



Statement of

**Carol L. Brown, M.D.
Assistant Attending Surgeon
Memorial Sloan-Kettering Cancer Center
Assistant Professor, Obstetrics and Gynecology,
Cornell University Weill Medical College, New York, NY**

On Behalf of

The Society of Gynecologic Oncologists

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Summary

- Gynecologic Cancer Research at the National Cancer Institute (NCI), including
 - Oncology biomarkers, Nanotechnology, and Cancer Genome Atlas;
 - Gynecologic Oncology Clinical Trials Cooperative;
 - Specialized Projects of Research Excellence (SPOREs); and
 - Cooperation between NCI and NICHD on Research Training Programs for Gynecologic Oncologists.

- Gynecologic Cancer Programs at the Centers for Disease Control, including
 - Breast and Cervical Cancer Screening Program;
 - Ovarian Cancer Control Initiative; and
 - Gynecologic Education and Awareness Program.

Mr. Chairman, Ranking Member and members of the Subcommittee, thank you for inviting me to testify at today's hearing. I am honored to be here and heartened by the interest of the Subcommittee in the Society of Gynecologic Oncologists' (SGO) views and recommendations regarding funding for gynecologic cancer programs for research, prevention, detection, and treatment in FY 2007 at the National Institutes of Health (NIH), National Cancer Institute (NCI), and the Centers for Disease Control and Prevention (CDC).

My name is Dr. Carol L. Brown, and I am Chairperson of the SGO Government Relations Committee. I practice medicine at Memorial Sloan Kettering Cancer Center in New York City, New York, where I am Director of the Office of Diversity Programs in Clinical Care, Research, and Training and as Assistant Attending Surgeon.

The SGO is a national society of 1,100 physicians who are trained in the comprehensive management of women with reproductive cancers. Our purpose is to improve the care of women with gynecologic cancer by encouraging research and disseminating knowledge. As gynecologic oncologists, we are women's cancer specialists who receive an additional three-four years of intensive post-graduate medical training in the comprehensive treatment of gynecologic cancers, including cancers of the ovary, endometrium and cervix. This training includes a year of bench research to develop the research skills needed to conduct studies that will positively impact patient care.

The SGO believes that Congress can take action, starting with this Subcommittee making a commitment to increase the funding in FY 2007 for Federal programs focused on saving thousands of women from dying from a gynecologic cancer. Today in the United States, one woman will be diagnosed with a gynecologic cancer every seven minutes. That's over 200 women today and close to 80,000 this year. One-third of these women will die unnecessarily. Early education and prevention, as well as effective screening, could save many of these lives. If detected early, the vast majority of these cancers are curable.

Maintain and Expand Gynecologic Cancer Research Opportunities

While our nation has made a tremendous investment in the National Institutes of Health, it is still not enough and increases in research funding has not been forthcoming for the deadliest of the gynecologic cancers, ovarian. Since FY 2003, the funding levels for gynecologic cancer research and training programs at the NIH, NCI, and CDC have not keep paced with inflation, with the funding for ovarian cancer programs and research training for gynecologic oncologists actually taking a hard cut every year for the last three fiscal years.

NIH Funding	FY 2003 - Actual	FY 2004 - Actual	FY 2005 - Est.	FY 2006 - Est.
Cervical Cancer Research	\$ 92 Million	\$ 94 Million	\$94 Million	\$ 93 Million
Endometrial Cancer Research	\$ 34 Million	\$ 35 Million	\$ 35 Million	\$34.5 Million
Ovarian Cancer Research	\$ 119 Million	\$ 112 Million	\$ 110 Million	\$108 Million

Having this trend continue in FY 2007 is unacceptable to SGO members as there is no early detection method for ovarian cancer leading to a five year survival rate of less than 25% for those whose cancer are detected at stage III, the mortality from endometrial cancer has started to

increase, and women are still dying from cervical cancer, a cancer that is preventable with routine screening.

As many are aware, Coretta Scott King recently died of ovarian cancer, frustrated by this country's lack of advancement in fighting this disease; Mrs. King went to Mexico to seek alternative therapies to treat her cancer. We must do better for the women of this great country. Therefore, the SGO joins with the broader public health and research community urging Congress to provide \$29.7 billion for the NIH in FY 2007. This is the minimal level of funding that will allow the NIH to maintain current initiatives and investments.

