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NCAB Committee Agrees On Seven Characteristics For Comprehensive Centers, Asks For New Division

The National Cancer Advisory Board Committee on Centers gave preliminary approval to seven characteristics for comprehensive cancer centers and recommended that NCI

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In Brief

Rod Heller Dead At 84; NCI Staff To Answer Questions About CCOP During ASCO Meeting

JOHN RODERICK HELLER, who was director of NCI (1948-1960) longer than anyone else in the institute's 52 year history, died May 4 in Bethesda after a stroke. He was 84. Heller left NCI to become president of Memorial Sloan-Kettering Cancer Center, but retired three years later after suffering a stroke. He returned to Bethesda and remained active as a consultant to NCI and the American Cancer Society. . . . **PROGRAM STAFF** of NCI's Div. of Cancer Prevention & Control will be available during the annual meeting of the American Society of Clinical Oncology May 21-23 in San Francisco to answer questions on the Community Clinical Oncology Program and the new minority based CCOP. The requests for applications for the two programs is scheduled for publication May 19; copies of the RFAs will be available at the main NCI booth in the ASCO exhibit area of Moscone Convention Center. A question and answer session on the programs will be conducted May 21, 3-4:30 p.m., in Room 228 of the convention center, by representatives of the Community Oncology & Rehabilitation Branch. CORB Branch Chief Leslie Ford will be on hand along with Carrie Hunter, program director and cancer control research coordinator; Anne Bavier, program director; and Karen Grotzinger, program analyst. . . . **JAMES PHANG,** chief of the endocrinology section in the Metabolism Branch of NCI's Div. of Cancer Biology & Diagnosis, probably will move to the Div. of Cancer Prevention & Control to set up a nutrition and cancer laboratory research program at the Frederick Cancer Research Facility. DCPC Director Peter Greenwald also is negotiating with the U.S. Dept. of Agriculture and Univ. of Maryland to form joint nutrition research programs. NCI and USDA have a $1 million per year interagency agreement for diet and cancer research, carried out in a "kitchen laboratory" at USDA. . . . **ROSELYN EPPS,** professor of pediatrics at Howard Univ. in Washington, is working in the Smoking, Tobacco & Cancer Program while on sabbatical.

Comprehensive Status Would Depend On Peer Review Along With Core Grant

(Continued from page 1)
establish a new division for the centers program at the committee's recent meeting in Chicago.

The committee will meet again May 14, prior to next week's meeting of the full board, to put the finishing touches on its recommendations. The board is expected to act on the recommendations May 15.

The key feature of the recommendations for recognition of a center as an NCI recognized or designated comprehensive cancer center is that "recognition will become an integral part of the peer review process, i.e., a center should appoly for comprehensive center core support and be reviewed according to guidelines and review criteria specifically for comprehensive centers," according to language in the draft report developed at the Chicago meeting. "The NCAB would approve the comprehensive designation as part of its approval of the grant award.."

The present system for recognition of a center as comprehensive, not used for 10 years, is for a less formal review by an NCAB committee. The review was carried out independent of core grant review.

That change, and the new language on the characteristics, probably will be acceptable to NCI Director Samuel Broder. However, the recommendation that a new division be established (which would also include the Research Facilities and Cancer Training Branches of the Div. of Cancer Prevention & Control) is less likely to gain his approval.

The draft report (still subject to change by the Centers Committee and the full NCAB) describes the role expected of comprehensive centers and the seven characteristics:

"It is appropriate to assume that comprehensiveness will include the capability to conduct fundamental research and apply that research to the areas of the center's special competence according to the particular type of tumors studied and the geographic locale and the unique patient population available.

"A comprehensive cancer center should be a major national source of the best new ideas in laboratory, clinical and cancer prevention and control research. A comprehensive cancer center should be a community of investigators with a distinct focus on local and national cancer problems of major importance. It should make maximal use of the scientific resources at its disposal and take optimal advantage of local resources and local problems in developing research strategies.

"In addition to its established role as a source of high quality investigator initiated research, a comprehensive cancer center should play a vital role through the definition, creation and implementation of treatment and prevention clinical trials, cancer prevention and control research, public and professional education, and information services which are both regional and national in scope.

