues, CFL joined three national coalitions, the Cancer Leadership Council, the National Coalition for Cancer Research, and the National Dialogue on Cancer.

“With a small and overworked staff, keeping up with even one, let alone all three of these coalitions, is a full-time job,” Miller said. “Not only is participation draining our time, but there are financial costs to participating in each of these forums as well.”

Miller said the Dialogue structure still mystifies her. “All partners should be briefed on decision-making process and goals,” she said. “The distrust that already exists among cancer organizations is fed when groups perceive behind-the-scenes decision-making.”

Still, a meaningful Dialogue would be worth the effort, Miller said. Cancer groups should share information and work toward goals that include increased funding for cancer research and access to clinical trials, she said.

“At the end of the day, it matters less who gets the credit, but that the cancer community is coordinated in our efforts,” she said.

Gilles Frydman, founder and president of the Association of Cancer Online Resources, agreed.

“The reality is that if you want to start a meaningful Dialogue or rewrite the National Cancer Act, it can only be done by working together with all the advocacy organizations,” Frydman, a participant in the Dialogue, said to The Cancer Letter. “I don’t see them at the Dialogue; definitely not as equal partners. What a wasted opportunity.”

While governance issues frequently surface in the Dialogue Steering Committee, ACS membership surveys do not reflect dissatisfaction, ACS officials said.

Recently, partners were asked to review a draft of the Dialogue structure. Altogether, 26 evaluations were returned, said Tom Kean, president of Strategic Health Concepts, of Englewood, CO, and chairman of the Dialogue Coordination Work Group. “Most of them were pretty positive, and most of them were suggesting editorial changes to the document,” Kean said. “Few people raised comments about the makeup of the Steering Committee and how decisions are made.”

Follow-up To The March

For better or for worse, the Dialogue is trying to pick up the pieces left behind by the March: Coming Together To Conquer Cancer.

Though the March brought 125,000 people to the National Mall in Washington on Sept. 26, 1998, it failed to create a “cancer community” of researchers and patients unified by a common political agenda.

For months before the March, the writing was on the wall: far from producing a United Front, the process of organizing the event severely wore down the groups’ willingness to collaborate, organizers of the March said.

“There was nothing that could sustain the continuation in terms of the fiscal and human capital required,” said Richard Atkins, president of the CaP CURE government research initiatives group and vice chairman of the National Prostate Cancer Coalition, who served as chairman of the board of directors of the March. “We were volunteers who came from our own organizations, and we went back to them.”

Meanwhile, the Atlanta-based ACS, a minor and reluctant player in the March, was preparing to take over political follow-up to the event.

According to materials obtained by The Cancer Letter, the Society convened a meeting of a small group of scientists, physicians, and ACS officials on Sept. 29, 1998, at a Northern Virginia hotel. There were no patient groups at the table.

“The National Dialogue on Cancer initiative has tremendous potential in terms of helping to identify and leverage the respective strengths of the key organizations and leaders involved in the cancer control effort,” Washington surgeon LaSalle Leffall wrote in an Aug. 25, 1998, letter of invitation to prospective members of Dialogue Steering Committee. Leffall, professor of surgery at Howard University, is the chairman of the Steering Committee.

The Society recruited the Bushes and Feinstein, as well as about 100 Collaborating Partners, the Dialogue’s rank and-file.

After learning that no patients were involved in the ACS planning meetings for the Dialogue, Ellen Stovall, president of the March and executive director of the National Coalition for Cancer Survivorship, picked up the phone and called Leffall.

“Dr. Leffall assured me that patients would be invited later, and I would certainly be included,” Stovall said to The Cancer Letter.
Patients should be involved from the start, Stovall objected. “If this had been 30 years ago, they may not have had any patients to invite, but because of the progress against cancer, they had about eight million of us out there,” Stovall said. “That’s a big constituency.”

**Control of the “National Cancer Act”**

More than a year after the Dialogue began, ACS chief executive Seffrin described the process to the President’s Cancer Panel.

Addressing the panel at its meeting Dec. 6, Seffrin said the purpose of the Dialogue was to bring together the public sector, the private sector, and the not-for-profit organizations.

“We have a couple of important principles,” Seffrin said to the panel. “First was to address the issue that seemed to be unanimously accepted: that coordination isn’t what it needs to be. And, second, that we need at the highest levels to get all three sectors together around a common table.”

In addition to bringing the players to the table through the Dialogue, the advisory committee Seffrin co-chairs with DeVita would seek to replace the National Cancer Act with something called the National Cancer Control Act, Seffrin said.

“I have a feeling that we can make a compelling case for new National Cancer Control Act that will see its public policy role enlarged in dealing with the issues of lack of access to state of the art cancer screening, diagnosis and treatment,” Seffrin said to the panel.

Consider the amount of political TNT packed into these seemingly innocuous statements:

—Seffrin’s central proposition that the federal and private sector cancer programs require “coordination” is quite controversial. Under the National Cancer Act, the federal program is research-driven and run by the NCI director.

Sources said that NCI Director Richard Klausner originally agreed to cooperate with the Dialogue only after receiving assurances that the process would be about “communication” rather than “coordination.”

—Seffrin’s reference to the “not-for-profit sector,” while technically correct, obscures the differences between gigantic voluntary health organizations like ACS and the cancer patient advocacy groups, which include the Society’s most vocal critics.

—The question of what happens when “all three sectors” come to the table has led to challenges from advocacy groups and professional societies. Does ACS get to set the agenda and write the record? For many ACS loyalists who believe in the goodness of the Society, this is not a problem; for many potential partners it is.

An examination of the Dialogue documents by The Cancer Letter reveals that members, or Collaborating Partners, are not systematically chosen, the lobbying function is not connected to the deliberations of the group, and the committee redrafting the National Cancer Act is independent from the Dialogue and not answerable to it.

The Cancer Act committee, which serves as “advisory” to Feinstein, was formed without discussion by the Collaborating Partners or the Steering Committee.

—An argument can be made that Seffrin’s reference to the “National Cancer Act” was a tad premature. The committee deciding whether an update of the 1971 law is necessary had yet to hold its first meeting. How did Seffrin know the title of the document it would produce? What would happen under the National Cancer Control Act? Would the cancer program be run by another entity?

In an interview, Seffrin said he has since abandoned the name, “I presume that was just my phraseology,” he said to The Cancer Letter. “We talked about it just last week. If you say the National Cancer Act, everybody thinks about the 1971 Act. And if you say something else, people say, well, are you overemphasizing cancer control? I believe the committee is going to look at some language like Cancer Legislative Initiatives.”

At the President’s Cancer Panel meeting, Seffrin said trust is replacing the “sense of territoriality” around the Dialogue table.

“I think early on—in the first couple of meetings—people were saying, does this have a chance of succeeding?” Seffrin said. “Perhaps, there was some sense of territoriality. Whose is this? Is this the ACS initiative? No. Is it a new organization? We already have too many organizations. No, it’s not that.”

Now, skepticism is receding, Seffrin said. “To many people’s surprise, we now have over 100 Collaborating Partners, and that represents literally millions of dollars and millions of people, both professionals and volunteers,” he said. “There is a synergy that comes when most if not all the key players are sitting around the table, able to strategize and understand better what our strengths and our weaknesses are.”

**Unconnected Structures**

According to ACS documents obtained by The Cancer Letter, organizers of the Dialogue seem to have taken special care to avoid creating any structure for the delegation of authority from the rank-and-file to the leadership.

A draft document distributed last October at a Dialogue meeting at the Bush home in Kennebunkport asserts that the Dialogue is not an organization, but a “forum.” By structuring the Dialogue as a forum, an entity that has no legal definition, ACS avoids getting bogged down in parliamentary disputes that often destroy coalitions, but, by the same token, accepts the absence of transparency.

How does one come to the forum?
By invitation only.
“Collaborating Partners are seated at the invitation of President and Mrs. George Bush after consulting with
Sen. Feinstein,” the documents state.

Collaborating Partners—there are 103 of them, according to the Kennebunkport papers—serve on committees studying various aspects of cancer research and cancer control.

Do Collaborating Partners represent their organizations?

Not necessarily. They “represent themselves first,” the document states.

The Dialogue activities are managed by a 16-member Steering Committee, which includes at least one representative of ACS, NCI, Centers for Disease Control and Prevention, and the Pharmaceutical Research and Manufacturers of America. The Steering Committee also must include at least one cancer survivor and one member representing the underserved.

Are Steering Committee members elected? Draft documents indicate no method for selection of committee members.

ACS appears to be especially thorough in severing any formal link between the will of the Collaborating Partners and the ultimate political agenda. In part, this link had to be severed because representatives of federal agencies—essential members of the process—are precluded from lobbying.

Resorting to the emphatic in-house parlance of ACS, which relies on an extensive use of underlining, capitalization and italics, the Kennebunkport documents describe this unusual separation:

“An independent voluntary roundtable of public policy representatives has been created to facilitate the efforts of those multiple participating entities that can engage in advocacy activities as they work together on collaborative and supportive agendas,” states an overview document describing the “Mission and Vision” of the Dialogue.

“This makes it absolutely clear that government agencies participating in the National Dialogue on Cancer are NOT challenged relative to the matter of lobbying, either directly or by implication,” the document declares.

Since the Dialogue is not an organization, it will not lobby, and will not need to be designated as either a 501(C)3 or 501(C)4 organization, documents state. Instead, Collaborating Partners who work in government relations would gather to explore areas of collaboration, the documents say. “It will serve as a forum for other groups that do lobby state and federal governments to work together,” the documents state.

**Relationship With NCI**

For NCI, the Dialogue is a potential minefield. Senior NCI officials describe the Institute’s position as detached. To avoid an appearance of boycotting the Dialogue, they show up at meetings, respond to specific proposals—and observe.

At the first meeting of the Dialogue Steering Committee, NCI Director Klausner cautioned against creating a new national organization. According to detailed notes kept by a participant of the Nov. 9, 1998, meeting, “Klausner had a great deal of concern that moving too far in the direction of action may create a situation in which the Dialogue would end up competing with its group members, or with NCI, and complicate or have negative impact on their own strategic planning.”

When ACS scheduled a March 19, 1999, press conference to announce the Dialogue, Klausner declined to participate, sources said.

The press conference lacked content. Klausner said to several people at the time. The fact that a group of prominent people agreed to talk about communications, or for that matter, coordination of cancer programs, cannot be expected to make the evening news, even if a former U.S. President and a U.S. Senator are among those doing the talking. Following the NCI pullout, ACS cancelled the press conference, blaming a minor snowfall.

Meanwhile, NCI officials were shocked to discover that the coordinator of the Dialogue was receiving $25,000 a year in the Institute’s funds for organizing tobacco control in Latin America.

According to documents obtained by The Cancer Letter, Allan Erickson, the Dialogue coordinator, used the money for organizing a bureaucratic infrastructure for tobacco control and for fundraising from pharmaceutical companies.

The Erickson funds—and the nature of his work—were thoroughly hidden. The money went through two contractors before it reached Erickson, sources said.

The expenditures were found during examination of the NCI Division of Cancer Control and Population Sciences contracts, which began with appointment of the new director, Barbara Rimer.

“Although we recognize a need to improve public health infrastructure for tobacco control throughout the world, that is not our mission or responsibility at NCI,” Rimer said to The Cancer Letter. “We do make modest investments in international research, but these investments are above board and handled through the front door, not the back door.

“Our resources would be depleted rapidly if we took the path of building infrastructure for tobacco control around the world,” Rimer said. “Taxpayers and legislators would be rightly distressed.”

To find out what Erickson did with the money, NCI officials asked him to submit a detailed “deliverable” paper.

“Over the past several months, I have continued to spend an incredible amount of time in developing relationships and bonds with a wide range of individuals and entities to help facilitate the capacity-building and program outreach processes in an effort to expand the ‘reach’ and lifesaving impact of tobacco prevention and a wide range of control interventions within 19 South and Central American countries,” Erickson wrote in a breezy,
procession, talking about cancer, how terrible it is, and with Prince Charles behind King Hussein’s funeral. “George wants to globalize the Dialogue idea. He walked Prince Charles here for a Dialogue meeting,” he said. Twice, and I think probably will succeed very soon to get of the Dialogue, Erickson said. “George Bush has tried formally brought up there. There are some of the individuals, and it may be a topic—I think it will—to be projects] to the Dialogue on the agenda. I brought it up to Letter. “I’ve not formally brought up [Latin American Dialogue. “It’s a logical thing,” he said to Erickson acknowledged raising funds through the Collaborating Partners of the National Dialogue on Cancer.

Of course, many of the organizations and agencies and institutions involved in this historic process have Latin American entities,” Erickson wrote. “It is for this reason that a special presentation on the tobacco control plight of Latin America be made to the 100-plus Collaborating Partners of the National Dialogue on Cancer. This intervention has already paid big dividends in terms of several organizations coming to me to express their desire to be supportive and to help them determine what they might do to advance the movement. This is exactly what we had in mind, and it has shown great promise and payoff.”

After Rimer declined to renew his funding, Erickson continued to place calls around the Institute in a futile search for a new patron. The telephone log of one NCI office shows seven calls and two faxes from Erickson over three months, sources said.