SGO is aware of the fiscal challenges facing the Subcommittee in FY 2007; however, more than 10 million cancer survivors can attest to the fact that when investments are made in cancer research-related programs thousands of lives are saved. Therefore, the SGO recommends that this Subcommittee provide the NCI with \$5.9 billion for FY 2007, the professional judgment budget prepared by the NCI Director.

Gynecologic Cancers: Becoming a Priority in the NCI/NIH Roadmap Initiatives

Existing NCI funding for gynecologic cancer research including SPOREs, Program Projects, the Early Detection Network, and Investigator Initiated grants have accelerated basic, molecular-based research discoveries for gynecologic cancers. Recent progress, combined with the need for further innovation, makes this group of cancers important to focus on under NCI's broader "Roadmap" initiatives. For three of these initiatives: Oncology Biomarker Qualification Initiative; Alliance for Nanotechnology; and the Cancer Genome Atlas giving priority to research projects that focus on a gynecologic cancer will allow for the translation of these recent laboratory discoveries into clinical applications at the bed-side, directly decreasing the mortality rates for women with gynecologic cancers.

- **Oncology Biomarkers:**

The NCI, the Food and Drug Administration (FDA), and the Centers for Medicare and Medicaid Services (CMS) recently announced the Oncology Biomarker Qualification Initiative (OBQI) – an agreement to collaborate on improving the development of cancer therapies and the outcomes of cancer patients through biomarker development and evaluation. Biomarkers are biological indications of disease or therapeutic efforts, which can be measured through dynamic imaging tests, as well as tests on blood, tissue, and other biological samples.

Ovarian cancer has a high mortality rate mainly because there is no proven effective method for early detection. This lack of an early detection method has been a catalyst for SGO members to advance the state of the science in biomarker development. Therefore, ovarian cancer is sufficiently advanced to warrant this cancer being one of the first cancers focused on under this new Biomarker Qualification Initiative. At the 2006 SGO Annual Meeting held last week in California, a group of scientific papers were presented where retrospective studies using samples from tissue banks had identified specific biomarkers that indicate the presence of ovarian cancer. These markers are now ready for randomized, prospective studies that would lead to their validation and acceptance. For example, glycomic profiling using MALDI/FTMS may identify unique patterns of glycosylation that may be more

sensitive and specific than CA-125, an existing blood marker, in identification of ovarian cancer patients. Also five circulating plasma proteins, another blood marker, were presented as possibly serving as biomarkers to differentiate women with ovarian cancer from healthy women.

SGO's FY 2007 Request: Congress will work with the NCI to set aside \$15 million of the resources available to the OBQI program in FY 2007 allowing the OBQI Team to work with the SGO and its members to develop a research program to further identify and refine these and other types of biomarkers for gynecologic cancers.

- **Alliance for Nanotechnology:**

Research to identify a screening strategy for ovarian cancer that is similarly as effective as cervical cancer screening is rapidly advancing, but clearly more work and effort must be done. As mentioned above, the death rate and new diagnosis rate of ovarian cancer have not changed in many years, mainly due to the inability to diagnose this cancer when it is in its early stages. Recent research has identified unique cellular and molecular profiling (or signatures) that correlate with early disease. Similar molecular profiling is allowing us to realize we can personalize the chemotherapy treatment for each patient to maximize her response to chemotherapy. These new clinical 'crystal balls' or molecular signatures use nanotechnology, one of the important new technologies in development that is a key initiative on the NCI Roadmap. The NCI Alliance for Nanotechnology is a comprehensive, integrated initiative encompassing the public and private sectors, designed to accelerate the application of the best capabilities of nanotechnology to cancer.

SGO's FY 2007 Request: Congress will work with the NCI to make available \$20 million of the \$145 million it has set aside over the next five years, starting in FY 2006, for the Alliance for Nanotechnology for use in studying the molecular signatures of ovarian cancer to improve the outcomes of these deadly disease.