"A comprehensive cancer center should address major national priorities based on national cancer statistics. Together with scientific excellence and leadership, the essential characteristics of a comprehensive cancer center include:

"1. **Basic Laboratory Research**. A critical mass of integrated personnel, laboratory facilities and financial support for basic research is essential. The center should promote interdisciplinary interactions between scientists engaged in cancer research, including critical collaborations between basic and clinical investigators. A significant portion of reserch support should be from sources that utilize peer review.

"2. **Basic/Clinical Research Lingkage (Technology Transfer**. A center should facilitate the transfer of exciting laboratory discoveries into innovative clinical applications including clinical treatment and prevention. Further, once a unique opportunity is identified, a distinguishing feature of comprehensive cancer centers is the ability to stimulate interactions either as basic/clinical collaborative research within the center or as collaborative research between elements of the center and other organizations, e.g., research institutions or the biotechnology industry.

"3. **Clinical Research**. A clinical research

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program utilizing patient resources of the institution and its region is essential. Ideally, such studies involve relevant center laboratories as well. A center should be a major source of innovative clinical studies which can later be exported, e.g., to clinical cooperative groups or into general medical practice.

"4. **High Priority Clinical Trial Research.** There exists a critical need for expeditious completion of clinical trials of major importance. In order to address this problem, centers should play a leading role in clinical trials when high national priority is identified by a mutually satisfactory process involving the centers and NCI and when better competing hypotheses are not available. Although a center may not enter patients in every trial so identified, it is expected that every center will contribute significantly to the National Cancer Program as a whole.

"5. **Cancer Prevention and Control Research.** Cancer control is the reduction of cancer incidence, morbidity and mortality through an orderly sequence from research on interventions and their impact on defined populations to the broad, systematic application of the research results. The center's plans may relate to any or all phases of cancer prevention and control research. A comprehensive center should develop linkages with appropriate organizations to move toward the demonstration phase when it is feasible and opportune. Involvement in cancer control on a regional and national basis, if funds were available, would be required in competing renewal applications. As with other areas of research, comprehensive cancer centers would be expected to have peer reviewed research in cancer prevention and control. Cancer prevention and control research also includes epidemiologic research and research on cancer etiology in humans.

"6. **Education, Training and Providing Updates on Current Technology.** It is essential that the center be a focal point for research training and for continuing education for health care professionals locally and within the region. In addition, the center should offer training in state of the art technology (procedures or instrumentation) to the extent of its capabilities. An important additional part of this educational effort would be to establish programs to train new investigators in cancer prevention and/or control research.

"7. **Information Services.** The comprehensive center should have an established education program and the ability to provide patients and their families with up to date information on local as well as national resources that may be needed. In addition, the center should participate in a Cancer Information Service in the area, giving accurate information on cancer prevention, diagnosis, treatment and rehabilitation to patients, the public and health professionals. Through the CIS (or center staff) each center should heighten public awareness of the importance of participation in prospective clinical trials."

Once granted, recognition would be for a specified time, probably to coincide with the length of the core grant award. It would automatically be rescinded if the center failed to get its core grant renewed.

The committee decided to drop the proposal that comprehensive centers would have a separate core grant, known as the P60.

The proposal for a new division does not deal with the fate of DCPC's Community Oncology & Rehabilitation Branch, which includes the Community Clinical Oncology Program. The current Centers, Research Facilities (construction) and Training Branches would go to the new division. The Organ Systems Section of the Centers Branch has already been moved to the Div. of Cancer Biology & Diagnosis.

One logical place for CCOP would be in the Div. of Cancer Treatment, where it would fit into the Cancer Therapy Evaluation Program that administers the cooperative groups and the Cooperative Group Outreach Program which, like CCOP, is directed toward community hospitals but on a smaller scale.

Creating a new division involves approval at the departmental level which may not be easy to obtain. It would require more staff positions at a time when NCI is hurting for slots.

More likely would be moving centers, construction and training into Broder's office. That would give centers the "greater visibility" sought by center directors, with more direct access to Broder. An argument against that move is that it would deprive the centers program of oversight by a board of scientific counselors. However, the National Cancer Advisory Board acts as the "BSC" for the office of the director and its various elements and could do that through its Centers Committee.

Other options considered by the committee included leaving the program in DCPC, with efforts to improve interactions between the

centers community and DCPC and increased representation on the division's board; to distribute the program as appropriate among the divisions (That would place the basic science centers in the Div. of Cancer Etiology and Div. of Cancer Biology & Diagnosis; the clinical centers in the Div. of Cancer Treatment; and comprehensive and consortium centers in DCPC); to create a new division for centers without construction and training; and to move the entire centers and resource programs into the Div. of Extramural Activities. None of those options appear to have much chance of approval either by the NCAB or Broder.