Ultimately, Erickson focused his efforts on Otis Brawley, director of the NCI Office of Special Populations Research. “It was not an appropriate area for this office to enter into,” Brawley said to The Cancer Letter. “My office supports research that has clear domestic implications.”

Erickson acknowledged raising funds through the Dialogue. “It’s a logical thing,” he said to The Cancer Letter. “I’ve not formally brought up [Latin American projects] to the Dialogue on the agenda. I brought it up to individuals, and it may be a topic—I think it will—to be formally brought up there. There are some of the Collaborating Partners who actually are putting up money.”

International projects are consistent with the goals of the Dialogue, Erickson said. “George Bush has tried twice, and I think probably will succeed very soon to get Prince Charles here for a Dialogue meeting,” he said. “George wants to globalize the Dialogue idea. He walked with Prince Charles behind King Hussein’s funeral procession, talking about cancer, how terrible it is, and Prince Charles said we’d like to try the Dialogue concept in UK, and we are trying to formulate that right now.”

Erickson said he would like to see a National Dialogue on Cancer in Latin America, too. “They need it more than we do,” he said.

Cancer Act Rewrite: A Procedural Curveball

Last summer, ACS sprung a procedural surprise on the Collaborating Partners.

At the Dialogue’s Public Policy Roundtable meeting Aug. 11, David Krawitz, head of Shandwick’s Washington office, casually mentioned that an independent committee had been formed to advise Feinstein on revising the National Cancer Act.

Surprised by this revelation, NPCC Vice Chairman Atkins and Kidney Cancer Association President Dixon questioned the process that led to the formation of the committee in a letter to Krawitz.

Three weeks later, Dialogue Collaborating Partners received a letter from Steering Committee Chairman Leffall. The impetus for creation of the National Cancer Act review committee came from Feinstein, not the Dialogue, he wrote in a letter dated Sept. 3.

“Sen. Feinstein has invited [DeVita and Seffrin] to co-chair a special advisory committee, and asked them to select a small group of individuals from the various components of the cancer community,” Leffall wrote. “Although this is not an initiative sponsored by the National Dialogue on Cancer, we want all NDC Collaborating Partners to have an opportunity to provide specific input.”

Thus, a year after Stovall warned Leffall about the flaws in the Society’s plan to invite patients to the table after the Dialogue was designed, she received an invitation from DeVita to join the new committee.

No soul-searching was required for Stovall to respond to the invitation.

“I declined,” Stovall said to The Cancer Letter. Her reasons were similar to ones she outlined to Leffall a year earlier.

“I didn’t want to be the only patient on the committee, because that to me was basically ignoring the fact that there is a burgeoning constituency of hundreds of patient groups out there,” Stovall said.

The patient perspective is represented by the Cancer Leadership Council, Stovall said. “If Dianne Feinstein wanted to have the National Cancer Act rewritten, the first place she should have come to is the patients,” she said.

ACS volunteer Helene Brown said Stovall’s position amounts to a “poor, lame excuse” that does not serve the NCCS constituency.

“There is a complaint coming from Ms. Stovall about the representation of the survivor advocacy movement,” Brown said. “I was not there from the start, either. I was not invited. That’s no reason I should say no when I was invited. Is that a problem, or is it a complaint? It seems to me she is complaining.”
Unlike Stovall’s group, the National Prostate Cancer Coalition sought a seat on the Cancer Act committee once it was formed, but was not invited to join.

“That patient groups are not a core part of the decision-makers—are not widely represented at the committee table—is confusing and appalling,” Atkins said.

“The astonishing increases in this country’s investment in cancer research are largely the result of patient-driven advocacy,” Atkins said to The Cancer Letter.

“Because of survivor activism, several hundred thousand people gathered across the country last year, at March-sponsored events, to demand ‘No more cancer’ and continue to put legislative platforms for cancer research and cancer control into the public and Congressional dialogue,” Atkins said.

“Where does the leadership of this committee imagine that the activist base that will help pass cancer-related legislation actually comes from?”

The proposed rewrite is no small issue, said NBCC President Visco, who is also a member of the President's Cancer Panel. “If the National Cancer Act needs to be rewritten, it doesn’t need to be rewritten by everyone involved in cancer, because the result would not be a visionary document,” said Visco.

“It would look like something written by a committee, and would be a watered down version of what needs to be done,” Visco said.

DeVita, director of the Yale Cancer Center, could not be reached for comment.

Separating Dialogue From Committee
Steering Committee member von Eschenbach makes a distinction between the Dialogue, which he helped start, and the Cancer Act advisory committee, which he said raises questions of transparency.

“Cancer is a national tragedy—it is a pervasive scientific, medical, social, economic and political problem demanding our national focus and cooperation in achieving a comprehensive solution,” von Eschenbach said. “The National Dialogue on Cancer was born with the vision that a forum could be created where leaders from the public, private, and for-profit sectors of our society could come together to achieve that cooperation.

“Much good has already been accomplished in this first year and the ongoing work of nine priority teams discussing issues such as research and the disparity in access to quality cancer care offer great promise,” he said.

“But there are also problems and the lack of input by the Dialogue partners into the formation of Sen. Feinstein’s advisory committee is one. It is our responsibility and that of the leadership of the cancer community to resolve such problems. Those who have suffered and died from this disease not only expect it—they demand it,” von Eschenbach said.

Ellen Sigal, chairman of Friends of Cancer Research and a member of the Dialogue Steering Committee, said the Dialogue deserves another chance.

“There is no question there have been mistakes, and there are process issues,” Sigal said to The Cancer Letter.

“However, the Dialogue has done something that nobody else has done.” Sigal said. “It’s brought together people who have never been at the same table: governors, patient groups, people from government agencies, the pharmaceutical industry, research people. I believe that any time you have a venue for that kind of communication, the community has the responsibility and obligation to work with it, and to see where it can go, and to look at the potential.

“It’s easy to criticize, and it’s a little more difficult to work together,” Sigal said.

Procedural Surprises (Continued)
Last October, at the Kennebunkport meeting, ACS staff sprung another procedural surprise on the Dialogue Collaborating Partners.

A draft of a new organizational schema contained an unexpected change: introduction of “Sustaining Members” of the Dialogue Steering Committee.

The new category was to include ACS, CDC, NCI, and the Pharmaceutical Research and Manufacturers of America. “By virtue of the respective leadership roles they played in the development of NDC, as well as their nationwide outreach and grassroots constituencies. these four founding groups are granted ‘Sustaining’ positions on the 16-member Steering Committee,” the document said.

In terms of realpolitik, the “Sustaining Member” category was not a success. At least two groups—NCI and PhRMA—did not seek the honor and were unpleasantly surprised to be designated as more equal than other Steering Committee members. On the other end of the spectrum, the oncology professional societies were infuriated to be relegated to the less equal status.

Naturally, this triggered protest from both ASCO and the American Association for Cancer Research, sources said.

The year of surprises concluded in December, when Collaborating Partners received a slick binder with a document titled “Tobacco Tool Kit.” The kit was designed to help lobby state legislatures to spend tobacco settlement money on cancer needs.

“Using the resource materials in the enclosed binder, you can make certain that state governments use a majority of the settlement money for public health and tobacco control programs,” Brown, then chairman of the Dialogue’s Cancer Control Priority Team, wrote in a cover letter dated Dec. 1.

What about cancer research? Was there a reason to leave it out?

“I was surprised when research was omitted,” said Kidney Cancer Association’s Dixon. “I don’t recall the Dialogue Collaborating Partners making the decision to
Promoting the Dialogue Agenda

Last week, ACS Washington staff and Shandwick employees attempted to win the hearts and minds of the patient groups at a meeting of the Cancer Leadership Council.

After the March, the CLC has become the patients’ single most important forum. Though professional societies and ACS are represented at the table, there is no question that the Council is the patients’ turf.

First, ACS staff asked to be invited to the Jan. 11 meeting, which was called to coordinate Congressional appropriations requests and election agendas of groups that included CLC, the National Prostate Cancer Coalition, National Coalition for Cancer Research, and Friends of Cancer Research.

Once invited, ACS attempted to shift the venue to their turf, a conference room at Shandwick, sources said. Unable to move the meeting, ACS staff submitted an agenda. In big bold letters, the proposed agenda read: “National Public Policy Roundtable on Cancer.”

Bringing an agenda to someone else’s meeting is a move of questionable wisdom, even in situations where trust abounds. Bringing an agenda to a CLC meeting also happens to run counter to the group’s traditions. CLC does not use agendas. If members choose to discuss an issue, they do so until nothing remains to be said.

Stovall and Atkins told ACS staff that their attempt was impolitic. “This is no way to do business with the patient groups,” Stovall said to The Cancer Letter. “At best, it was poor manners; at worst, it was an insult.”

ACS public policy vice president Smith said the Society staff thought the CLC would have its meeting in the morning, then reconvene as the Dialogue Public Policy Roundtable.

“There were some crossed signals about how the meeting would be set up,” Smith said.

At the meeting, Smith, a former aide to Sen. Tom Harkin (D-IA) who recently joined the Society, acknowledged that the Society may not have been always open and forthcoming about its plans. That done, he asked CLC to send a representative to the Public Policy Roundtable.

The value of having CLC represented at the Roundtable would have been largely symbolic: Nine of the CLC’s 20 member organizations are also represented at the Dialogue, and four take part in the Roundtable.

Moreover, CLC takes no positions as a group, and does not seek to reach consensus positions. “We are not trying to blend and amalgamate people’s thinking or their participation,” Stovall said. “What we are looking for is independent thought and good analysis. It’s very simple. They know how we operate. Their representatives have sat at that table for a long period of time.”

The Dialogue was free to apply for participation in the CLC, she said.

Smith said he was not aware of the manner in which CLC conducts business. “Being new to the community, I wasn’t familiar with their internal processes,” he said. “My point in being there is that the Dialogue and all the spin-offs of the Dialogue are an important exercise and an important activity. I am a person who always tries to find a common ground, and if there are problems, to deal with them openly and honestly.”

Later that day, Stovall learned that ACS was planning a Jan. 13 press conference announcing a voter education campaign pegged to the 2000 elections. Failure to disclose the effort during discussion of the cancer groups’ agenda stunned Stovall.

“They were saying that they want to work with the patient groups, yet they didn’t mention what they were doing,” Stovall said. “If you want patients and consumers to be part of a political process, you have to put your cards on the table. If you don’t, it means you really don’t want patients around,” she said.

Smith said no insult was intended. “Frankly, that wasn’t on my mind when I was at the meeting,” he said. “There are always going to be skeptics.”

PR Firm Hired By American Cancer Society Also Represents “Team KOOL Green”

(The Cancer Letter, Jan. 28, 2000, Vol. 26 No. 4)

The public relations company hired by the American Cancer Society to conduct a voter education campaign aimed at making cancer an issue for the 2000 presidential elections also represents tobacco companies, including Brown & Williamson Tobacco Corp.

Edelman Public Relations, widely known to represent tobacco clients internationally, remained in the shadows as it conducted the ACS Campaign Against Cancer, which at this point has entailed placing advertisements in conjunction with the Iowa caucus and the New Hampshire primary.

According to an Edelman press release, the campaign is aimed to “educate the presidential candidates on cancer issues and urge them to adopt a cancer cure and prevention agenda for the 2000 presidential election.”

Edelman appears on a list of 70 “Tobacco Industry Supporters” compiled by the state of Florida two years ago.
On behalf of Louisville-based Brown & Williamson, Edelman handles publicity for Team KOOL Green that competes on the Championship Auto Racing Teams circuit.

Edelman operates a “mobile media coach,” a 45-foot mobile home that serves as a media center for the Indianapolis-based team. “It looks like a motor-coach; a mobile-home-type motor-coach,” Brown & Williamson spokesman Steve Kottak said to The Cancer Letter. “It’s equipped with fax lines and modems, so the press can do stories on-site.”

At a time when national promotional opportunities for tobacco products are becoming increasingly scarce, promoting the team, the sport—and ultimately KOOL cigarettes—is an important project for Brown & Williamson, which plans to invest $50 million in the team between 1999 and 2001.

According to Brown & Williamson studies cited in Business First, a Louisville weekly, 15 of the 20 CART events are conducted in the US, draw mostly male crowds of about 150,000 per event, and are covered on national television.

Kottak as well as CART racing circuit officials identified Edelman Public Relations as the contact for Team KOOL Green. The team’s 1999 media guide also lists a Tampa-based Edelman employee as a press contact. In a taped message, the employee identifies himself as “Ed Nicholls with Edelman Public Relations and Team KOOL Green.”

“We are not engaged in public affairs on behalf of the tobacco industry in the U.S.,” said Leslie Dach, vice chairman of Edelman’s Washington office. However, Dach acknowledged that the agency’s international division does work for tobacco companies. The company’s client relationship with Brown & Williamson exists outside the U.S., he said. “The international division supports motorcar racing,” Dach said.

Edelman official Eric Hoffman said Nicholls, despite being stationed in Florida, is not a U.S. employee. “He reports to our international operations,” Hoffman said.

Edelman’s representation of Brown & Williamson is the second embarrassment in a week for the Society that has a policy of not doing business with companies that handle tobacco. Earlier this week, ACS fired Shandwick International after learning that the public relations company also represents R.J. Reynolds Tobacco Holdings.


“You reported something that you had learned, and we inquired, and we studied the facts, talked to Shandwick, and made a decision,” ACS spokesman Greg Donaldson said to The Cancer Letter.