- **Cancer Genome Atlas:**

A more systematic understanding of cancer genetics could provide important insights into the molecular pathways that, when disrupted, lead to the uncontrolled growth of cancer cells and enable their spread throughout the body. This genetic information could provide powerful advances in cancer clinical research and disease management. In the past 10 years, SGO members have identified two hereditary gynecologic cancer syndromes, familial breast-ovarian cancer syndrome and hereditary non-polyposis colorectal cancer syndrome (HNPCC). The discovery of these syndromes, based on mutations in BRCA 1 or BRCA 2 or a family history of colon cancers and gynecologic cancers, will now allow for the development of diagnostic tests that can point to the most effective intervention. The speed with which these tests can be developed, hinges on gynecologic cancers being a priority of the Genomic Atlas Project, allowing the many genetic changes that occur with these cancers to be cataloged, first.

SGO's FY 2007 Request: Congress will work with the NCI to gynecologic cancers some of the first cancers that are cataloged allowing SGO members and other to have free public access for use in research projects by the end of FY 2007.

Gynecologic Cancers: Clinical Trials Cooperative Bringing the Research to the Bedside

The Gynecologic Oncology Group (GOG) is one of the National Cancer Institute's (NCI) funded cooperative cancer research groups. GOG is the only group which focuses its research on women with pelvic malignancies, such as cancer of the ovary, uterus, and cervix.

Organized in 1970, the GOG has grown from 11 original member institutions to over 50 principal centers and over 160 affiliate institutions. The GOG is a multi-modality group with over twenty-one hundred participants. The GOG is recognized as the leader in the development of new procedures in each of the relevant diagnostic and therapeutic disciplines. The GOG has an active and effective program for the study of new chemotherapeutic agents in the treatment of gynecologic cancers. Currently over 3,300 patients are registered each year to GOG research trials. To date, GOG has completed over 300 clinical trials and contributed over 550 manuscripts to the peer reviewed medical literature.

SGO's FY 2007 Request: We ask this Subcommittee to commit an additional \$5 million to the GOG for translational research involving biologic prognosticators and therapeutic effects of chemotherapy to speed the development and delivery of new cancer treatments to women with gynecologic cancer.

Gynecologic Cancers: Specialized Projects of Research Excellence (SPOREs):

SPOREs are funded through specialized center grants to promote interdisciplinary research and move basic research findings from the laboratory to clinical settings. In FY 2006, the NCI determined that it would not continue the funding for all five ovarian cancer SPOREs, despite the excellent and essential research focusing on the development of molecular markers and other early detection that may be ready for clinical trials in the near term. 16, 210 women died from ovarian cancer in 2005 and ovarian cancer ranks fourth in cancer deaths amongst women. Furthermore, we are concerned that the research infrastructure developed by these SPORE programs over the last five years will be destroyed with the cut in funding.

SGO's FY 2007 Request: We ask this Subcommittee to commit an additional \$2.5 million in FY 2007 to allow the NCI to continue to fund all five ovarian cancer SPOREs. Reduced funding for such research at this critical time will make it even more difficult to develop an early detection method for this cancer.

Gynecologic Cancers: Training the Next Generation of Researchers

NCI previously partnered with NICHD to co-fund career development awards targeting gynecologic oncologists through the Women's Reproductive Health Research Career Development (RSDP) program. This was an extremely successful partnership with over 80% of the gynecologic oncologists who participated in this program choosing a career in research and the majority successfully competing for investigator initiated (R01) grants. However, this partnership was discontinued starting with FY 2004.

SGO's FY 2007 Request: The Subcommittee should direct the NCI to re-establish the partnership with the NICHD by contributing \$2.3 million to cover the costs of the gynecologic oncologist position in the RSDP program.

Increasing Our Nation's Investment in Prevention, Early Detection, and Awareness of Gynecologic Cancers Will Save Lives

The Centers for Disease Control and Prevention (CDC) state-based cancer programs provide vital resources for breast and cervical cancer screening, state cancer control and planning and implementation, and awareness initiatives targeting gynecologic cancers. The programs discussed below having proven to be highly effective, an excellent rate of return for our Federal dollars.

