THE CANCER LETTER

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NCI Advisors Set SPORE Review Criteria, Approve Plan To Fund New Ovarian Grant

Judging the merits of the Specialized Program of Research Excellence grants is no easy task. In fact, the NCI Board of Scientific Advisors found the subject big enough to sustain *two* spirited debates in *as many days*.

—First, on June 22, the board adopted a set of five criteria for evaluating the program and comparing it with other NCI funding mechanisms. The review process is expected to begin in the year 2000, when the first generation of SPORE grants come up for renewal.

—Then, on June 23, the board moved from considering the program as a whole to considering a specific proposal to fund at least one SPORE (Continued to page 2)

In Brief:

House Bill Boosts NIH Funding By \$1.2 Billion; ASCO Counted More Than 17,000 Registrants

HOUSE APPROPRIATIONS COMMITTEE'S Subcommittee on Labor, HHS, Education earlier this week approved an appropriations bill that would provide NIH with \$14.862 billion in fiscal 1999, \$1.24 billion more than the current year and an increase of 9.1 percent. The amount is \$99 million more than the President's request. The bill also provides \$159 million for the Centers for Disease Control's Breast and Cervical Cancer Screening program, an increase of \$16 million over the current year. The bill next goes to the full committee for approval. . . . FINAL **REGISTRATION** figures for last month's annual meeting of the American Society of Clinical Oncology: Total, 17,785, including 14,819 attendees, and 2,966 exhibitors. Foreign attendees, including Canada, made up 52 percent of the total.... FAYE AUSTIN was named Director of Research at the Dana Farber Research Institute. Austin, director of the NCI Division of Cancer Biology, said she will assume her new job sometime in the fall. . . . ANDREW CHIARODO, chief of the NCI Organ Systems Coordinating Branch, in the Centers, Training and Resources Program, plans to retire from the Institute on Aug. 1. Chiarodo began working at NIH 25 years ago as a grants associate in the Division of Research Grants. He moved to the NCI organ systems program, becoming acting branch chief in 1978 and branch chief in 1980. . . . HARVEY GOLOMB was named chairman of the Department of Medicine at the University of Chicago. Golomb remains in his job as chief of the department of hematology and oncology.

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Review Will Judge Whether SPORE Mechanism Adds Value

(Continued from page 1) grant in ovarian cancer.

Though both proposals were approved overwhelmingly, board discussion indicates that the jury is out on the SPORE program. In both debates, the board focused on the question of whether the program creates a value added and whether it is able to accomplish something other grant mechanisms cannot.

While the SPORE program has the advantage of fostering translational research and giving the investigators flexibility no other program can offer, the program competes for resources with investigator-initiated grants and limits the number of institutions that are able to participate, several board members said.

"An Unbelievable Miracle" In North Carolina

The first debate was triggered by a presentation of the recommendations of a BSA subcommittee that was formed last November to develop evaluation criteria, time table, and a structure for evaluating the SPORE program (**The Cancer Letter**, Dec. 12, 1997).

"There is an extremely unique breast cancer SPORE in North Carolina that simply could not possibly have been done through any other



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Subscription \$275 per year US, \$295 elsewhere. ISSN 0096-3917. Published 48 times a year by The Cancer Letter Inc. Other than "fair use" as specified by U.S. copyright law, none of the content of this publication may be reproduced, stored in a retrieval system, or transmitted in any form (electronic, mechanical, photocopying, facsimile, or otherwise) without prior written permission of the publisher. Violators risk criminal penalties and \$100,000 damages. **Founded Dec. 21, 1973 by Jerry D. Boyd** mechanism, because it involves all sorts of outreach and development of statewide programs in mammography screening, and education in rural communities in ways that could not be easily done elsewhere," said Robert Young, president of Fox Chase Cancer Center and chairman of the BSA subcommittee.

"We saw—believe it or not—an actual collaboration between two major centers close to each other in the same state, which is an unbelievable miracle," Young said. "We saw examples of things that simply don't easily happen through other mechanisms."

However, to be viable, the SPORE program has to demonstrate something more tangible than prompting the University of North Carolina and Duke University to look beyond turf and basketball in the name of research. The question is how do you define that something extra?

"It became clear to [the subcommittee] that if you want to evaluate whether or not the SPORE grant program has been a major success in terms of changing the course of cancer, then we are talking about a review in maybe 2025," Young said.