After being told by The Cancer Letter that Edelman, too, is involved in the tobacco business, Donaldson said the Society intends to not renew its contract with the firm.

“We certainly believe that we did due diligence on the front end of this relationship,” Donaldson said. “However, that relationship will expire in 60 days, and we intend to not renew it.”

Donaldson said the Society does not do business with firms that work for tobacco clients, foreign or domestic. “We hope that the folks at Edelman—just as we hope that the folks at Shandwick—will do the right thing and put themselves in a position where we can do business with them at some point in the future,” he said.

Edelman has made no secret of its tobacco ties. In April 1998, company chairman Daniel Edelman told The Wall Street Journal that the Florida list of 70 tobacco supporters was “a little extreme” and said that tobacco is a legal product.

Recently, on its web site, Edelman displayed a “case history” in which it took credit for creating an invitational golf tournament for Imperial Tobacco Ltd.

At the tournament, which coincided with du Maurier Ltd. Canadian Open, the chairman of the board of Imperial Tobacco invited selected guests to share 18 holes with golfers Jack Nicklaus and Arnold Palmer. The “prestige event” had “an impact on the company’s important client and customers,” Edelman materials said.

Edelman’s involvement with ACS was not as obvious as its representation of tobacco clients.

The company’s name does not figure in ACS press materials distributed at the campaign’s unveiling at a Jan. 13 press conference in Washington that featured Sens. Connie Mack (R-FL) and Dianne Feinstein (D-CA), and actor Eliot Gould.

The press contact named on the ACS press materials was a Society employee, and Hoffman is named as a contact for obtaining the television spot, but not identified as an Edelman employee.

Donaldson said the Edelman name was omitted at his request. “They were working on our behalf, but it seems to me that ACS should be an appropriate contact,” he said. “There was definitely no attempt to cover up anything.”

Tobacco business is spread out generously among lobbying, public relations and law firms in Washington, many observers said. Finding a public relations firm that doesn’t take tobacco clients is a challenge, especially among the top tier firms.

“The practical reality is that in this day and age of mergers and acquisitions, it is very difficult in some cases to get vendor support from certain areas where there has never been tobacco relationships,” Donaldson said. “Nonetheless, we are extremely mindful of the issue, and it’s very important to us.”
Firing Shandwick was probably the easiest of actions ACS could take in addressing the problems plaguing the National Dialogue on Cancer. Other problems include skepticism on the part of Dialogue participants about the ACS claim that the process is aimed at enhancing communications between cancer groups rather than promoting the Society’s agenda.

Several leading participants of the Dialogue said they were disappointed by the appearance of a spin-off committee formed to advise Sen. Feinstein on the rewriting of the National Cancer Act. The decision to form the committee and the selection of its leadership were never discussed by the Dialogue’s Collaborating Partners and its Steering Committee.

On Jan. 20, the day before the story was published, Steering Committee chairman LaSalle Leffall sent a fax to all collaborating partners, pledging that the Dialogue would comment on the story.

“When we receive the full text of the piece, we will share it, along with any explanations or rebuttals that may be indicated.”

As of this writing, The Cancer Letter has not received a response.

**Bush Says National Dialogue On Cancer Needs To Correct Problems And Move On**

(The Cancer Letter Vol. 26 No. 11, March 17, 2000.)

Facing about 100 people at the fourth meeting of the National Dialogue on Cancer, former President George Bush said the problems of the American Cancer Society-funded initiative are far from insurmountable.

Holding up a copy of what he described as “that darn Cancer Letter,” Bush jokingly assured the audience that the story that questioned the structure, goals, and strategy of the Dialogue was not the cause of his recent heart problems.

“It’s not The Cancer Letter that got my heart fibrillating,” said Bush at the meeting March 11.

“The goal is bigger than the problems discussed,” said Bush, chairman of the Dialogue, referring to a story in the Jan. 21 issue of The Cancer Letter. “We need to correct the problems and move on,” he said.

The meeting, held at a Northern Virginia hotel, was closed to press coverage. However, documents and interviews with participants indicate that ACS officials and Dialogue organizers were correcting the organizational flaws of the initiative aimed at bringing together the major cancer groups to create an overarching cancer agenda.

A substantial portion of the March 11 meeting was devoted to discussion of a draft paper and concepts for rewriting the National Cancer Act of 1971. The documents were produced by the National Cancer Legislation Advisory Committee, a spin-off of the Dialogue.

The committee advises Sen. Dianne Feinstein (D-CA), the Dialogue vice-chairman.

The effort to rewrite the fundamental legislation of the National Cancer Program is controversial because Dialogue participants were not involved in the decision to form the committee and the selection of its leadership. The committee, co-chaired by ACS chief executive John Seffrin and Yale Cancer Center Director Vincent DeVita, has held two meetings, on Feb. 8 and March 10.

In an apparent attempt to give the Dialogue’s “Collaborating Partners” a sense of ownership of the final document, Dialogue organizers presented the documents for discussion by small groups, and, later, by everyone at the meeting.

“Significant time has been set aside, at Sen. Feinstein’s request, to receive your insights and reflections on the policy recommendations, compiled thus far from interviews with cancer experts and stakeholders,” Seffrin and DeVita wrote in a memorandum to the Dialogue participants. “Ultimately, our efforts should yield a consensus policy report or white paper, and rationale, from which specific legislation might be drawn.”

It’s not clear when the legislative proposal would be completed, several insiders said. At the meeting, Feinstein said she also planned to solicit opinions from groups not involved in the Dialogue.

One new Dialogue participant, Ronald Herberman, president of the Association of American Cancer Institutes, said that he sees a need for the new legislation.

“I came in being a bit wary, given the concerns that have been raised, but after my first meeting, I ended up being encouraged that something useful might come from this that might not only advance cancer research, but also address the issues of improving cancer care in ways that are more on the forefront than they were when the first iteration of the National Cancer Act was written,” said Herberman, director of the University of Pittsburgh Cancer Institute, who also joined the DeVita-Seffrin committee.

The wide-ranging draft document, the outcome of interviews conducted by Abt Associates, a consulting firm, lists potential, un prioritized goals for cancer research and control. The draft paper is remarkable for its elaborate disclaimer:

“NOTE: This outline is not to be quoted, copied, or distributed in any way. It is designed solely for discussion purposes. Ideas represented are those of the individual respondents and do not represent the views of the National Cancer Legislation Advisory Committee or any other organization or entity.”

A few of the 50 goals listed in the 18-page document, a copy of which was obtained by The Cancer Letter, include:

—“Substantially increase the nation’s investment in...
cancer research through the National Cancer Institute, and government agencies and institutes.”

—“Additional funding to provide coverage for 50 percent of all research proposals.”
—“Develop incentives such as patent extensions and tax preferences to encourage research into drugs for specific cancers that affect small numbers of individuals.”
—“The federal government should support education of both patients and health care professionals about the need for clinical trials.”
—“Enactment of a national goal of a smoke-free society.”
—“Commitment to make the federal government and states equal partners in campaign to conquer cancer.”
—“Expand current [Centers for Disease Control and Prevention] program to provide screening and diagnosis and provide link to treatment and insurance coverage.”
—“A national long-term strategy to improve insurance coverage and guarantee universal access to health care.”
—“Fund and assist development of a set of measures where quality of cancer care can be measured.”
—“Fund and incentivize expansions of cancer patient information Web sites.”
—“Provide enhanced support for the creation and utilization of standard definitions for special population.”
—“Establish benchmarks for cancer eradication initiatives and revise them when new information changes future objectives.”

The draft is a starting point. The final paper will be put together by the committee. Besides DeVita and Seffrin, the co-chairs, the committee includes: Leonard Abramson, Abramson Group; Jim Armitage, University of Nebraska Medical Center; Anna Barker, president/CEO, BIO NOVA Inc.; Nancy Brinker, CEO, Susan G. Komen Breast Cancer Foundation; Helene Brown, UCLA Jonsson Cancer Center; Paul Calabresi, professor of medicine, Rhode Island Hospital; Robert Day, president and director emeritus, Fred Hutchinson Cancer Research Center; Carl Dixon, president and executive director, Kidney Cancer Association; John Glick, director, University of Pennsylvania Cancer Center; Albert Einstein Jr., medical director, Swedish Cancer Institute; Ronald Herberman, president American Association of Cancer Institutes; Alan Holmer, president, Pharmaceutical Research & Manufacturers of America; Amy Langer, executive director, National Alliance of Breast Cancer Organizations; Deborah Mayer, chief nursing officer, CancerSource.com; William Roper, dean, School of Public Health, University of North Carolina; Ellen Sigal, chair, Friends of Cancer Research; Joseph Simone, medical director, Huntsman Cancer Institute, University of Utah; George Van de Woude, director, Van Andel Institute, Armin Weinberg, co-chairman, Intercultural Cancer Council.

“Sustaining Members” No More

In another move, the Dialogue has abandoned the “Sustaining Member” category of its Steering Committee. The category guaranteed seats to ACS, CDC, NCI and Pharmaceutical Research and Manufacturers Association. This membership structure caused protests from professional societies, who were excluded, and did not earn gratitude from either PhRMA and NCI, which did not seek Sustaining Member seats.

Sources said NCI was not represented at two of the most recent Steering Committee meetings, and was not represented at the meeting of the Dialogue.

ACS officials say the Dialogue functions separately from the Society and is not intended to further its goals. However, the argument that the two entities are separate has been difficult to support since the Society’s Washington staff has had to conduct Dialogue activities.

Separation between the two entities was more clear when the Society employed a contractor to provide staff support for the Dialogue. However, Shandwick International, the contractor, was fired after The Cancer Letter reported that one of its units also represented R.J. Reynolds Tobacco Holdings Inc. ACS has a policy of not employing contractors who represent tobacco interests.

Disputes Over CDC Funding, Rockefeller-Mack

In recent weeks, the Society’s Washington office has been involved in two serious altercations with professional societies and patient groups.

In one skirmish, the American Society of Clinical Oncology and the American Association for Cancer Research declined to sign the Society’s letter seeking a nearly 61-percent appropriations increase for the CDC Division of Cancer Prevention and Control.

The letter recommended an allocation of $622 million, a $235-million increase over the current budget. According to the letter, “this amount represents merely a starting point for CDC to build greater capacity and augment its current awareness, outreach, and screening efforts in order to more effectively reach and serve all at-risk populations.”

The two professional societies declined to sign the letter largely because it lacked detailed justification for the increase, sources said.

In another battle, ASCO officials and patient groups challenged ACS on its lobbying effort over the Patients’ Bill of Rights. ACS urged Congress to mandate that private health insurers cover routine care costs for patients enrolled in clinical trials for all serious diseases, as opposed to just cancer clinical trials.

Sources said ACS inserted the following language into a letter from the National Health Council, a coalition of voluntary organizations, to members of a conference committee reconciling the House and Senate versions of the Patients’ Bill of Rights: “We also strongly urge you not to limit coverage to clinical trials related to cancer. Limiting coverage to one disease is not in the best interests of scientific discovery.”

This language surprised ASCO and patient advocacy
groups.

Though these groups support broader coverage, as a practical matter, they have advocated a narrower proposal mandating cancer clinical trials coverage by Medicare, in a demonstration project. The Medicare legislation is proposed by Sens. Connie Mack (R-FL) and Jay Rockefeller (D-WV) and Reps. Nancy Johnson (R-CT), and Benjamin Cardin (D-MD).

“How can we continue to justify cancer-specific relief in Medicare bills—which have a very real chance of succeeding—when we are at the same time saying cancer-specific coverage is not acceptable in the private sector?” ASCO president Joseph Bailes wrote in a Feb. 28 letter to Seffrin.

“If we are not careful, we will lose the support of some of the very best friends in Congress that cancer has ever had, including Sen. Mack and Rep. Johnson,” Bailes wrote. “This position risks substantially undermining the efforts of the entire cancer community to achieve coverage for cancer clinical trials.”

Two days later, 12 patient groups belonging to the Cancer Leadership Council similarly challenged Seffrin. “We fully endorse coverage of patient care costs for all serious and life-threatening diseases, but are not prepared to accept that coverage of cancer trials should be put on hold until that larger goal is achieved,” the patient groups wrote.

Responding to the ASCO letter, Seffrin said the Society’s position was misunderstood. “We would hope that Congress enacts legislation that provides the widest possible coverage for clinical trials, including cancer trials,” Seffrin wrote in a letter dated March 4.

“To this end, we have continued to advocate that broad language be included in the legislation emerging from the managed care conference committee,” Seffrin wrote. “It is this position which has likely been the source of the misunderstanding. The language in the National Health Council letter attempts to articulate the position that a broader, rather than a narrower cancer-only provision, should be adopted.”

To dispel possible confusion on Capitol Hill, ACS sent out a three-page letter to members of the conference committee reconciling the House and Senate versions of the Patients’ Bill of Rights.

**CDC Contribution To National Dialogue Raises Questions About Ties With ACS**

(Sept. 1, 2000, Vol. 26 No. 34)

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 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.

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.
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 pre-selection 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 naive,” 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 “Health, Outreach, Prayer and Education.”
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 office. 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 co-chairmen 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 contolling 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. 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 website 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 committee-sponsored 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.”