Cancer Program Depends On Vitality Of Cancer Centers, Broder Says

The success of federal cancer research depends on the vitality of the Cancer Centers Program, and efforts will be made to award core grants to all centers with fundable priority scores, NCI Director Samuel Broder said last week.

He made the remarks at a meeting of the Div. of Cancer Prevention & Control Board of Scientific Counselors, essentially repeating what he had previously told **The Cancer Letter**.

In his first major statement on the Cancer Centers Program since becoming NCI director, Broder announced to the DCPC board that NCI will develop a five year plan for the program.

A report released by the Institute of Medicine on the centers program late last month recommended that NCI review the program over the next year.

Broder said the plan will be developed in consultation with the National Cancer Advisory Board and any changes will be reflected in modified guidelines for the core grant application and the peer review process.

Deputy NCI Director Maryanne Roper will head the planning effort. She will be assisted by Judy Whalen, who has served as secretary to the NCAB Committee on Cancer Centers and was liaison to the IOM staff that worked on the cancer centers report.

"I view our Cancer Centers Program as a national resource of incomparable value," Broder said. "Today's biological revolution offers unprecedented opportunities for applying research advances. The success or failure of the National Cancer Program depends on the vitality of the cancer centers."

An effort will be made to reprogram money from other areas to the centers program, but resources are limited. He emphasized that core grants are not the only grants cancer centers receive from NCI.

The NCI Executive Committee has reviewed priority scores for the 15 cancer centers competing for grant renewal and the two new centers for fiscal 1989, Broder said.

"A special effort will be made for careful reprogramming of limited resources to support all centers with fundable priority scores at 85 percent of peer review recommended levels, particularly when there is clustering around the payline," Broder said. "We feel that we cannot readily go below 85 percent without severely harming the peer review process.

"We need to do whatever we can to protect our portfolio of core grants. However, many different funding mechanisms within NCI exist, for example RO1 grants, clinical cooperative groups, cancer prevention and control activities, research management and support grants, that also are seriously challenged by the fiscal realities of the budget.

"Perhaps it is worth stressing that the centers themselves receive considerable support from NCI beyond their core grants," Broder said.

Broder noted that the program's funding is not totally dependent on NCI.

"We need to make sure that the message we need to convey about cancer centers is not confined to members of the cancer community, but is spread to the entire scholarly community," he said.

"I'd like to emphasize that the cancer centers budget is not flat," he said. Excluding AIDS activities, the cancer portion of the centers budget fell by $1.2 million, or 1 percent, to about $96 million for fiscal 1990.

"The professional assessment of the needs of the Cancer Centers Program, as for other components of NCI, is articulated in the bypass budget," Broder said. "I urge that all of you familiarize yourselves with it, because it does represent NCI's strong commitment to the centers program."

Although HHS will submit a formal response to the IOM report, Broder offered his own thoughts on the program.

The designation as a comprehensive cancer center should be for a limited amount of time and an inherent part of the peer review process, he said.

As for the organizational structure of the program, Broder did not give any specific suggestions, but said he is reviewing "the

entire organizational structure of the institute, including the location of the centers program."

"I hope you will share your ideas with me," he told the Board.

"NCI will continue to encourage the independence and diversity of the centers. But we also want to work with centers to establish them as a crucial foundation for the entire National Cancer Program in the eyes of the public."

Broder continued: "How can we have an accurate assessment of the cancer centers and at the same time recognize the centers for their achievements? We would be pleased to have the centers provide annual statements of their major accomplishments to us, including in their submissions any materials they want for possible presentation to appropriate hearings before Congress, particularly the appropriations hearings."

Following Broder's remarks, Board member James Holland asked whether Broder believed in zero based budgeting.

"If I knew what that was, I guess I would believe in it," Broder said.

"Meaning that centers that come up for renewal don't have a ceiling or a floor on their grant and must justify every expenditure," Holland explained.

"In theory, I believe that the best way for any process to work in peer review it that the entire request be considered in toto," Broder said. "We cannot have a situation where someone says, 'What I've got now is not on the table for discussion, it's only the add on.'