"But if we want to review the program at some point before that, then the criteria should be:

"First, it ought to demonstrate that good science is coming out of that money. If you can't show that in publications and presentations at national meetings important science is coming out, then it's a failure no matter what else is going on.

"Second, in the context of producing first-rate science, is it using mechanisms—is it creating mechanisms—that couldn't be easily developed by some other existing entity?"

The subcommittee report recommended that review of the program begin in the year 2000. "The first group of SPORE grants would be fully through their first five years with a little time to spare by the year 2000," Young said.

The subcommittee recommendations adopted by BSA will be used by NCI staff to develop formal review criteria for the program. Meanwhile, the program should be allowed to continue to expand, the report recommended.

Five Criteria, A Structure, And A Timetable

The text of the subcommittee's recommendations follows:

The subcommittee believes that the criteria for evaluation of the SPORE program in general will be

different from the criteria for evaluating each individual SPORE. However, any general evaluation must recognize the specific guidelines and instructions given to the SPORE grant applicants in the RFAs.

The principal criteria for evaluating the success of the SPORE program should include the following five areas:

1. Significant scientific advances toward the diagnosis, prevention or treatment of cancer.

These should be demonstrated by publications in peer-reviewed journals, presentations at major national meetings, and by citation of the SPORE grant in publications. The SPORE grant program should also demonstrate enhanced productivity in the majority of individual institutions since SPORE grant funding was received.

2. Translational Research.

This should be widely demonstrated throughout the SPORE grant program. This includes not just translation from basic science to clinical application, but should be viewed flexibly as bi- or tri-directional translation including diagnostics, therapeutics and prevention. After extensive discussion, the committee believes that any attempt to specifically define translational research would probably result in a preconceived narrowing of opportunities and ideas. We concur with the staff in their efforts to broadly illustrate the ideas of translational research without producing a specific definition.

3. Novel Research Programs.

Ultimately, the majority of the SPORE grants funded should demonstrate novel research ideas and productivity, not simply the duplication of other existing research programs at new institutions, or the simple expansion of research activities at SPORE centers.

4. Unique Research Interactions.

There should be evidence that novel and productive collaborations have resulted from SPORE grant funding, and there should be evidence of a translational shift in focus as a result of the SPORE.

5. Creative Use of Flexibility.

The program should demonstrate that it can produce a facile change of course when necessary to accomplish the mission of the SPORE or to enter into new research areas of high productivity.

When to Evaluate the SPORE Program.

The SPORE grant program should be evaluated when two-thirds of the original SPORE grantees have completed the first five-year funded cycle. This would occur sometime in fiscal year 2000.

Structure of Evaluation:

The evaluation should be carried out by a working group comprised of approximately 15 people, including members of the Board of Scientific Advisors; appropriate NCI program staff, and external experts. One member of the review group should be a principal investigator of a well established SPORE program.

In addition to review using the above criteria, part of the evaluation should include written or verbal presentations from both SPORE grantees and staff as to how the SPORE program has addressed the five specific criteria established.

This or some alternative review process for the SPORE program should be undertaken at periodic intervals (i.e. 5-7 years) to insure that the program is fulfilling its principal goals.

Size of the Program.

The size of the SPORE program will ultimately depend upon its success, its uniqueness and the need for research focused on specific disease entities. Because the size of the program will be influenced by overall NCI funding as well as the need to balance research opportunities throughout the various grant mechanisms, no specific recommendation as to size, spectrum of diseases or future expansions of the program are appropriate at this tine. However, the subcommittee believes it appropriate to continue the current policy of presenting new or expanded SPORE grant initiatives to the Board of Scientific Advisors for approval.

What Is To Be Done In The Interim?

The recommendation that the program should be allowed to expand prior to review triggered a debate within the debate at the June 22 meeting.

"I am puzzled by the recommendation that the program should be allowed to continue to expand," said Robert Greenberg, director of the Norris Cotton Cancer Center. "It seems that five years ago there was a strategic decision made to try a new approach to funding this melding of basic and clinical research. If there is a sense that this decision needs to be evaluated, I wonder why we would continue to commit additional money while evaluation is not through.

"If we approve a new initiative in ovarian cancer, whatever comes from that initiative will not figure into the determination of whether the SPORE mechanism has been effective. Every time one funds additional SPOREs, you increase political support for this mechanism, and it becomes very hard to turn these ships once they have a lot of baggage on them.