ACS Defends Dialogue,
Calls Story "Misleading"


In internal communications, officials of the American Cancer Society and the National Dialogue on Cancer said a recent article in The Cancer Letter made assertions that were “patently false to the degree that they do not merit a formal response.”

The communications, which responded to a story published in the Sept. 22 issue, were circulated to the society’s senior employees and participants of the Dialogue, an ACS-funded effort to develop an overarching cancer agenda.

“In one of the two memos, LaSalle Leffall, chairman of the Dialogue’s Steering Committee, said the story ‘is built on a good deal of speculation, grossly misleading, and less than credible.’

“One of almost 100 national organizations that make up the National Dialogue Cancer, the American Cancer Society was targeted once again in this issue of The Cancer Letter,” Leffall wrote in the memo dated Oct. 10 and addressed to Dialogue participants.

“Given the valuable work we are all doing for and with our own entities, the millions of prospective cancer patients and hundreds of thousands of cancer survivors we are dedicated to serve, it is my hope that The Cancer Letter and all other similar documents will find it possible to get behind and support our collective efforts in order that we might reach our ultimate goal at the earliest possible time,” Leffall wrote.

Leffall’s memo was circulated with a memo from Harmon Eyre, the ACS chief medical officer. Copies of the two documents were obtained by The Cancer Letter.

“These memos fail to point out specific errors in the story,” said Kirsten Boyd Goldberg, publisher of The Cancer Letter. “The story was well-reported and accurate. We stand by it.”

The story, which is posted on The Cancer Letter web site (http://www.cancerletter.com/headlinenews.html) reported that:

—Centers for Disease Control and Prevention recently gave a $100,000 grant to the ACS to support the Dialogue. Citing legal opinions, the story said the contribution raises questions about some of these funds being used for lobbying.

Government agencies are prohibited from lobbying. The Dialogue, which is not a legally defined entity, operates a spin-off committee that is developing a plan for rewriting the National Cancer Act. The two entities are not completely isolated from each other, and are funded
primarily by ACS.

Legal experts quoted in the story pointed to a structural problem: the apparent absence of a firewall separating the legislation committee from the Dialogue.

—The CDC contribution to the Dialogue was added to a multi-million-dollar sole-source grant. Citing assessments from public health experts, the story argued that the work done under this grant could have been performed by other entities. At least one project funded through the agreement would have been unlikely to survive peer review, experts said.

—The relationship and financial dealings between CDC and ACS are significant because ACS has been a persistent lobbyist for the Atlanta-based government agency, and since the leaders of the cancer legislation committee publicly called for the elevation of the agency’s status and budget.

—The rewriting of the National Cancer Act as well as the activities of the Dialogue on Cancer are being carried out behind closed doors.

In a memorandum addressed to senior management of the ACS national office and chief executives of the society’s divisions, Eyre said the society has not “redirected federal funds to support inappropriate lobbying activities.”

“Of course, these assertions are patently false to the degree that they do not merit a formal response,” Eyre wrote. “However, knowing that you might receive inquiries about this matter, I felt it important to share a few important facts for the record.”

Eyre’s memorandum states:

—“The ACS has tremendous interest in the collaborative power of the Dialogue with its 125 member organizations. The ACS also participates in NCLAC, which is a separate and distinct effort to bring together a diverse group of organizations and individuals in the cancer community. NCLAC exists to evaluate the wide variety of policy options lawmakers could consider to help advance the fight against cancer. To that end, the ACS has agreed to provide source funding to both organizations. However, the Society has created separate financial project numbers for expenses related to each initiative, as well as separate budgets and funding sources. No CDC grant funds received by the ACS has been used to support NCLAC.

—“The two projects are staffed by different teams of Society executives. I manage our involvement in the National Dialogue on Cancer, with assistance from Allan Erickson, who serves as a consultant on this special project. The NCLAC project itself is managed by independent consultants, and our involvement comes through our national government relations team under the direction of National Vice President Dan Smith.

—“As a recipient of government grants, the ACS is required annually to have these grants audited by an independent accounting firm. The independent auditors insist upon full compliance with the government grant management process. The National Home Office has a finance team staffer dedicated to the tracking, reconciliation and overall management of these federal grant funds.

—“Perhaps most importantly, the CDC will not reimburse the Society for the use of the grant monies in question until after they have been spent—and spent on the purpose for which they were specifically intended. The CDC requires rigorous documentation of the way in which grant dollars are spent before it will release funds; and only then will release the dollar amount that was actually spent, even if that amount is less than the amount of the grant.”

The memorandum emphasized accounting structures and did not address the question of propriety of the sole-source cooperative agreement between CDC and ACS or the question of appropriateness of developing the National Cancer Act in closed meetings.

The memorandum offered no discussion of a project that gave ACS $300,000 last year to develop and carry out health information campaigns.

These campaigns disregarded evidence-based methods for designing health messages, failed to define target populations, and did not monitor outcomes, public health experts said.

Bushes Restate Commitment To Dialogue

In a letter to participants of the National Dialogue on Cancer, former President George Bush said he and former First Lady Barbara Bush remain committed to the initiative to develop an overarching cancer agenda.

“Although we have been distracted a time or two lately by current events, Barbara and I have been carefully watching the progress—including many positive changes—of the National Dialogue on Cancer,” Bush wrote in a letter dated Oct. 16. “This letter is simply to let you know that we are still with and behind you every step of the way as we work toward our mutual goal: to control cancer as a major public health problem at the earliest possible time.”

The Dialogue, which has no legal structure, has spun off a committee, which is working on a plan for writing a new version of the National Cancer Act. Both entities are funded by the American Cancer Society and operate behind closed doors.

In a recent article, several legal and public health experts raised questions about appropriateness of a recent $100,000 grant given by Centers for Disease Control and Prevention to ACS for the operation of the Dialogue.

The amorphous relationship between the Dialogue and the legislation committee make it unclear whether CDC funds would in fact support lobbying. Legal and public health experts also raised questions about the appropriateness of a multi-year sole-source cooperative agreement that funded $850,000 worth of ACS projects

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over the past year. CDC is a major beneficiary of ACS lobbying (The Cancer Letter, Sept. 22).

In a memorandum to senior staff, ACS officials said its accounting procedures ensure that CDC funds are not used for lobbying and are properly spent. Another letter, addressed to Dialogue participants said The Cancer Letter story was “built on a great deal of speculation, grossly misleading and less than credible information” (The Cancer Letter, Oct. 20).

The Dialogue, which has about 125 participants, has held no meetings since last March, and is scheduled to meet again on Dec. 2.

“Since we last met in March, we’ve heard about many, many examples of collaboration within the cancer community that may well not have happened were it not for NDC,” Bush wrote. “That in itself is a huge accomplishment that we can all be proud of.”

The letter repeatedly urges Dialogue participants to attend the next meeting:

“Hopefully, when we meet on Dec. 2 in Washington, we will be able to continue our progress by focusing on two of our more pressing issues. Every single one of you needs to be involved in that decision-making process and then, based on your area of expertise, take an active role in how the decisions are executed. That is why it’s very important you make every effort to be with us at our meeting on Dec. 2.

“Barbara and I have come away from every single Dialogue meeting with a feeling of accomplishment and also pride in being associated with such a dedicated group of people. We have a lot of work to do, but the Dialogue has brought together the right group of people at the right time to get the job done.

“We’ll see you in December.”

DeVita, Seffrin Present Cancer Czar Plan To Feinstein, Without Committee Sign-Off

(The Cancer Letter, June 1, 2001, Vol. 27 No. 22)

The co-chairmen of the American Cancer Society-funded effort to rewrite the National Cancer Act recently presented a blueprint for a fundamental change in the management of billions of dollars the federal government spends on cancer, documents show.

The plan presented to Sen. Dianne Feinstein (D-CA) by Vincent DeVita and John Seffrin, chairmen of a committee advising the Senator on rewriting the 1971 law, would displace NCI as the lead agency in the cancer program.

Under the plan, authority over the program would pass to a 20-member commission that would include heads of government agencies that deal with cancer, and representatives of advocacy groups and the private sector. The commission’s director, who would be appointed by the President and confirmed by Congress, would, in effect become the federal Cancer Czar, a post similar to the Drug Czar.

Documents show that DeVita and Seffrin presented the proposal to Feinstein before obtaining approval of the National Cancer Legislation Advisory Committee, the group formulating a “white paper” for the proposed law. Seffrin is the ACS chief executive, and DeVita is the director of Yale Cancer Center and former NCI director.

NCLAC members learned about the Feinstein briefing on May 10, more than a week after it took place, when a document titled “Briefing Background For Honorable Sen. Dianne Feinstein, May 2, 2001,” was emailed to everyone on the committee.

Though six NCLAC members objected to what they described as a premature briefing, their objections may be moot. In an email addressed to NCLAC executive director Rebecca Kirch and a select group of committee members, DeVita indicated that Feinstein “already approved” the plan.

In the email, dated May 20, DeVita described the formation of the commission as “the one thing most needed, an effective mechanism for overview.” DeVita declined to speak with a reporter.

The DeVita-Seffrin plan would make the following changes in the cancer program:

—Currently, the NCI director serves as head of the National Cancer Program. The structure proposed by DeVita and Seffrin would place the Cancer Czar above the NCI director, thereby downgrading research to the status of just one of the constituencies of a broader program.

—The proposed structure would be likely to threaten NCI’s existing “bypass” budget authority, which allows the Institute director to go over the heads of the NIH director and HHS secretary to inform the President about research opportunities in cancer.

—Under the DeVita-Seffrin plan, the National Cancer Advisory Board, which advises the NCI director on the implementation of the cancer program, would become an institute council. Unlike members of other NIH institute councils, NCAB members are appointed by the President.

—The President’s Cancer Panel, a group that advises the President on obstacles to progress in the war on cancer, would be abolished, and the National Cancer Policy Board, a group funded by NCI, but operated by the Institute of Medicine, would become a resource to the new commission and the Cancer Czar.

—The new 20-member board, which would be called the National Cancer Council or National Cancer Commission, would “set government-wide goals” and “review and comment on cancer budgets of cancer programs,” the document states.

—This new entity would be similar to the Office of National Drug Control Policy, and the Council on Environmental Quality, the document states. Heads of these agencies are the principal White House advisors in their areas. The drug control agency, and its director, the Drug Czar, coordinates federal, state, and local anti-drug
programs, runs counter-drug technology assessment programs, and programs aimed at cutting the supply of drugs and their use. The director of the environmental council coordinates federal environmental programs, and intervenes when agencies clash over environmental assessment.

—If the proposed cancer council and the Cancer Czar are able to influence the allocation of funds in the President’s budget proposal, the new administrative structure could become more vulnerable to political manipulation. Money could be shifted from NCI, where it is distributed through peer review, to agencies like Centers For Disease Control and Prevention, which uses block grants to states. While peer review is usually immune to pork barrel politics, block grants are not protected from mandates and other forms of interference.

—Unlike the White House environmental council and the Drug Czar’s office, the new government entity would engage advocacy groups and industry representatives in policy-setting roles. This would be unprecedented in the federal government.

ACS would be well positioned to place its representatives on the policy-making commission. Also, the Society would be represented through its common interests with CDC, its Atlanta neighbor. Lobbying for CDC has emerged as the principal thrust of ACS efforts in Washington in recent years. CDC has awarded the Society a sole-source, multi-year cooperative agreement (The Cancer Letter, Sept. 22, 2000).

The central controversy in this debate is as old as the National Cancer Act: a clash between advocates of research and advocates of public health interventions. Advocates of interventions argue that quality cancer care does not reach all Americans equally.

“I find it incredibly important that we look at going to linkages, so we can pass the baton from science to its application in the community,” said NCLAC member Armin Weinberg, professor at Baylor College of Medicine and co-founder of the Intercultural Cancer Council.

Advocates of research urge caution in the design of such linkages, arguing that a firewall should protect funds devoted to peer-reviewed research, and that the cancer program should be driven by science—and therefore by NCI.

“Majority is Usually Enough in a Democracy”

NCLAC was expected to complete its white paper early this year. However, the process dragged on, and the issue of oversight for its plans was not addressed in detail. At a committee meeting last April, DeVita asked for volunteers to design an oversight structure. Several hands went up, and the group got together once on a conference call, where NCLAC member Paul Calabresi, professor of medicine at Brown University, was asked to write the work group report.

Documents obtained by The Cancer Letter indicate that no written report existed at the time of DeVita’s and Seffrin’s presentation to Feinstein.

NCLAC members learned that the briefing had taken place when they received the one-page background document in an email from Calabresi. The May 10 email described the document as “an outline prepared by Vince DeVita for his presentation to Sen. Dianne Feinstein, which I heard was extremely well received.”

Refraining from comment on the recommendations, Calabresi diplomatically described the briefing document as “an excellent format for a report,” and invited the members’ “contributions to provide supporting data for this proposal.”

After Calabresi distributed the document, at least six members voiced objections to what they described as a premature presentation. These letters were written by Anna Barker, president and CEO of Bio Nova Inc., a Portland biotech firm; Joan Brugge, professor of cell biology at Harvard Medical School; John Glick, director of the University of Pennsylvania Cancer Center; Ronald Herberman, president of the Association of American Cancer Institutes; Ellen Sigal, chairman of Friends of Cancer Research; and George Vande Woude, director of Van Andel Institute of Grand Rapids, MI.