"I don't mean this to be hyperemotional, but we don't have entitlement programs at NCI, for grants, PO1s, contracts or anything else. The core grant program is incredibly important, but each application must be reviewed on its merits. I hope the peer review process is doing that. Does that fit your definition of zero based budgeting?"

"I'd say you are a passionate advocate," Holland said.

"I don't see how else to do it," Broder said.

DCPC Director Peter Greenwald said that members of the NCAB are discussing removing the cap on center grants. "The idea is that peer review should do what it's supposed to do and look at the whole thing," Greenwald said.

"I'd like to stress that this isn't just a discussion on centers," Broder continued. "I feel the centers mechanism is a grant in aid mechanism that is designed for certain types of critical interdisciplinary support, but fundamentally it is not different from other granting mechanisms we have. (After a three or five year award) there is no moral commitment that centers will be funded (on renewal)."

Holland suggested that NCI could help centers get funding from other sources if it were more explicit in saying that grants are for only 85 percent of the recommended level.

"The public perception is that what NCI gave is what it is worth," Holland said. "Perhaps NCI press releases announcing grant awards could say that the grant was 85 percent, but that it is really worth more."

In his opening remarks to the Board, Greenwald referred to centers issues.

"In your discussion of the IOM report on cancer centers, I hope you will focus on the overall context as part of the National Cancer Program," Greenwald said.

"Centers have been able to make major contributions not only because of core grants, but because biomedical research in the U.S. is strong, NIH is strong and NCI is strong. Many of us, including many center directors, are concerned about maintaining this overall biomedical research strength.

"I am worried that it is slipping," Greenwald said.

"In my view, salaries at NCI, in addition to core grants, may have a fundamental importance to keeping centers and the rest of the National Cancer Program strong. The board and center directors should speak out on this. For without strong NCI scientists, we could not have a strong nationwide program.

"RO1 grants, clinical cooperative groups, cancer prevention and control, and construction all are important for keeping centers strong. Let's be sure we consider NCI as a whole."

DCPC Board member Alfred Haynes, who served on the IOM committee, said, "The report recognizes that cancer centers can play a very important role in the future of the cancer effort. It did not make a specific recommendation on the crucial issue of the placement of the centers program within NCI, primarily because we did not want to become involved in micromanagement. But it did recognize the need for more staff support for the cancer centers. The committee didn't say what the full needs are for the centers budget because there was no real justification for saying the cancer centers ought to get $200 million or whatever, without a more detailed

plan. That is the reason we recommended that NCI develop a plan for the program."

Concept For Minority Demonstration Centers Tabled After Bitter Debate

A grant concept that would use $2 million from the Cancer Centers Program budget to fund two minority cancer prevention demonstration centers ignited debate between centers representatives, NCI staff members and proponents of the concept.

The Div. of Cancer Prevention & Control Board of Scientific Counselors tabled the concept, but the idea has strong support at NCI and probably will resurface in the fall.

The board also turned down a concept for a cancer control education program.

The controversy over the minority centers pits NCI officials and advocates of stronger minority programs against some centers supporters who see a steady deterioration of their budget. The concept's proponents say the idea would encourage Congress to allocate more money to the centers; opponents say there's no guarantee that will happen.

In the middle of the controversy is a goal that NCI Director Samuel Broder has made a high priority: reducing cancer incidence and mortality among minority and low income groups.

The grant concept, Minority Cancer Prevention and Clinical Care Demonstration Centers, developed by the Special Populations Studies Branch, would provide $2 million per year for five years for two cancer centers to develop cancer prevention, screening, early detection and treatment services for minority and low income groups.

"Minority and low income populations have less than adequate access and availability o quality cancer control services, including primary and secondary prevention services," the concept statement said. "Health care utilization patterns coupled with inaccurate knowledge of cancer preventive strategies contribute to the poor cancer survival and mortality rates in these groups.

"The transfer of appropriate technology now would make a profound difference on the cancer burden in the Black population. Cancer mortality rates can be dramatically reduced for certain cancer sites--laryngeal, buccal cavity and cervical--if quality cancer detection and treatment regimens were now applied.

"The focus of the demonstration centers will be on determining how to meet the full spectrum of cancer control needs for populations at the most extreme in terms of risk of cancer and the morbidity from cancer," the concept statement continued. "Consortium or consortia like arrangements of health providers, relevant health departments and cancer centers should demonstrate the extent to which state of the art cancer care can be brought to populations in greatest need."