YOUNG: "That was one of the first conversations we had: Should we strongly recommend that until the time that this evaluation took place, that we would recommend that the SPORE program not be expanded?

"I think one of the things that happened during the course of this process is that the committee became more impressed by the productivity and the novelty of this structure than perhaps we had at the outset.

"And the conclusion was about how big the SPORE pie would be at any given time depended on so many factors that we wouldn't make the decision *on how big the pie should be.* Therefore we came to the conclusion that we would not want to send the message to NCI leadership about whether it should be expanded."

GILLIES McKENNA, chairman of the Department of Radiation, Hospital of the University of Pennsylvania: "As I recall the [November 1997] discussion, we were concerned about how do you go about stopping a program once you've started it. What we were searching for were criteria that would allow us to decide whether or not it has been a success, and it seems to me that your committee has almost preempted that decision, because you've decided it's a success."

YOUNG: "It's true, I did. But I don't think these criteria preordain the mechanism. It seems to us that this provides us with the opportunity to give a rigorous evaluation of whether or not it works.

"One of the things that the committee did conclude is that there is not something drastically wrong about this, that this is not a mechanism gone haywire, that it's not funding a lot of crappy research, that it isn't getting something done."

Round Two: The Ovarian Cancer SPORE

The debate over what should be done with the SPORE program pending review set the stage for the consideration of an RFA concept for a SPORE in ovarian cancer.

The first slide NCI staff member Andrew Chiarodo put on the screen put the issue in political perspective: the ovarian cancer SPORE was mandated in the House and Senate appropriations reports for 1997 and 1998.

"Having said that, I should point out that I do

believe that there is also scientific basis, scientific rationale, and opportunity for considering such a request," said Chiarodo, chief of the Organ Systems Coordinating Branch. "The interest is there. The investigators are there. I can think of at least a half a dozen groups around the country who would be able to submit competitive applications."

Gynecologic oncology may be particularly well suited for a SPORE approach, said BSA member John Minna, director of the Harmon Center for Therapeutic Oncology Research.

"In a sense there is a better jumping off point for an ovarian cancer SPORE because of the way gynecologic oncologists are trained," Minna said. "They are trained in both surgery and cancer chemotherapy, and as part of their training fellowship, there are requirements for doing research projects, too. It's my sense that this group is hungry for interaction and recognition with basic researchers and population cancer control people.

"I think there is going to be an extraordinary interaction that can come out of that," Minna said.

This extraordinary interaction comes at a cost of committing funds to a set-aside program that reduces the funds available for investigator-initiated grants, said BSA member Barbara Weber, director of the Breast Cancer Program at the University of Pennsylvania Cancer Center.

"It seems to me that everything that we hear about SPOREs is that they are wildly successful and that they have done a lot to change the cultures of institutions, to bring people working together that didn't used to, and to do translational research and to move basic science into clinical application," Weber said.

"I am worried that we are making a mistake by deferring our judgment on SPOREs by not opening it up to a mechanism that's more investigatorinitiated, and to let it work more like a programproject mechanism, where people can have the resources to put together a program that meets these criteria—and not have this program be so limited," Weber said.

The restrictive nature of the SPORE program is precisely what makes it conducive to translational research, said Robert Wittes, NCI deputy director for extramural sciences and director of the Division of Cancer Treatment and Diagnosis.

"Sharing general enthusiasm for this mechanism, I've also wondered whether there would be ways to allow an increase in the amount devoted to and—as Barbara suggested—basically to open it up; not to be so RFA-driven, but to allow things to come in in a freely submitted way," Wittes said.

"But the problem is this: if you want to maintain the 'SPORE-ness' of the mechanism and continue all the stipulations around the program that have been responsible for its success, it seemed unlikely to us other than to isolate increasing amounts of money from the general grant pool into this mechanism," Wittes said. "It's not inconceivable to me that the SPOREs may in fact in time become the major mechanism that we use in translational research....

"There are a number of things that separate SPOREs from program projects, things like a mandate for translation, and flexibility, and the ability for the principal investigator to move funds around more liberally, and the explicit support of training," Wittes said.

"All of these things could be features in program projects, but they are not mandatory features in program projects, and therefore if you throw in P01 grants that are SPORE-like into a program project review process where the program project review committee is not conditioned to look at them and treat them that way, my suspicion is that a review will be helter-skelter.

"It won't detect the special quality of a 'SPORE-oid' P01," Wittes said.

The board agreed that the SPORE program has prompted applicants to think in terms of translational research.