In a May 20 email to Kirch, copied to Seffrin and Calabresi, DeVita noted opposition from Sigal and NCI.

“Ellen saw to it that anything like that was taken out of past studies to suit the needs of one person,” DeVita wrote in an apparent reference to NCI Director Richard Klausner, who opposes diluting the research emphasis of the cancer program.

In the email, DeVita urged Calabresi to stand by the recommendations. “Paul, I hope you will wind up the committee report unaltered,” DeVita wrote.

Two days later, on May 22, DeVita explained to a wider group of NCLAC members that the briefing in question was requested by Feinstein, and that the Senator had specifically asked about the subcommittee’s recommendations.

“I explained what the committee had discussed, and the direction of the final report, but we were clear to make it an incomplete ‘work in progress,’” DeVita wrote to committee members.

In another widely circulated email that day, DeVita wrote that the controversy would be resolved democratically—by a vote.

“I have never felt that consensus and unanimity were the same,” DeVita wrote. “I have never believed that we would achieve unanimity of opinion on all these difficult issues.

“Majority is usually enough in a democracy,” he wrote.

Sigal agrees that the controversy should be resolved through NCLAC. “I am deeply opposed to the proposed commission, which puts politics—not the NCI director—at the helm of the cancer program,” Sigal said to The Cancer Letter.
Cancer Letter. However, Sigal said the DeVita-Seffrin proposal was preliminary, and did not merit coverage.

“I believe this story generates more heat than light, because the proposal to establish a commission has neither been fully discussed nor vetted by NCLAC,” Sigal said. “Reporting speculations rather than facts only fuels divisiveness in an already fractious cancer community, which spends too much time beating up each other, rather than beating the disease.”

**Why NCLAC?**

It is unclear how the principles of democracy apply to NCLAC. Even the words “advisory committee” in the committee’s name are misleading. NCLAC has no charter, and since it is funded by charity funds raised by ACS, the committee is exempt from open meetings requirements that apply to government-funded groups.

The committee operates entirely behind closed doors.

ACS officials describe the committee as an offshoot of the National Dialogue on Cancer, a Society effort to develop an overarching cancer agenda. However, ACS officials are always quick to point out that NCLAC and the Dialogue are separate entities.

The committee’s formation was announced to Dialogue participants in August 1999, as were the names of the co-chairmen.

The intricate, related-yet-unconnected structures of the Dialogue and NCLAC were put in place by the consulting group Shandwick International. Shandwick was fired by ACS after *The Cancer Letter* reported that the firm also represented R.J. Reynolds Tobacco Holdings Inc. (*The Cancer Letter*, Jan. 21, 2000).

NCLAC has assembled a group of 25 members, many of them individuals respected in cancer research, cancer care, and advocacy. The committee has held many hours of hearings, and examined a wide range of documents.

Now, the committee members will be asked to cast their votes, and, technically, 13 votes may be enough to give weight to legislation. However, NCLAC member Calabresi said he would prefer to develop a plan that would generate wide acceptance.

“We should get the writing committee together to come up with a plan that would offer one or several options for coordination, and this ought to be brought to the entire group for discussion,” said Calabresi. “This should be something that Rick Klausner, and the scientific community, and the advocacy community, and the medical community would agree with.

“My feeling is that there should be a great-majority consensus,” Calabresi said. “If NCLAC came out with a 13-12 plan, it wouldn’t be very effective.”

If the DeVita-Seffrin plan survives, it will end up in the “white paper” that would be used in the drafting of a bill. If the proposal dies, it may still end up in the bill, especially if Feinstein has indeed “already approved” it.

A spokesman for Feinstein was unable to comment on the Senator’s position on the plan by press time.

**Plan Consistent With Earlier Statements**

The recommendations presented by DeVita and Seffrin are consistent with their earlier public statements.

In an address to the President’s Cancer Panel in December 1999, Seffrin made repeated references to the NCLAC product as the National Cancer Control Act. The new law would be based on two principles, he said.

First, coordination of cancer programs isn’t what it needs to be, and, second, “we need, at the highest levels, to get all three sectors together around a common table,” Seffrin said to the panel (*The Cancer Letter*, Jan. 21, 2000).

Two months later, in an interview with Yale Bulletin and Calendar, DeVita provided a more detailed description of the plan.

“The issue has come up of establishing a National Cancer Authority of some sort,” DeVita said in an interview published Feb. 4, 2000. “For example, the Centers for Disease Control would handle a lot of the cancer control of the plan.

“You could see a scenario where 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 (*The Cancer Letter*, Sept. 22, 2000).”

This “anxiety” has been gaining intensity in recent months, as the Bush Administration has made it a priority to fund biomedical research at NIH, while cutting some health programs.

In the budget proposal for fiscal 2002, NIH is slated to receive a 13.5 percent increase, while CDC is cut by 3 percent. The most severe cut—23 percent—affects the principal beneficiary of ACS lobbying, the CDC Chronic Disease Prevention and Health Promotion Program.

**Administration Support For NIH, Klausner**

Funding research at NIH is a matter of strategy for the Administration, said HHS Secretary Tommy Thompson as he discussed the budget proposal at a recent press conference.

“This whole budget, with NIH leading it, is going to have some real breakthroughs in the near future,” Thompson said (*The Cancer Letter*, April 13). “There are encouraging signs coming out of NIH and the scientific community of breakthroughs that I happen to be very excited about, and I hope you are, and I know the President..."
Peer-reviewed research is a good investment, Thompson continued. “To me, that is going to be one of the best things that we can do to control health costs in the future,” he said. “If you have a breakthrough in one of these diseases, it’s going to hold exponentially the health care costs.”

Thompson has been consistent in expressing support for NCI Director Klausner.

“In my months at HHS, I’ve come to greatly appreciate Dr. Klausner and his fine stewardship of NCI,” Thompson said at a May 25 meeting of the President’s Cancer Panel. “He is a valued member and partner and friend of all the HHS team.”

Thompson said he recently stopped formal participation in the National Dialogue on Cancer, which he joined as Wisconsin governor. After he took over HHS, Thompson was advised by attorneys that his continued formal participation would be inappropriate.

“I was a member of the Dialogue until my attorneys told me I had to resign,” Thompson said. “But I still go to the meetings.”

Feinstein Slams Cancer Act Proposal, Calls White Paper Vague And Unrealistic

(October 19, 2001, Vol. 27 No. 38)

A rollout of the long-awaited report of the National Cancer Legislation Advisory Committee lost its celebratory spirit when Sen. Dianne Feinstein (D-CA), the patron of the effort to rewrite the National Cancer Act of 1971, said the committee’s 12 recommendations were vague, unrealistic, and not prioritized.

“When you get down to the actual recommendations, they get pretty vague, in terms of what we are used to, which is a piece of legislation that costs X, that does Y, within Z amount of time,” Feinstein said at a hearing of the Senate Cancer Coalition Oct. 10.

The panel’s recommendations to fund NCI at the Bypass Budget level and extend Medicare coverage to all cancer patients were unrealistic, Feinstein said.

Urging the cancer groups to formulate a consensus plan, Feinstein said, “I need the cancer community to be in agreement with it. Otherwise, I have to fight the fights with each of you, and I don’t have the time to do that. So, if there is a unified—even if it’s a four-pronged plan—but in your options... it’s such a big grab bag, that it’s almost impossible to cope with it all at one time.

“I haven’t been able to cope with it,” Feinstein said at the hearing.

Several observers said they were surprised to hear Feinstein express her criticism in an open meeting. After all, the committee held its meetings in Feinstein’s conference room, and the Senator’s staff members worked closely with the panel as it developed the white paper.

There is no question that Feinstein had ample opportunities to express her frustration privately. Public criticism may represent a dramatic turnaround for the Senator who has been the chief proponent of the American Cancer Society-funded effort to rewrite the National Cancer Act and place a greater emphasis on interventions.

In fact, it was Feinstein who initially suggested rewriting the 1971 legislation. At a meeting of the leadership of the National Dialogue on Cancer, another ACS-funded initiative, Feinstein asked for what she described as a “specific battle plan.” Feinstein is the vice chairman of the Dialogue. George and Barbara Bush are chairmen of the ACS-funded effort to create an overarching platform for all cancer organizations.

According to detailed notes taken by an individual present at the Dialogue steering committee meeting Nov. 10, 1998, at the George Bush library at College Station, TX, Feinstein urged the cancer groups to come up with specific recommendations for the new cancer legislation.

“Sen. Feinstein... stressed the need for clear goals and a specific battle plan,” the notes state. “Without such specificity, it will be very difficult for national policy makers, such as herself, to make a clear case for increased support.”

It appears that Feinstein expected the report to cover a wide range of issues. “She discussed the need for national strategy to increase investment in research and clinical trials, improved support for investigators and educational programs, mechanisms to address quality of care and patient protections, and better ways of addressing issues of the poor and the underserved,” the notes state.

In the summer of 1999, Feinstein formally named ACS Chief Executive John Seffrin and Yale Cancer Center Director Vincent DeVita as co-chairmen of the advisory committee (The Cancer Letter, Jan 21, 2000). Other members of the committee were picked by Seffrin and DeVita.

Feinstein and her staff kept close watch on the process. At one point, the committee presented an earlier version of the report to the full meeting of the National Dialogue on Cancer in an effort to build that group’s support for the legislation effort. ACS and Dialogue officials describe NCLAC as a spin-off of the Dialogue (The Cancer Letter, March 17, 2000).

NCLAC is unlike any other advisory committee in the U.S. government. The group is advisory to Feinstein alone. Since it’s funded by ACS, the panel is exempt from the Senate’s open meetings rules, which made it free to meet behind closed doors.

Last spring, in a move that generated great controversy, DeVita floated a proposal to create a White House level office of the Cancer Czar. An e-mail from DeVita indicated that the plan was formally presented to Feinstein, and that she agreed with it (The Cancer Letter, June 1).

**Hearing Begins On Congratulatory Note**

Feinstein began the Oct. 10 hearing by lavishing praise on the committee.

“Today, I salute you, the members of this advisory committee, 21 experts who worked so hard, who labored many long hours—for your dedication and vision and for preparing this report,” Feinstein said in a prepared statement. “I know the American people will thank you.”

In her remarks, Feinstein drew on the optimistic view advanced by the American Cancer Society and the National Dialogue on Cancer that the cure is around the corner. “I now believe that in my lifetime we can find a cure for cancer,” Feinstein said.

These advances require that the cancer program should be broadened beyond research. Feinstein said. “Along with the scientific advances, we must move ahead on all the other fronts that this report presents: translational research, training of researchers and a cancer workforce, accelerating drug approvals, access to care, quality of care, preventing cancer.”

Following this salutation, the five-member panel presented the NCLAC vision of the cancer program of the future.

In addition to Seffrin and DeVita, the panel included Anna Barker, president and CEO of BIO-NOVA, an Oregon-based biotechnology firm and an activist with the National Dialogue on Cancer and the National Alliances for Cancer Research; George Vande Woude, director of the Van Andel Institute of Grand Rapids, MI; and Amy Langer, executive director of the National Alliance of Breast Cancer Organizations.

In his testimony, Seffrin said the expansion of the cancer program must proceed despite America’s new priority, the war on terrorism.

“Taking our lead from the President and Congress, we will not be deterred from our important work,” Seffrin said. “The members of NCLAC have responded to the recent events with a renewed sense of purpose to our goal of preserving and protecting human life.

“It is in that spirit that we submit to you NCLAC’s final report,” Seffrin said.

**Feinstein’s Lament**

After the panel members presented their prepared statements, Feinstein’s tone became less congratulatory.

“I’ve spent a considerable amount of time going over these recommendations, and let me tell you what I think,” she said. “The cancer community is enormously contentious and territorial. It’s very difficult to pull people together, and get everyone on one sheet. Because they all have specific interests. I am not saying they are bad interests. But there is a natural competitiveness. When you get down to the actual recommendations, they get pretty vague, in terms of what we are used to, which is a piece of legislation that costs X, that does Y, within Z amount of time. If you came in, for example, with a recommendation that, based on need, we believe there should be 750,000 research grants specifically directed for research in these areas of X amount for X period of time, it’s something specific that we can assess cost effectiveness of.”

Feinstein said she had trouble interpreting the report’s recommendation to enhance the NCI Cancer Centers Program, turning it into a network of “translational centers” that would emphasize clinical research, spearhead clinical trials, and develop partnerships with the private sector.

“It’s hard for me, when you say, set up these translational centers,” Feinstein said. “I don’t know how many. I don’t know what the cost is. It’s a vague kind of concept out there.”

DeVITA: “It’s easy…”

BARKER: “Twenty. Allocate $1 billion. Fund 20. And pay some attention to geographic distribution.”

FEINSTEIN: “But are these private sector centers?”

BARKER: “They are combinations. I think you are going to have to give these centers enough resources to build the public-private partnerships in areas like drug development or device development, but it’s a different sort of paradigm than we are currently dealing with in cancer centers. They will not all be translational centers. Let’s say we start with 20, and it’s not going to be cheap.

“These are doing preclinical development, devising the animal models. We don’t have animal models that are predictive for human cancer. We have very few things that are predictive for human cancer.”