National Breast and Cervical Cancer Early Detection Program:

Large-scale screening for cervical cancer has clearly decreased the mortality from this potentially preventable cancer. Part of the reason for this success is the development of an excellent screening test, the liquid-based Pap test. More recently, directly due NIH-funded research objectives, triage of patients with an abnormal Pap test who need more therapy is improved with the addition of testing for Human Papillomavirus, the infectious agent implicated in over 95% of cervical cancers. Development of these effective screening strategies have effectively cut the rate of cervical cancer in this country, however the rates of newly diagnosed cervical cancers have not changed considerably in 10 years, due to a lack of access to and education about cervical cancer screening due to a lack of Federal funding. 3,710 women died last year from this totally preventable cancer. These deaths were unnecessary.

SGO's FY 2007 Request: We ask this Subcommittee to commit an additional \$50 million in FY 2007 in Federal funding for the National Breast and Cervical Cancer Early Detection program, a total of \$250 million, allowing an additional 130,000 women to be served by this program.

Ovarian Cancer Control Initiative:

The Ovarian Cancer Control Initiative partners with academic and medical institutions to spur discovery of techniques that will detect this cancer and through the creation of guidelines, develop more successful treatments by fostering collaboration and cooperation.

SGO's FY 2007 Request: We ask this Subcommittee to commit an additional \$3 million in FY 2007 in Federal funding for the Ovarian Cancer Control Initiative, a total of \$7.5 million, restoring hope to the more than 20,000 women who will be diagnosed with this devastating disease this year.

Gynecologic Cancer Awareness and Education Program:

Starting in FY 2006, the CDC in cooperation with the Office of Women's Health at the Public Health Service was directed through report language to conduct public education and awareness programs to explain the facts about the early warning signs of gynecologic cancers using various forms of communication, in cooperation with nonprofit organizations.

SGO's FY 2007 Request: We ask this Subcommittee to commit \$1 million in FY 2007 in Federal funding for the Gynecologic Cancer Awareness and Education Program, arming women with the basic facts about these cancers.

Statement Regarding Disclosure Requirement:

Dr. Brown has not received a grant or a contract from a Federal source in FY 2006, FY 2005 or FY 2004.

The Society of Gynecologic Oncologists has not received a grant or a contract from a Federal source in FY 2006, FY 2005, or FY 2004.

Biography for Dr. Carol L. Brown:

Carol L. Brown, M.D., is a board-certified gynecologic oncologist who is the Director of the Office of Diversity Programs in Clinical Care, Research, and Training at Memorial Sloan-Kettering Cancer Center. She holds academic appointments as Assistant Attending Surgeon, Memorial Sloan-Kettering Cancer Center, and Assistant Professor, Obstetrics and Gynecology at Cornell University Weill Medical College, New York, NY.

Dr. Brown's academic and research activities in gynecologic cancer are concentrated in cervical and ovarian cancer and focus on novel treatment strategies as well as screening and prevention of both diseases. She is currently focusing on lowering cervical cancer rates for women in high-risk groups by designing interventions to improve screening rates, and increasing public awareness about ovarian cancer.

Dr. Brown currently holds several committee positions including Chairperson for the New York State Department of Health's Ovarian Cancer Information Program Advisory Council and Advisor for Special Populations for the Gynecologic Oncology Group. She is Chair of the Government Relations Committee of the Society of Gynecologic Oncologists and is a delegate to the American Medical Association. She is a member of numerous professional societies including the National Medical Association, the American Medical Association, and the American Society of Clinical Oncology. Dr. Brown is a fellow of the American College of Obstetricians and Gynecologists and of the American College of Surgeons.

Dr. Brown is the recipient of several awards, including Harvard University's Joseph Garrison Parker Prize, the Malcolm X Memorial scholarship from Columbia University, and the American Cancer Society Clinical Oncology Career Development Award, and was recently named one of "America's Leading Physicians" by Black Enterprise magazine.

Dr. Brown graduated with honors from Harvard University and received her medical degree from Columbia University's College of Physicians and Surgeons, New York, NY. She completed her residency at Obstetrics and Gynecology Hospital of the University of Pennsylvania, Philadelphia, PA. She completed her fellowship in Gynecologic Oncology at Memorial Sloan-Kettering Cancer Center, New York, NY.