"One of the advantages of the SPORE application, I think, is the actual process of going through preparing the application," said BSA member Frederick Appelbaum, director of the Clinical Research Division at Fred Hutchinson *Cancer Research Center*.

"It gets people together, gets them talking. Gets them thinking about collaborations that did not exist before.

"I am a bit concerned when you only offer one SPORE [in ovarian cancer]. People will say, I know who is going to get it, why even try. I just wonder, if there is a way to try to encourage more applications," Appelbaum said.

NCI Director Richard Klausner said the Institute will change the RFA to say "at least one," leaving open the door for funding several ovarian cancer SPOREs.

"Whenever we put out a Request for Applications, we are open to see whether we can fund more," Klausner said. "The limitation will be how much is available to us. But certainly, if peer review said there ought to be two, we would not be averse to it. It's the question of how much we feel at this moment we can set aside from the predicted 1999 budget."

Early in the discussion of the concept, Minna invited Chiarodo, a veteran of political battles over site-specific research at the Institute, to put the SPORE program in historical perspective.

"Andrew, I just learned recently that you are coming to the end of a long, distinguished career," Minna said. "You have seen some good things and some bad things at varying times here at NCI. What's your feeling about the SPORE program? We are not going to have you to kick around anymore.

"Tell us what you really feel," Minna said.

"Obviously, I am biased," said Chiarodo. "I think the SPORE program is the most innovative program I have seen in my 25 years here at NCI. I would like to think of it as a model for a diseaseoriented effort. Clearly, it has had a dramatic impact of changing the basic culture within institutions. I do think that partnerships are the way of the future in approaching disease oriented research.

"With new and novel mechanisms, the question is always asked, can we do it better with an R01? It's interesting that over the years, the R01 has been accepted as the golden rule. And it is. But R01 was created for basic research. And in my opinion the R01 is not going to give us the kinds of translational efforts that we need.

"If we were to close down all other non-R01 mechanisms and just raise the payline to 50 to 60 percentile, what would that give us in terms of translational efforts to come?

The text of the concept follows:

Specialized Program of Research Excellence in Ovarian Cancer. Concept for a new RFA, total cost at least \$12 million over five years, at least one award, first year set-aside \$2.5 million.

Ovarian cancer is currently the leading cause of death from gynecologic malignancy in the U.S. In 1997, it is estimated that 26,800 new cases of ovarian cancer will be diagnosed in this country and that 14,200 women will die from the disease.

Although the cure rate for stage I disease is nearly 90 percent, the majority of patients present with disease spread beyond the ovary. Despite aggressive surgical debulking and platinum based chemotherapy the 5-year survival rates for women with clinically advanced disease is only 15-20 percent. The magnitude of this problem is reflected in the recent SEER data which indicates the fiveyear survival of patients with ovarian cancer has increased only from 36 percent in 1976 to 46 percent in 1993.

In 1992, the Organ Systems Coordinating Branch of the NCI convened a Workshop on Investigational Strategies for Detection and Intervention in Early Ovarian Cancer. It became clear from this workshop that the scientific base for ovarian cancer is expanding, and that new investigators are turning to research in this field. Since then, the scientific information base for ovarian cancer has continued to expand; however, application of this scientific base to clinical and preventive activities has not been commensurate with this expansion.

Based on evidence from the workshop and in view of increasing numbers of investigators entering the field, it would appear that research in this area could benefit from a SPORE.

There is a need to encourage translational research that would require interdependence between basic and clinical investigators in both the planning and implementation of research and would emphasize the application of basic research findings to patients and populations. Translational research also applies clinical findings to advance basic research that ultimately may lead to hypothesis-driven clinical trials or prevention and control interventions.

The objective of this initiative is to establish a Specialized Program of Research Excellence in Ovarian Cancer.

A SPORE is at an institution that will make a strong institutional commitment to the organization and conduct of the program. The SPORE must demonstrate a balanced approach to research on prevention, etiology, screening, diagnosis and treatment of human ovarian cancer that translates basic research findings into more applied, innovative research settings involving patients and populations.

A SPORE must provide career development opportunities for new, independent investigators who wish to pursue active research careers in translational ovarian cancer research; develop human ovarian cancer tissue resources that will benefit translational research; develop extended collaborations in critical areas of research need with laboratory scientists and physician scientists within the institution and in other institutions; and participate with other SPORES on an annual basis to share information, assess scientific progress in the field and identify new research opportunities that may have an impact in reducing ovarian cancer incidence and mortality.