FEINSTEIN: “Wouldn’t it be better to say, all right, we will create a grant program of X to go to institutions either in the public, such as university systems, or in the private sector, for those who will develop these centers, provide the basic guidelines for these centers, but to say that federal government should go out there again with brick, mortar, people?”

BARKER: “I don’t think we are talking about bricks and mortar. No bricks and mortar. Just basically, exactly what you just said: empower NCI, give them the funds, but set this up as something that would be different and new in terms of pulling together resources for translational research. That could be virtual, actually.”

Sen. Sam BROWNBACK (R-KS), the second member of the two-member Senate Cancer Coalition: “My only question, as we hope to put legislation forward is when… When is it that if we do those things by X date, we really should be able to look and say that these types of cancer [are] no longer [a threat.] We work best when we shoot at targets. When do we get the product?”
DeVITA: “May I address the issue of centers again. We have a centers program. I am a center director. Leland Hartwell, who won the Nobel Prize is a center director. It’s $150 million a year, period, which is woefully inadequate to do what Anna Barker has suggested.

“But it does provide the structure to build on to make these new centers of the future. It’s running on the program structure that was invented in 1970, and is no longer accurate today. It would not be an insuperable task to take the existing product and reshape them into the product that we talk about in the report, and we could also do the necessary accounting to come up with the actual cost. It’s there, it’s just that we didn’t feel that we were in a position to do that.”

FEINSTEIN: “I am going to ask you to go to the next step. Sit down and say, okay, we need a medical school repayment of debt program. A stipend program for X years for X number of research scholars, costing X, and present it in that form, so it is tangible.

“Okay, cancer screening today—we spend $175 million and we cover 12 percent of women. We’d like to raise that to 20 percent. Here is the cost, and here is how we would do it. Now, this is concise, it’s specific, instead of vague. If you are really serious about extending Medicare to cover cancer—I have no idea what we are talking about.

“I wouldn’t get out on a limb and say that. I don’t know how to pay for it, either. That’s where we have to take this next, because I have now been through this four or five times.

“Each time, I got more questions. Each time they appear to me more vague and more difficult to deal with in the practical terms that we need to deal.

“Let’s say you have four compartments, and the total is X, and you look at the doubling over a period of time—you go over the budgets—and find out that isn’t enough, then a methodology for funding the remainder. This is really what I need for the next step.

“I need the cancer community to be in agreement with it. Otherwise, I have to fight the fights with each of you, and I don’t have the time to do that. So, if there is a unified—even if it’s a four-pronged plan—but in your options... it’s such a big grab bag, that it’s almost impossible to cope with it all at one time. I haven’t been able to cope with it.”

DeVITA: “This is a cost-accounting job. It can be done. We didn’t feel, and I don’t feel, that the committee was constituted to be able to do that themselves. It’s not a difficult task.

“In fact, it’s an easier task than what we had to go through. Sit down, and take these programs, and do the cost-accounting, using vehicles Congress has its disposal to tell us how much it would cost if Medicare was extended to all the cancer patients.

“That could be done. It’s a task that should be done. All of us feel that way. It’s just that it should be done in a slightly different way than the process that we went through.”

FEINSTEIN: “And I will tell you what will happen. Then you will have diabetes, which is a huge problem out there... it’s difficult. And you will have virtually every other disease and saying, you are doing it for them, do it for us as well.

DeVITA: “You know, my own feeling about that is... cancer is different. Cancer is life. When you understand cancer, you understand how the process of life developed. The whole developmental biology has derived all the information from cancer research. It’s a different disease.

“Also, it’s the most feared disease in the minds of the American people. While we should attack all health problems, it does not seem to me to be illogical to tackle cancer and show how it’s done, and then go on from there. The report from Funding First, which is a stunning report, [states] that if we reduce cancer mortality by 20 percent, we will bring $10 trillion into the economy.”

FEINSTEIN: “I know that, but after you’ve said that, we all want to do it. The question is how? You know, I’ve thought a lot about it, and I keep coming back to Ground Zero. How do you put something together that’s practical... And I will tell you, the minute you go to Medicare, I know what’s going to happen...”

SEFFRIN: “The question ought to be asked, though... The numbers could be run, and one might be shocked to find out what benefits could be derived... We have to acknowledge that how cancer develops is no longer a mystery. It was, in 1971, by-and-large. We don’t have all the answers. But we have many, many answers, Sen. Feinstein, that are not now being applied. That’s wrong.

“We know that research is not a good bet anymore; it’s a sure bet.

“We can’t name the day, and the week, and the month, and the time, but we—NCLAC—can offer a virtual guarantee that if we redouble the nation’s commitment to biomedical research, the return will come. We can also say that the gaps are growing. And this is why it becomes such an extraordinarily important systems and public policy issue.

“We can say that more people were saved from cancer last year than ever before because of progress. The NCLAC report—the 12 goals—are very ambitious. And one can take one goal at a time, one sub-piece of one goal, or you can take the whole thing, and look at the omnibus approach. It does take a lot of fleshing out.

“We all agree with that. There are second and third steps. But as a first step, we haven’t come up with a battle plan you asked for earlier, but at least we have a battle outline of the kind of things that ought to be done.”

FEINSTEIN: “Well... Let me... I’ve got to... I have other commitments, but... is this in priority order? Now, realistically, the Bypass Budget is how much this year?”

BARKER: “$5.02 billion.”

FEINSTEIN: “Realistically, it’s not going to happen.”
BARKER: “Right.”

FEINSTEIN: “You have to be realistic. $4.1 billion in 2002. If we hang on to that, we will be doing well. But if those things that are clearly on this list of 12, if you could put together two or three and cost it out, maybe we could proceed along the lines of some of those...

“Right now, Medicare is very difficult. Because, as you know, we are going into the red downstream. And I doubt very much that there is a willingness to take on more. I am not going to delve into the Sept. 11 aftermath. But I think that within this amount that we are increasing, if you could put together programs that would strengthen research, that would better coordinate care—those kinds of things—they would be very well received.

VANDE WOUDE: “I would encourage funding of the Bypass Budget, which is a consensus document. I am especially concerned about what would happen in 2004, when the plateau [occurs], and how we can prepare for that.

“There was some understanding that the Bypass Budget would become a vehicle for sorting out what areas we can exploit, what needs to be done. That would be a great benefit to the research community. Our investment in research is a continuum. We can’t have shortfalls and then hope to recover from them in a short period of time. So, let’s insure that research—which in principle the process by which the promise of tomorrow for cancer and treatment comes from—really has to be supported.”

FEINSTEIN: “Well, let me say, you’ve given 12 areas, all of which need further exploration. Any help you can provide in that exploring will be appreciated. And I just want to thank you so much for the tremendous effort.

“I recognize that.”

Bush Appoints Andrew von Eschenbach, Of M.D. Anderson, As 12th NCI Director


President Bush this week appointed Andrew von Eschenbach, a surgical oncologist and two-time cancer survivor, to lead the National Cancer Institute.

A specialist in prostate and urologic cancer, Von Eschenbach was director of prostate cancer research at University of Texas M.D. Anderson Cancer Center. He also directed the Genitourinary Cancer Center at M.D. Anderson and served the center as vice president for academic affairs, executive vice president, and chief academic officer.

“Andy von Eschenbach is one of America’s finest medical researchers,” Bush said in prepared remarks for the announcement at the White House on Dec. 7. “He understands that basic research is the foundation to any success in eliminating cancer, and that research breakthroughs must be translated into effective treatments for patients. Andy also understands personally the importance of our war on cancer. He will bring to his new position not only expertise and talent and dedication, but compassion for for the millions of cancer patients and their families who are struggling with this disease.”

Von Eschenbach, 60, becomes the 12th director of NCI and first surgeon to head the Institute since it began in 1938. He succeeds Clinton appointee Richard Klausner, who stepped down last September to become president of the Case Institute of Health, Science and Technology, based in Washington, DC.

Until this week, von Eschenbach was president-elect of the American Cancer Society, a voluntary position he resigned after accepting Bush’s offer. He was a founding member and leader of the National Dialogue on Cancer, an effort by ACS to bring cancer organizations together. The President’s parents, George and Barbara Bush, are honorary chairmen of the Dialogue.

Von Eschenbach also has been co-chairman of the National Prostate Cancer Coalition’s scientific advisory board since its inception in 1997, and served as chairman of the Prostate Cancer Research Integration Panel for the Department of Defense.

“Dr. von Eschenbach is one of the nation’s leaders in the battle against cancer,” said HHS Secretary Tommy Thompson. “I am extremely pleased to welcome his leadership at the NCI. I am confident that he will guide NCI to successes in the pursuit of discoveries in the biology, treatment, and prevention of cancer as well as continued progress in reducing the burden of this disease.”

Alan Rabson, who has served as acting NCI director since Klausner’s departure, will return to his position as deputy director.

Von Eschenbach said he plans to start his new job early next month. The appointment does not require confirmation by the U.S. Senate.

Marks 30th Anniversary of Cancer Act

In brief remarks at the White House, President Bush recognized the 30th anniversary this month of President Richard Nixon’s signing of the National Cancer Act, authorizing the NCI director “to develop an expanded, intensified and coordinated cancer research program.”

Since its signing on Dec. 23, 1971, while American forces were fighting in Vietnam, the Act has been popularized as the beginning of a “war on cancer.”

Thirty years later, with American forces involved in Afghanistan, it was inevitable that Bush would mention both shooting war and cancer war.

“Today our nation is in a war to defend our way of life,” Bush said. “But we’ve been engaged in a war to defend our quality of life for many decades. The war on cancer has been a top priority of medical and research communities, and it’s a top priority of this administration.”

Bush said that science stands “on the brink of amazing breakthroughs in cancer research, breakthroughs that will lead to new cancer therapies and, hopefully, to cancer cures.”
NCI’s Cancer Progress Report, released this week, contains “good news,” Bush said. “We’ve made substantial progress in the war on cancer over the past three decades. Advances in science to prevent, detect and treat cancer have directly contributed to an overall reduction in both new cancer cases and cancer death rates. The National Cancer Institute has provided the funding and the expertise to make many of these advances possible.

“We still have a long way to go,” Bush said. “Despite our victories, each day 3,400 Americans are diagnosed with some form of cancer, and more than 1,500 die from the disease. Almost every American family has been touched by cancer. But each new discovery brings hope. And the government can bolster that hope by funding vital medical research and by attracting talented people to conduct the research.”

NCI is guided by “several principles,” Bush said. “The Institute will fund and conduct aggressive, basic research in order to understand the fundamental nature of cancer. NCI researchers and clinicians will collaborate with other federal health agencies to translate advances in research into new tools to fight cancer. NCI will work cooperatively with other government agencies and with private organizations to expand research opportunities.

“Researchers and practitioners will not only strive to eliminate and cure cancer, but to help cancer survivors lead richer and fuller lives,” Bush said. “And the Institute will conduct research to help close the prevention and treatment gap for minorities who are disproportionately affected by cancer.”

Emphasizes Basic And Translational Research

In his remarks, von Eschenbach thanked Bush for “bestowing on me the greatest honor and responsibility of my life.”

“As the director of the National Cancer Institute, I will be devoted to nurturing and promoting the paradigm of discovery through basic research,” von Eschenbach said. “But we have recognized that scientific discovery, although essential, is not sufficient. We cannot rest until we translate our new understanding of cancer into interventions that will detect cancer, new drugs that will treat and even prevent cancer. Only then can scientific discovery result in saved lives and reduced suffering. And once discovered and developed, we must assure that these new interventions are delivered to patients and communities at risk.

“Discovery, development and delivery of state-of-the-art cancer care and control requires collaboration,” von Eschenbach said. “As NCI director, I am determined to support Secretary Thompson and our department’s effort to create collaborations among federal and state agencies, public and private institutions, cancer organizations and cancer survivors, groups that are crucial to accelerating the process from discovery to delivery.

“Working together one-on-one, or collectively, through entities like the National Dialogue on Cancer, we will discover, and we will assure state-of-the-art cancer care for all Americans, especially those who are bearing a disproportionate burden of this disease.

“To the more than 1 million Americans who are diagnosed each year with cancer and in remembrance of all those who have died of this disease, I pledge that we will not rest or yield until we have fulfilled the promise of eliminating the suffering and death caused by cancer,” von Eschenbach said.

“And in response to God’s abundant blessings on America, we will not do this for ourselves, but will reach out to share our gifts with all nations, and respond to the call to eliminate from the world the horror we call cancer.”

A native of Philadelphia, von Eschenbach earned his medical degree from Georgetown University in 1967. He completed residencies in general surgery and urology at Pennsylvania Hospital in Philadelphia, then was an instructor in urology at the University of Pennsylvania School of Medicine. He served as a lieutenant commander in the U.S. Navy Medical Corps. Von Eschenbach went to M.D. Anderson for a fellowship in urologic oncology in 1976 and was invited to join the faculty the following year.

In the early 1970s, von Eschenbach’s father died of prostate cancer, which influenced his decision to specialize in the disease.

Von Eschenbach was diagnosed and treated for a skin cancer in 1989, and two years ago, learned he also had prostate cancer. Both cancers have been successfully treated with surgery.

Von Eschenbach has contributed more than 200 articles, books, and chapters to the scientific literature. He is an editorial board member of four leading journals and serves on the board for the National Coalition for Cancer Research.

Described As A “Consensus-Builder”

Leaders of cancer advocacy organizations said they were pleased with the appointment.