DCPC Director Peter Greenwald, in his report to the Board, said the concept "addresses one of NCI's highest priorities, that of how best to investigate and correct population disparities in cancer rates. We hope it also will help us to document the centers' participation in addressing this issue, and thus to obtain the needed resources for this effort."

Discussion following the concept presentation by Special Populations Branch Chief Claudia Baquet focused on two issues: the need for the program and the setting aside of funds from the cancer center core grant budget for the program.

Board member Edward Bresnick asked whether the program is necessary in light of the new centers that would be developed under the minority Community Clinical Oncology Program approved at the last DCPC Board meeting. "Why establish another bureaucratic structure to handle a problem that the centers could do?" he asked.

Baquet said the concept "will provide a mechanism for a problem that we feel is not currently addressed by the centers."

"We are encouraging (existing) centers to take part," said Greenwald. "We think this will help the centers program. Sam (Broder) feels he can better defend the centers to Congress with this kind of program."

Bresnick also said he recalled that previous attempts at establishing demonstration centers failed. "I have an antibody response to demonstration centers," he said.

"The demonstration projects of the 1970s were very different," Greenwald said.

"They were bad," Bresnick said.

"The reason they were bad was they excluded research," Greenwald replied. According to the concept statement, the program would encourage basic research on unexplained disparities in cancer rates.

Joseph Cullen, who will depart at the end of June as DCPC deputy director, defended the demonstration projects. "I wouldn't characterize them as bad, I'd say they were ahead of their time. Today many of those centers are in the foreground of basic research."

Board member Frank Meyskens objected to the number of awards, suggesting the money be split up for four awards rather than two.

Cullen said the $1 million per award would provide "a critical mass under one roof or a consortium. Driving it down to $500,000 apiece would severely limit the ability of this program."

Board member Shirley Lansky asked Greenwald if the division could provide a report on the minority activities already under way. "We've approved several minority efforts recently and I'm a little unsure about the need for this," she said.

Greenwald said the division releases a report every October on the subject.

Board Chairman Paul Engstrom said he objected to calling the demonstration project "phase 5." "That implies you've worked out all of the necessary interventions and centers can just replicate the ideas."

"We don't have all the answers," Baquet said. "Applicants should say what interventions work in their communities. We need investigators to tell us how to get people in."

"I'm worried about funding the centers before the interventions have been worked out," Engstrom said.

"This is figuring out how to reach those populations," Greenwald said. "I share your concern about calling this phase 5."

Board member James Holland opposed the idea on the grounds that it would take money out of the cancer centers program budget.

"We do not have our centers budget yet, we only have the President's budget request," Greenwald countered. "We are not arbitrarily setting priorities, we are taking our priorities from the national statistics, from SEER, on the disparity (of the cancer rate among minorities). This puts an incentive in the centers program to address this. Our ability to defend the centers budget may depend on our ability to address this."

Board member William Darity said he supported the concept. "We want to get people into these activities. I would hope the centers would use this as a mechanism to reach into the poor community."

Board member Donald Hayes said he agreed and moved for the concept's approval.

Cullen then stepped in: "The worst scenario we get into is blaming the victim. This is not taking money away from the centers. Somehow Congress is not as pleased as one would think about the centers program, otherwise they would put more money into it. One reason, we think, is that centers are not doing what was originally intended. It may be that none of this will ever be funded, but unless you do it, it will never get done."

Engstrom: "We're not questioning the need, but wonder where the money is going to come from."

Lansky: "I think this is very important, but I think it's before its time. Let's reconsider it at that time. There's not enough information here for me to go forward."

At that point, Holland and Greenwald spent several minutes trading arguments.

"This is the first time I've ever seen a specific set aside in the centers budget. Is there a precedent for this?" Holland asked.

"I have not seen anything, but we do have the minority consortium cancer center (Drew-Meharry-Morehouse)," Greenwald said. "There are two flat budgets in a row, I don't know the worth of trading one against the other. The aim is to encourage centers to get involved in this. We always hear from centers saying that their core grant doesn't provide an incentive to do this."

"Wouldn't it decrease the core grant for centers?" Holland asked.

"If you accept that we will get the President's budget, then it would be a decrease," Greenwald said. "But I'm not ready to accept that."

"Wonderful, but if you don't get more..."