It is expected that each SPORE will support a mix of interactive basic and applied research that "translates" into areas of early detection, diagnosis, therapy, and prevention and control.

The SPORE mechanism is not intended to support basic research to the exclusion of clinical or applied research.

Special requirements of SPORE:

The institutions selected for award of SPORES must assemble a critical mass of basic and clinical scientists dedicated to the translation of basic findings into more applied, innovative research settings involving patients and populations with the ultimate objective of reducing incidence and mortality to the disease.

Each SPORE must include the following elements:

1. A strong institutional commitment. Institutions receiving these awards must incorporate the SPORE into its institutional priorities. It must provide a plan which addressees how the institutional commitment will be maintained and sustained and how it will maintain accountability for promoting scientific progress. A SPORE application can originate from an institution with or without an existing P30 core grant. If a P30 already exists, lines of authority should be clearly indicated such that the SPORE does not interfere with the P30 chain of authority.

2. A qualified Program Leader. A leader must be selected as the principal investigator who can oversee, conduct planning activities and provide direction to SPORE with a translational research emphasis.

3. A substantive ovarian cancer patient population. A SPORE must be a recognized leader in the treatment of ovarian cancer and have access to a patient population that can participate in and benefit from the innovative applied clinical and population research activities of the SPORE.

4. Research Projects. Finch research project must be headed by basic and clinical co-investigators. This should facilitate exploiting the translational potential of the research. The research must be oriented toward translational activities using human materials and human subjects which address new, innovative possibilities in ovarian cancer research. This program will not support basic research that is without translational potential or significance nor will it support clinical studies that are not "translated" from basic research. At least one research project must be on ovarian cancer prevention or early detection and screening. There is also a strong interest in developing genetic methods for determining high risk to ovarian cancer either through inheritance or through environmental exposures. However, the NCI is open to all novel innovative approaches to prevention.

It is expected that all SPOREs will have a balanced approach to ovarian cancer that encompasses the areas of prevention, etiology, screening, diagnosis and treatment. This balanced approach may be either through research being conducted in their institution, or through collaborative associations they have developed or plan to develop with other SPOREs or with other investigators in the biomedical research community.

5. Specialized Resources. The SPORE must have a dedicated activity to human ovarian cancer tissue collection. This resource must benefit the specific research activities of the SPORE as well as the research activities of other scientists within and outside of the parent institution who are concentrating on translational research issues. The SPORE must be willing to participate in any national prioritization for distribution of tissues through NCI supported tissue networks. A plan must be proposed for prioritizing distribution of tissues to SPORE scientists and others based on the most innovative ideas in translational ovarian cancer research. This plan should be flexible enough to accommodate and complement broader national priorities as they are developed. The development of other resources of special significance to translational ovarian cancer research is also encouraged.

If the SPORE is part of a NCI-designated Cancer Center, the development of resources should not duplicate resources already provided by the center on an existing Cancer Center Support Grant (P30). The applicant should show that the P50 will become an effective, integrated research arm of the cancer center when it is supported by a P30 grant.

6. Career Development. The SPORE must demonstrate an increased commitment to career development. A minimum of \$100,000 in direct costs per year must be dedicated to the salaries and research activities of new, independent investigators who wish to pursue translational research careers on ovarian cancer and who would be expected to leave the SPORE with the necessary research experience to develop independent ovarian cancer research programs within or outside of the parent institution.

7. Developmental Research Funds. The SPORE must allocate a significant proportion of its budget and efforts to the conduct of pilot projects that continually explore new innovative ideas in collaboration with scientists within the institution and with other institutions. It is important that SPOREs use developmental funds to stimulate projects that take maximum advantage of new research opportunities.

8. Annual Meeting of SPORE. Ovarian Cancer SPOREs will be expected to participate in an annual SPORE Investigators' Meeting with the Organ Systems Coordinating Branch of the NCI to share data, assess progress, identify new research opportunities, and establishing priorities relative to the most effective approaches for reducing incidence and mortality.

If a SPORE is located in an institution that is already an NCI-designated Cancer Center, the Program Director of the SPORE must be a senior leader in the cancer center and the SPORE must be a major programmatic element. However, there must be a separate and distinctive commitment of financial resources and/or positions in the institution to ovarian cancer research.