“This is going to be a new and different NCI director,” said Richard Atkins, vice chairman of the National Prostate Cancer Coalition, who has known von Eschenbach from his involvement in prostate cancer research and the coalition’s scientific advisory board.

“Andy von Eschenbach is the best consensus builder I know and will do his best to unify the cancer community around crucial issues,” Atkins said.

John Seffrin, ACS chief executive officer, said the society will “greatly miss” von Eschenbach’s leadership.

“As the chair of our cancer control committee and numerous other posts within the Society throughout the years, Dr. von Eschenbach has proven his compassion and commitment to eradicating cancer as a major health threat here and now,” Seffrin said. “The National Cancer
Institute will do well by his leadership and passion.”

“During Andy’s tenure as part of the society’s national leadership, the society’s commitment to cancer research has grown substantially,” said Robert Young, the current volunteer president of the society and president of the Fox Chase Cancer Center in Philadelphia.

“We have recently announced 84 research grants, totaling $46,352,380 to begin January of this coming year,” Young said. “Furthermore we have worked hard to identify research areas where we could productively supplement the work of the NCI.

“I know that Dr. von Eschenbach will bring this same commitment to his new position and we stand ready to assist him in those endeavors,” Young said.

“Dr. von Eschenbach is an excellent choice,” John Mendelsohn, M.D. Anderson president, told the Houston Chronicle. “He’ll bring a breadth of experience—he’s a superb clinician, a thoughtful communicator and advocate for public education, and someone who understands both basic and applied research.”

Sen. Feinstein Introduces New National Cancer Act


Sen. Dianne Feinstein (D-CA) last week introduced the National Cancer Act of 2002, a bill intended to replace the 1971 document that began the federal government’s War on Cancer.

“This important legislation will form our new battle plan to fight cancer and help us find a cure,” Feinstein said. “The measure will: improve basic cancer research; create incentives for the transformation of that research into new, effective treatments; and prevent cancer when possible and improve the quality of care to patients.”

The bill, S. 1976, is a compendium of measures that include a restructuring of the cancer centers program, changes in coverage of cancer care, and FDA regulation of tobacco (The Cancer Letter, Feb. 22).

The legislation also authorizes a nearly 50 percent increase in the NCI budget over five years, starting at $4.8 billion in fiscal 2003, and ending with $7.1 billion in fiscal 2007. The measure was cosponsored by 29 other Senate members.

“The battle plan takes into account the advances that have been made in understanding the human genome, making it possible to move forward with a whole new series of drugs—such as Gleevec—that could stop cancer as the devastating disease that it is today,” said Feinstein. “I believe the promise of these drugs is now so bright that we might well be able to find a cure for cancer in my lifetime.”

The writing of a white paper that frames the foundations of the bill was funded by the American Cancer Society as an offshoot of another ACS-funded program, the National Dialogue on Cancer. The panel that wrote the white paper was headed by ACS chief executive John Seffrin and former NCI director and Yale Cancer Center Director Vincent DeVita.

Since the funding for the committee didn’t come from the government, the panel was exempt from the Senate’s open meetings rules and was able to meet behind closed doors throughout its existence. Feinstein is the vice chairman of the Dialogue, an ACS-funded effort to develop an overarching cancer agenda, and co-chairman of the Senate Cancer Coalition.

Feinstein said the goal of her legislation is to transform cancer into a fully treatable disease. “It is my hope that this legislation will become the rallying cry for the entire cancer community. In order for this bill to pass Congress, we need a united front,” Feinstein said. “I urge all Americans to rally behind this measure so that we can soon find a cure.”

The legislation would:

—Establish a network of at least 20 “translational cancer research centers” that would be distributed evenly throughout the US. The centers would be operated by “public or nonprofit private entities.” Their mission would combine basic and clinical research, and transfer technologies to private companies that would assume development and commercialization of discoveries made at the centers. Also, the centers would “develop and implement a plan expanding and disseminating the efficacious products of translational research to providers of cancer care in the region of the translational research center.”

According to the document, the program would require $100 million a year. It is unclear how the translational centers would affect the NCI-designated cancer centers, cooperative groups, and other programs.

—Private insurers would be required to reimburse patient care costs associated with clinical trials.

—The application of Orphan Drug Act would be broadened in the case of cancer drugs. Now, the act applies to cancer types defined by primary site. Instead, the incentives should be extended based on targets and mechanisms of pathogenesis of diseases, the bill states. This provision of the bill is unlikely to have significant impact since many cancers meet eligibility of the current law: 200,000 patients per year.

—Authorize a $100-million-a-year Health Resources and Services Administration program to pay the tuition of health care professionals, primarily nurses, who commit to providing cancer care to the underserved.

—Require private and government insurers to pay for cancer screening, smoking cessation, genetic testing and nutritional counseling. The screening would be based on ACS guidelines.

—Direct the Institute of Medicine to conduct a study of the costs and benefits of providing Medicare coverage to cancer patients who lack other insurance.

—Develop standards of quality of cancer care, Under
this provision, AHRQ would convene a panel of experts who would develop and disseminate consensus protocols and practice guidelines for optimal cancer treatments.

—Authorize Medicare and Medicaid to pay a bonus to physicians who manage the care of cancer patients. These physicians would act as “cancer quarterbacks,” the bill states.

—Authorize $65 million for the Centers for Disease Control and Prevention to provide grants to the states to prepare cancer plan. Altogether, 24 states have such plans. States would be able to use the CDC grants for linking cancer registries to environmental data bases, studying disparities in the access to appropriate care; and promoting cancer education and prevention.

—Give FDA the authority to regulate tobacco products. The bill doesn’t call for creation of an oncology center at FDA. The center, which was recommended in the white paper, would consolidate the agency’s handling of all oncology-related products.

The bill doesn’t include a plan for oversight of the new cancer program. Last year, the legislation committee apparently rejected a proposal to create a White House Office of the Cancer Czar (The Cancer Letter, June 1). That recommendation was not included in the white paper (The Cancer Letter, Sept. 28).

Cospromators of the Feinstein bill include: Sen. Gordon Smith (R-OR), and Senate Majority Leader Tom Daschle (D-SD), Jim Jeffords (I-VT), Kay Bailey Hutchison (R-TX), Hillary Clinton (D-NY), Olympia Snowe (R-ME), Barbara Mikulski (D-MD), Barbara Boxer (D-CA), Susan Collins (R-ME), Mary Landrieu (D-LA), Blanche Lincoln (D-AR), Patty Murray (D-WA), Lincoln Chafee (R-RI), Debbie Stabenow (D-MI), Maria Cantwell (D-WA), Jean Carnahan (D-MO), Robert Torricelli (D-NJ), Charles Schumer (D-NY), Ben Nelson (D-NE), Tim Johnson (D-SD), Jack Reed (D-RI), John Breaux (D-LA), Jon Corzine (D-NJ), Patrick Leahy (D-VT), Harry Reid (D-NV), John Kerry (D-MA), Bob Graham (D-FL) and Bill Nelson (D-FL) Christopher Dodd (D-CT).

Groups Say Bill Is Flawed

Several patient groups that belong to the patient-led Cancer Leadership Council said the legislation is flawed.

The letter was signed by the American Society of Clinical Oncology, the American Society for Therapeutic Radiology and Oncology, Cancer Care Inc., The Children’s Cause, Foundation for the Children’s Oncology Group, National Coalition for Cancer Survivorship, National Prostate Cancer Coalition and North American Brain Tumor Coalition.

The text of their letter to Feinstein follows:

The undersigned cancer patient, provider and research organizations believe the time is right to review and possibly revise the National Cancer Act as it moves into its fourth decade. After more than 30 years of qualified success in the effort against cancer, the national cancer program has reached a new crossroads characterized by certain developments, including (1) many new basic science discoveries that require translation into clinical applications if patient care is to benefit; (2) a proliferation of government programs sited in different agencies, all of them related to cancer but not appropriately coordinated, and (3) increased demands for cancer investment in a time of relatively constrained government resources.

These new opportunities and challenges call for a new National Cancer Act designed specifically to address those matters. We believe that legislation should be guided by the following general principles: first, the government should be able and willing to provide new mechanisms to facilitate translational research or other needs as they arise; second, the focus of cancer policy should remain squarely with the National Cancer Institute, eliminating confusing duplication or overlap of responsibilities; and third, every effort should be made to make the national cancer program more efficient and cost-effective, including incentives to the use of public-private collaborations where appropriate. Aside from these general principles, we have the following specific concerns and comments regarding certain elements of the proposed National Cancer Act of 2002:

—NCI Appropriations Authorization. The draft Act authorizes specific levels of appropriations through fiscal year 2007, the amounts roughly tracking anticipated increases in the Bypass Budget of ten percent annually. Such limits on NCI appropriations are at least theoretically inconsistent with the concept of a professional judgment budget. It would seem to us that we should encourage the NCI to use its Bypass Budget authority to indicate to the President and the Congress the amounts which its experts believe could reasonably be invested in the national cancer program, even if appropriations in those amounts are extremely unlikely. Utilization of “such sums as may be necessary” authorization levels would allow the Bypass Budget process to continue without restraint.

—Translational Research. As indicated above, translational research is one of the priority goals of the national cancer program, and we endorse the draft Act’s attention to this issue. However, it is important to note that the cancer program already includes comprehensive cancer centers and extensive nationwide clinical trials networks in the form of the NCI cooperative groups. Every effort should be made to incorporate translational research into the existing infrastructure to minimize expense and avoid duplication. Specifically, we note that, while geographical diversity is critical for cancer centers, we do not necessarily believe that translational research centers need to be geographically dispersed so long as the technology developed in such centers is readily available nationwide through the cooperative groups.

—IOM Study of Expanded Cancer Coverage. We endorse the concept of an Institute of Medicine study of
insurance coverage for the uninsured with cancer, but believe it should not be limited to Medicare. Recent experience with such extended coverage—i.e., in the case of uninsured women identified as possible breast and cervical cancer patients through the screening program of the Centers for Disease Control and Prevention has focused on Medicaid, not Medicare.

—Role of AHRQ and Other Non-NCI Agencies. The development of outcome measures for quality cancer care is already well underway by private provider-based organizations and by NCI itself. We do not believe it is necessary to replicate these ongoing efforts with a new quality assessment program at the Agency for Healthcare Research and Quality (AHRQ). Moreover, AHRQ is no longer involved in the development of practice guidelines but instead has developed a clearinghouse for those guidelines published in the private sector; this division of responsibility between the public and private sectors related to practice guidelines strikes us as appropriate.

We also have concerns which can be fleshed out later about potential for duplication and lack of coordination as a result of involvement of CDC and other agencies in the national cancer program. In our view, the program will operate most efficiently and most in accordance with strong scientific principles if NCI remains the lead agency on cancer matters, with others involved where there is a specific unmet need for their expertise.

—Clinical Trials Coverage. We have some specific concerns about the provisions of the Act relating to coverage of routine patient care costs in clinical trials. For example, the coverage provisions that would be mandated for Medicare are less liberal than those already put into place voluntarily by the Medicare program, and coverage in the private sector is addressed by provisions in the pending Patients’ Bill of Rights.

—“Cancer Quarterback.” This is another provision that requires additional discussion. We are concerned that reimbursement for coordination activities as contemplated by the provision will be so insignificant as to have no impact on cancer care. An IOM study has been proposed in order to evaluate a broad range of physician reimbursement issues for cancer care, and a requirement for such a study might be an appropriate addition to the draft Act.

—Tobacco Regulation. We strongly support legislative and regulatory measures that will help to eradicate the scourge of tobacco use. It is unclear whether regulation by the Food and Drug Administration, as previously proposed, is the best mechanism, but we look forward to working with you to arrive at an approach that will achieve the common goal of tobacco elimination as expeditiously as possible.

—Orphan Drug Incentives. The draft Act proposed to extend orphan drug coverage to “targets and mechanisms of pathogenesis of diseases,” rather than just the traditional disease classifications. This is yet another area that bears further thought, but we are not yet clear how effective the current orphan drug incentives can be in accomplishing the desired research results. We note, for instance, that most cancers already meet the statutory definition of “orphan” as having no more than 200,000 patients. The suggested changes would thus have relatively limited impact. We would be interested in exploring with you and your colleagues additional ways in which to enhance the incentives available under the Orphan Drug Act or otherwise.

—FDA Review of Oncology Drugs. One frequently mentioned initiative that we were disappointed not to see in the draft Act was a provision establishing an Oncology Center at FDA. Given the multidisciplinary nature of modern cancer care, we find the current organization of the review divisions at FDA to be inefficient and unscientific. We would urge you to consider a legislative requirement that all review of oncology products be consolidated in one Center, including not just drugs but also biologicals, devices and diagnostics. We appreciate your consideration of this proposal in any later draft of the Act.

Thank you for the obvious effort and thought that have gone into the drafting of the National Cancer Act of 2002. We hope you will welcome the involvement of patient, provider and research advocates in the further development of provisions for inclusion in this important legislation.

Interview:

Von Eschenbach’s Goal: Speed The Development Of Products To Benefit Patients


Just five weeks after Andrew von Eschenbach became the NCI director, he sat down with The Cancer Letter for an interview on March 4. In the interview, von Eschenbach outlines his general approach to the job of directing the Institute. He comes to the position after more than 20 years as a practicing surgical oncologist at M.D. Anderson Cancer Center, and is himself a cancer survivor.