"When I came here in 1981, the centers budget was in the $60 million range. Now it's around $100 million," Greenwald said. "I don't see this as a tradeoff (higher core grants vs. minority demonstration centers)"

"I do," Holland said.

Board member Rumaldo Juarez said, "If we pull back on efforts to get minorities in to centers, then budgets will go down. I agree with Dr. Cullen. We've been assuming that what we've done in the past is right, but has it? Have we been identifying the right problems."

Referring to NCI's "Year 2000" goals to lower the cancer incidence rate, Juarez said, "We can probably wait, but the year 2000 is only 11 years away and we're playing catch up with the centers."

He made a motion to decrease the awards to $500,000 each for four centers. Board member Mary-Claire King suggested that six awards would get more centers working on the problem.

Bresnick also wanted clarification written into the concept that it would not create two

new centers, but would go to the existing centers.

Engstrom noted that Hayes's motion to approve the concept as written was already on the table. "I'm concerned that this will get voted down," he said.

Holland then made the motion to table the concept. That motion passed 8 to 6. At Juarez" request and Holland's concurrence, the concept was brought up again the following day, with the same result. That discussion was tinged with bitterness.

"It seems like we're getting into a 'we and they' situation," Darity said. "I'm disturbed by the attitude of this board."

"I resent the implication that members here are not fulfilling a commitment to minorities," Holland responded, adding that his center (Mt. Sinai) has extensive programs for minorities. "But I oppose this concept because Dr. Greenwald insists on limiting the support for it to the centers budget."

After the second day motion to table was approved by a 7-6 vote, Lansky said, "I hate to end the discussion on this note. There is no opposition to minority programs here. The opposition is to the way it was constructed."

"My motion to table was crafted to avoid having this program go down to defeat," Holland said.

"My feeling is that the decision will not be made at this meeting," Engstrom said. "The concept should be redrafted and brought back in October.

Bresnick suggested that a subgroup of board members be named to work with Greenwald and his staff on the new proposal, and Engstrom agreed.

The Board rejected a concept that would have developed a cancer prevention and control education program at established universities in any department relevant to cancer control, such as epidemiology, community or preventive medicine.

The grant supported program would have awarded a total of $2.5 million per year to five institutions for five years.

Vincent Cairoli, chief of the Cancer Training Branch, said the goal of the project was to develop a core curriculum that would prepare students seeking to enter careers in chronic disease prevention, with a focus on cancer.

Board member Kenneth Warner of Univ. of Michigan asked what would prevent his school from "including one course on cancer biology and showing what we're already doing," in applying for the grant. "It would be a nice redistribution from NCI to us," he said.

The concept failed, with 10 board members voting against and four in favor.

Cancer And AIDS Patient Advocates List Concerns On Drug Development

Cancer and AIDS patient advocacy groups testified about their concerns regarding the drug development process at a meeting last week of the special governmental committee to review drug approval procedures.

FDA's treatment investigational new drug program was criticized by the groups as well as members of the National Committee to Review Current Procedures for Approval of New Drugs for Cancer and AIDS, commonly referred to as the Lasagna committee after its chairman, Louis Lasagna.

FDA has weakened the treatment IND, which is supposed to get experimental drugs to critically ill patients before marketing approval, some of the advocates said. James Eigo of the AIDS Coalition To Unleash Power said the program now serves merely as a step between final human studies and marketing approval, cutting only six months from the time the drug would be approved anyway.

FDA has said it will bypass phase 3 trials for drugs proven effective after phase 2 in life threatening diseases. Marilyn Koering of the National Coalition for Cancer Survivorship, and Grace Monaco, chairman of Candlelighters Childhood Cancer Foundation, said they approved of that move.

"There now seems to be little if any demonstrated difference of opinion on appropriate endpoints between NCI and FDA," Monaco said.

Lloyd Ney, president of Patient Advocates for Advanced Cancer Treatments, a prostate cancer survivors' group, charged that FDA was "inept" in dealing with flutamide. The drug was released through a treatment IND for a double blind placebo controlled study on American patients after a Canadian study demonstrated its effectiveness. However, Ney charged, even after the second study confirmed that patients had a longer survival time, FDA asked NCI to conduct a similar study, creating a three year delay in the drug's approval.

NCI Director Samuel Broder reiterated his testimony to the committee earlier this year: "It is the strongly held view of NCI that in many cases experimental therapy is the patients' best hope for survival."