A SPORE is supported through the P50 mechanism. This mechanism supports any part of the full range of research and development from basic to clinical. The spectrum of activities comprises a multidisciplinary attack on a specific disease entity or biomedical problem area.

These grants differ from program project grants in that they are usually developed in response to an announcement of the programmatic needs of an Institute or Division and subsequently receive continuous attention from its staff and are more complex and flexible in terms of the activities that can be funded.

This initiative proposes to award one SPORE grant. A P50 SPORE application may request a maximum annual direct cost of \$1.5 million and maximum annual total cost of \$2.5 million. Future year increases are limited to 3 percent but may not exceed this cap.

A P50 SPORE grant application may request funding for up to five years.

Food & Drug Administration: Clinton Nominates Henney For FDA Commissioner

President Clinton earlier this week nominated Jane Henney for the position of commissioner of the Food and Drug Administration.

Henney, 51, an oncologist and nationally recognized academic leader and public health administrator, worked at NCI and FDA during the Carter, Reagan, Bush and Clinton Administrations. If confirmed by the Senate, Henney would become the first woman to serve as FDA commissioner.

Since 1994, Henney has been the vice president for health sciences at the University of New Mexico where she presided over consolidation of the *university's hospitals*, schools of medicine, nursing and pharmacy, and specialized facilities for mental health, cancer and pediatrics.

From January 1992 to March 1994, Henney served as deputy commissioner for operations at FDA, under then-Commissioner David Kessler. At FDA, Henney managed the agency's daily activities, revitalized FDA's six science centers and implemented key legislation, including the Prescription Drug User Fee Act of 1992, the White House said in a June 23 statement.

"Henney revitalized FDA's centers for biologics, drugs, medical devices, foods, veterinary medicine and toxological research to make them more effective and efficient and to more closely align their research and review functions," the White House statement said. "In addition, she developed a strategic planning process and recruited new leadership for five of the agency's six centers."

From 1985 until joining FDA, Henney served as interim dean of the University of Kansas School of Medicine, as vice chancellor for health programs and policy, and as acting director of the Mid America Cancer Center at the University of Kansas.

Henney joined NCI in 1976, rising from senior investigator in the Cancer Therapy Evaluation Program in the Division of Cancer Treatment to become NCI deputy director from 1980 to 1985 under then-NCI Director Vincent DeVita.

At NCI, Henney was "instrumental in the development of two innovative programs which engaged community-based oncologists in research and provided physicians and patients with up-to-date information on state-of-the-art therapy and investigational research protocols," the White House statement said.

"Dr. Henney has a proven track record at FDA, and if confirmed by the Senate, she will continue to shape the agency to respond to the changing nature of the industry and the health care marketplace," HHS Secretary Donna Shalala said in a June 23 statement. "Dr. Henney will encourage and nurture collaborative relationships with consumers and industry alike—this is crucial to FDA's success in the years ahead.

"A talented manager, Dr. Henney has the solid medical and academic credentials that are needed to understand the burgeoning field of biomedical research and development," Shalala said.

Shalala also recognized Acting FDA Commissioner Michael Friedman, who has been leading the agency for the past 14 months since Kessler left. "I would like to commend Dr. Michael Friedman for the outstanding service and dedicated professionalism that he has demonstrated while serving as Acting FDA Commissioner," Shalala said.

Henney has been a member of the American Society of Clinical Oncology since 1979. "As an oncologist and longtime member of ASCO, Dr. Henney brings an understanding of the needs of cancer patients and others with life-threatening illnesses," John Durant, ASCO executive vice president, said. "ASCO looks forward to working with Dr. Henney on remaining issues of concern to the oncology community."

These issues include accelerating new and supplemental drug indications for life-threatening illnesses, and relaxation of restrictions on the dissemination of accurate information about off-label uses of drugs, as referenced in peer-reviewed journals, ASCO said in a statement.

Henney was born in Woodburn, IN. She received a B.S. in biology from Manchester College, Indiana, in 1969. Henney graduated from the Indiana University School of Medicine in 1973, and took an internship at St. Vincent's Hospital in Indianapolis, a medical residency in Atlanta, and a fellowship in oncology at M.D. Anderson in Houston.

Henney is president of the United States Pharmacopeia, a non-profit organization that publishes the annual compendium of medicines used in the U.S. She serves on the Advisory Committee to the Director of NIH.

Henney is married to Robert Graham, executive vice president of the American Academy of Family Physicians in Kansas City, MO.