Q: When you were at M.D. Anderson Cancer Center, how did you become interested in this job and how did the White House become interested in you?

A: I think it had been a process where I clearly was interested in trying to make a contribution to the larger picture. They had some idea that I had been involved in larger issues, whether it was the National Dialogue or the American Cancer Society, and that started a conversation that ultimately led to the offer of this particular position when it became available.

Q: At that time, did you have any strong opinions about NCI, and what were they?

A: I think my opinions then have been reinforced
now that I’ve been here, I think the NCI has been doing an absolutely spectacular job, especially under [former director] Rick Klausner’s leadership of promoting this basic science infrastructure, being able to communicate that with a sense of vision and strategy, and communicate in a way that the world was understanding and appreciating that. That agenda needed to be continued, nurtured, and promoted. As I’ve said, I told Rick when I first got here, I came to compliment him, both with an “i” and an “e.” I had strong opinions and strong impressions of how much and how effective the NCI was in promoting and creating the scientific agenda.

Q: Did you feel there were weaknesses in NCI?
A: No, no weaknesses in that sense. I think my view was that different times present different opportunities. Different people bring certain skills or perspective to the process, and if this opportunity were available to me, what I would like to bring to it, what I would like to add, is to help continue to promote the focus on not just nurturing the base and developing and promoting it, but also accentuating the complementary, translational piece, the creation of products, so to speak. To really enhance our portfolio of biologic-based interventions that have to do with prevention, treatment, as well as detection and diagnosis.

So I’m seeing this landscape out there from the clinician’s perspective, from the practicing oncologist’s perspective, seeing all the opportunity, all the need, all of the areas that are crying out for this exciting progress, and thinking, gee, this might be a great opportunity for me to help contribute to that interactive process, as this incredible base has been created and developed.

Not weakness, just bringing whatever else I could contribute to what was an unfolding and ongoing story.

Q: Do you have any specific plans for promoting translational research?
A: Well, as I alluded to, I think there are a number of pieces. First of all, there’s a lot of translational research that’s going on even within the Institute. One of the things that may not be as well appreciated is the Intramural Program, under Carl Barrett’s leadership. There has been a fantastic integration of both the basic research side and the clinical side. In fact, it’s a wonderful model where you have fabulous basic scientists, and they are communicating and collaborating with clinicians who are doing clinical research, and they are really accelerating that discovery-to-delivery model. So one of the things is to continue to support and promote the Intramural Program in what it is contributing and use that as a model system and a platform.

I think there are opportunities in the Extramural Program, where, in a variety of ways, we have the opportunity to accelerate that translational piece. Whether it’s what’s happening with centers, SPOREs, and cooperative groups—those are all platforms we are looking at. I think what I want to see is more collaboration and integration between the various components, and NCI serving as a kind of catalyst and supporting player in that whole interactive relationship.

Q: Do you think there are areas where there’s not communication or collaboration?
A: No. You are asking questions that go along the lines of what’s broken, and I don’t really view this as something that’s broken. It’s very difficult when you come into an organization that’s incredibly successful. The first question is: What can you do? Nothing’s broken.

Having said that, I don’t think any of us, any individual or organization, should not be looking at opportunities for ways you can be even better. I don’t come in here to fix anything that’s broken. I come in here to nurture and support the wonderful things that are going on, but also to ask the question: Are there opportunities we might be able to seize that could accelerate this process even further, even more quickly?

No matter how good we are, as long as there are people suffering and dying of cancer every day, we’re not good enough. My goal is to see if we can find new ways of accelerating the process. Find new ways to develop the innovative ideas and support the investigators who are demonstrating that kind of creativity, make sure that we are accentuating the development of the pipeline, so that we have investigators coming into it, such that when we get to the point where we really do have this extensive portfolio, there will be people out there who are adept at being able to deliver it.

So you step back and realize there are these various parts and pieces to this process that are working quite well, but you need to go through them in a systematic way and say, can they be even better?

At the same time, if you’re asking me: What do you think your unique skill is? Not only looking at the individual parts, but how they fit, how they integrate, how they connect. So if you ask me to define myself, one of the things I’m very interested in is systems engineering. Cancer is a systems problem. The solution to cancer is a systems problem. It’s how do you get the pieces and components working effectively together.

Not only it is a challenge to promote excellence in each of the various components, but there is an even bigger challenge to getting those components to work collectively together. That’s what I’d like to contribute to, is that orchestration and integration.

Q: Can research be engineered?
A: I don’t think it’s a matter of engineering research. That’s not the right question. The question is, can you promote excellence in research and then take the products of that and begin to create the connectedness so that you can see how, in fact, the problem may be solved by taking the fruits of all of the various pieces that have evolved or emerged in the scientific process. I think scientists do what they do exceedingly well and need to be nurtured. The R01 mechanism is a fabulous mechanism for stimulating
creativity and allowing ideas to be developed. But you complement that by the ability to see how those ideas fit together.

Q: Let’s go back to your work in the American Cancer Society and starting the National Dialogue on Cancer.

A: For the most part, what that was basically was, a time and a place where everything comes together. It seemed to me that one of the things I had been appreciating after 20 some years as an oncologist was that cancer is really a societal problem. You can think about it as a scientific problem, a medical problem, but it is also an economic problem, a social problem, a cultural problem, a political problem. If we as a society were going to eliminate the scourge of this disease that is taking such an incredible toll on all of us, it’s important that we have a societal solution that really addresses all of the components and dimensions of that problem. Although you can work on it in its various pieces, it would be helpful if there was someplace, somewhere, where everyone who was working on the problem could at least get together and talk about the problem from a larger, more global perspective, and begin to think through this systems approach.

It seemed like the right time to create that discussion. It seemed like the right time to bring some of the key components to the problem. There were obviously groups, individuals, organizations, who were out there struggling, working hard, and doing everything they possibly could to contribute in each of these components or pieces. Maybe it was a good time to have them come together in some way at some place to talk through what the overarching challenge is for us as a society.

In order to convene a group of people like that, you had to have some infrastructure that could support it, and you had to have some leadership to convene it. The wonderful gift was that [former] President and Mrs. Bush were, because of their personal commitment to cancer—they lost a daughter to the disease and they were involved at M.D. Anderson long before he ever became President of the United States—had the ability to convene people to something like this. And the American Cancer Society happened to have the infrastructure that could support getting the thing off the ground.

So, that was the unfolding of the process. At the outset of that, NCI and a variety of other organizations were invited to even think about: Does this make sense? Is this a good idea? Within certain constructs and certain constraints, everyone agreed it would be a good idea. No one wanted another organization. No one wanted something that was going to be superimposed on everything else. But everyone agreed that a forum—the words we used were a virtual town hall—would be a great idea. That was the genesis of it.

Q: What is the role of the Dialogue now?

A: I think the role now is to continue what the role was in the beginning, to be a town hall, so to speak, this opportunity where various parts of the community that normally would not necessarily be interacting over questions of cancer can come together and look at what the opportunities are for cooperation, collaboration, identification of challenges, new opportunities, and promote that comprehensive process. I think it’s still has a very significant contribution to make as a forum.

Q: How do you see NCI’s involvement in it?

A: I think NCI has to be a part of that dialogue, has to be a part of that discussion. We have a very significant perspective in regard to cancer. We have to be engaged. If there’s going to be a meeting at the town hall to talk about cancer, it makes sense that we’re there to contribute.

Q: It’s not a conflict for you to be involved in it?

A: No. The question doesn’t even make sense to me. How could it possibly be a conflict for the National Cancer Institute to be engaged in a discussion of the problem of the cancer.

Q: HHS Secretary Tommy Thompson mentioned last year at the President's Cancer Panel that he stepped down from formal participation in the Dialogue.

A: I can’t speak for Secretary Thompson. As far as the role of a Cabinet officer is concerned, I think at that point, his focus was not the Dialogue. His focus was things bigger than cancer, the global problem of health in this country. From the point of view of his personal participation in the Dialogue process, I can understand that he has other things to do.

Q: Do you see it as an open forum and all are invited?

A: I think it’s an open process where all are invited. I think the forum, in terms of how it evolves and how it unfolds, has been what I’ve described as concentric circles, widening concentric circles. Not everybody can fit in a room, but at the same time, everybody can contribute. So the way that things need to be structured and organized is to allow a networking to occur where many, many people have the opportunity to participate and contribute, especially in areas or places where they think they have something that they want to be involved with.

For example, this past weekend, there was a meeting around the issue of accelerating the development of interventions or drugs based on the emerging understanding of genomics and proteomics. There were a substantial number of people involved in that meeting, and only a small number of them were Collaborating Partners in the Dialogue. But it was a Dialogue-sponsored meeting. I think that’s a great mechanism. That’s one of the things about it. It’s not exclusive.

Q: You were going to be ACS president-elect this year. You don’t have any current role in ACS.

A: No. None. I had to sever all of my relationships with M.D. Anderson and the American Cancer Society. To do this job, I had to give up some of the other things I was doing.

Q: Does your coming from a cancer center [M.D. ...
Anderson] give you a different perspective on NCI and its programs?
A: That’s a good question. I think it gives you an incredible appreciation for the impact that the National Cancer Institute has. You realize that you are working in an environment that you think of as one of the most significant cancer centers and you realize that that came about because of the support and the nurturing that the National Cancer Institute was able to contribute. This idea of comprehensive cancer centers are things that the NCI has been responsible for nurturing over a period of time. So you have that perspective, of appreciating the importance of basic laboratory research in our understanding of the cancer problem, and at the same time, the interventions that are going to be required to correct or eliminate the problem of cancer. That, again, is the wonderful portfolio of the NCI. I think coming from a cancer center, you sort of have been on the receiving end, and now you’ve come to the place that is able to make that happen.

If I had to make it succinct, I’d say, coming from a cancer center like M.D. Anderson probably gave me an innate appreciation and respect for this institution, because I could see its tangible impact in that environment.

Q: In your remarks to the National Cancer Advisory Board, you said you would be looking at the Cancer Center Program right away. Why?
A: I think there are a couple of things. There are two parts to this process. One is the basic research engine, if you will. Although I didn’t speak to that in specifics, my remarks did include the fact that I’m going to continue to focus, and nurture, and make certain that that piece is continuing to be promoted. Because without that, nothing else happens. However, having said that, I really want to focus on making sure that we are delivering that discovery to patients in terms of these new interventions that will detect, treat, and prevent. Coming from a cancer center, I see the cancer centers as great vehicles for doing that. I want to focus on them as a way on focusing on what I consider to be the delivery part of that discovery piece. For me, it’s just a natural area for me to begin to think about what I’d like to contribute to what Rick has already put in place.

Q: Do you see funding more cancer centers or more SPORE grants?
A: I don’t know that. That’s the point of what I said to the NCAB, is that I think that those questions are questions that I’m going to want to address early on. Those are questions that I’ll look for advice and input and direction on as we begin to look ahead at how we are going to continue to move forward. I don’t have any hard decisions, but I do know the areas that I want to explore and get answers to so that we can strategize.

Q: Politically, the centers program can be sensitive. Sen. Dianne Feinstein’s new National Cancer Act legislation includes a provision for “translational research centers.” Can you comment on that?
A: That’s not anything I can get involved in at this point.

Q: What about NCI’s role in cancer control and behavioral research. How do you see that, and NCI interaction with the Centers for Disease Control and Prevention?
A: That’s again another area of a work in progress. With regard to all of the other agencies, we’ve got to be dialoguing, discussing, and talking about where there are opportunities to work effectively together. I think we’ve got to look at areas where we can work effectively together to achieve what we recognize is the ultimate mission, and that is, that we can eliminate the pain and suffering and burden of cancer, and the deaths that are occurring. To do that requires the ability to interact with others who bring something to the process that we don’t necessarily have or don’t have as fully and completely as they might. That’s where, hopefully soon, I’ll have a chance to sit down with CDC and begin to talk about how what they’re involved in at the state level and how we’re doing can dovetail.

[von Eschenbach’s assistant, Martha Fewell, tells him it’s time for his next appointment.]

If you finished this interview and you wanted to ask what is the core, what is the theme, why is he here, what’s he doing there? I learned early on that to solve the problem of cancer required multidisciplinary, if not interdisciplinary, collaboration and cooperation, and that you couldn’t solve a problem you couldn’t understand. So you had to have basic research as your underpinning, and research had to be the underpinning so you could understand the problem in order to deal with it better.

That’s what I want to do. I want to create those multidisciplinary, interdisciplinary, interactive processes that help us deal with the problem more effectively tomorrow than we did yesterday.

I don’t know exactly how to do that yet, and I don’t know exactly what the right equation will be, but I want to explore those interactions. I want to explore how we can work effectively with other federal agencies. How we can work effectively with the basic science community. How we can work effectively with cancer centers, state cancer plans, etc.

All of it ultimately will, in my way of thinking, if we find those synergies and those interactions, and we can complement and support and work effectively, we’ll get to the goal quicker.

For me, every day we don’t is a day that people die, people suffer. We may be great, and we are. I just think we can be greater. We may be working together quite well. Maybe we can work together better.

I don’t get up every morning knowing what I’m going to do. I get up every morning knowing what I have to do, which is to make it better.