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Presidential Address

# The Society at a Crossroads: Milestones and Imperatives for Cancer Clinical Trials

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The Society of Surgical Oncology (SSO) has evolved into the leading academic oncologic society for surgeons. Major contributions by members of the SSO include significant participation in cancer clinical trials and basic biomedical research, which should be maintained and enhanced. Progress with outcomes research for basic, translational, and clinical investigations must be sustained with supportive biomedical technology to complete clinical trials in Phases I–IV. Investment in the development and support of translational researchers is of paramount importance to the future of the discipline.

**Key Words:** Cancer clinical trials—Translational research—Biotechnology—Biomedical research—Surgical oncology.

It is with personal gratitude and appreciation that I close the year as the President of the Society of Surgical Oncology. Whether this honor was bequeathed me by fate, luck, or hard work, I shall always treasure the opportunity I have had to serve this body of distinguished surgeons in this office of the preeminent academic surgical oncology society. This has been a great personal honor for me and my family, and I thank you. I owe many in this audience—members, residents, and administrative staff—my sincere thanks for your contributions to both professional and governance issues that allowed decisions to be formulated which I feel have positively impacted the Society. To begin to mention these persons would, perhaps, also beg the question of omission of individuals who have made equal contributions; therefore, I will only express my gratitude to the membership and to the Executive Council for your sustained support, query, and advice.

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This manuscript is dedicated to those individuals with cancer whose hope in sustaining life was invested in a prospective study in which the outcome was yet unproven for themselves and future cancer patients.
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As we celebrate the 50th Annual Scientific Assembly of the Society, I feel that it is important that we acknowledge the foundation of the SSO, and this will be comprehensively reviewed in a commemorative presentation by Dr. Irvin Fleming. The origins of the Society date to the mid-1930s, when Dr. Hayes Martin and Mr. George Holmes (administrator) proposed the development of an alumni association for physicians who had trained at Memorial Hospital. No progress occurred until November 1939, when a meeting that included Hayes Martin, Bill MacComb, Al Hocker, Sam Binkley, John Blady, Gordon McNeer, and John Wirt, who served as a committee to ascertain the feasibility of creating an alumni organization, was held at the old Memorial Hospital on Central Park West. On June 10, 1940, the Society was launched with a meeting at the Lexington Hotel in New York City, and Dr. MacComb was appointed as its temporary chairman. Moreover, Dr. MacComb was designated as spokesman to approach the renowned Dr. James Ewing, pathologist and Director at Memorial, to obtain his permission to name the alumni society "The James Ewing Society" in his honor. This was expeditiously accomplished, with some reluctance on the part of "the Chief." The original committee thereafter appointed an Executive Council and established a committee to develop and institute the constitution and bylaws of the new society. The second annual meeting, in June 1941, was, again, an

organizational meeting that included the presentation and acceptance of the constitution and bylaws. The third annual meeting, on January 9, 1942, held in Atlantic City, was significantly impacted by the December 7 attack on Pearl Harbor and the entry of the United States into World War II. Only ten members were present. New officers were elected, and the first Executive Council was appointed, including election of the new President, Dr. George Sharpe, who served in this office for the 5 years until the next meeting, which took place on June 10, 1947. The expansion of membership to include residents, fellows, and special fellows trained at Memorial allowed the progressive enlargement and development of this nascent alumni association. The first James Ewing Cancer Society Scientific Assembly was held in New York City in January 1948.

At the annual meeting in 1975, upon recommendation of the Executive Council, the membership voted to change the name to "The Society of Surgical Oncology, Inc. (founded as the James Ewing Society)." Despite a change in name of the Society in the spirit of egalitarianism, the constitution and bylaws have not changed appreciably since its inception. Subsequent inclusions to the Society have been the Standing Committees on Continuing Medical Education, Training, Clinical Affairs, and Corporate Relations. The Committee on Issues and Government Affairs has been established, and the American Board of Surgery has appointed a Director from the Society to the Board. Moreover, representation has been included to the National Cancer Advisory Board, the Board of Governors of the American College of Surgeons, and the Commission on Cancer of the American College of Surgeons.

Steeped in tradition and dedicated to the enhancement of quality surgical education, training, and research in oncology, the Society continues to pursue the goals for which the founders developed this alumni association in honor of Dr. Ewing. The James Ewing Foundation was organized to perpetuate the memory and contributions of Dr. Ewing in a manner that acknowledges his dedication to education, research, teaching, and care of the cancer patient (1). The extraordinary talents and contributions by the membership to the Society, and its humble origins as an alumni association dedicated as a lasting memorial in Dr. Ewing's honor, will sustain this prestigious society as we enter the next millennium. Major contributions to clinical cancer care have been originated, implemented, and conducted by members of the Society. The Society is now the preeminent surgical oncology society; its members are indebted to its founders, who molded the Society into an organization that is recognized internationally as the voice of surgical oncology.

Throughout my surgical career I have been involved with the design, initiation, and conduct of clinical trials. Those of us involved with the support of and investment in these scientific studies have grave concerns for the preservation and future of clinical trials. My address, therefore, focuses on cancer clinical trials, the forces threatening them, and what the SSO and its members can do to ensure continuance of these trials and the enhancement of patient enrollments. Clinical oncologic studies began in the late 1960s and 1970s, and rapidly evolved into the prospective randomized scientific trials in which we currently participate. Whereas Dr. Ewing, and few of his original associates, had little opportunity to participate on a regular basis in organized scientific prospective studies, our current approaches result from contributions by many individuals in the Society. These methods for oncologic research form an objective scientific basis on which to plan future research outcomes. Residents in training and oncologists in various disciplines commonly apply the results of cancer clinical trials in the daily management of cancer patients.

I, therefore, would like to enumerate my concerns for preservation of these oncologic trials and methodologies. The future of the Society and our commitment to research and education are inculcated into the methodology, conduct, and implementation of such trials. This lecture is dedicated to the thousands of patients who have participated in prospective clinical trials in the hope that their investment in scientific query will enhance survival and quality of life both for themselves and for other patients who subsequently develop cancer.

## MAJOR TRENDS INFLUENCING CANCER CLINICAL TRIALS OF THE 1990s

When one reviews the scientific progress and major achievements in cancer treatment of the past two decades, it is evident that the most prominent accomplishments occurred through controlled clinical trials. Examples include the conservation management of breast cancer, progress in the treatment of acute leukemia, increased cures for pediatric solid tumors, and the advancement of potential cure for testicular cancer (2). At present, cancer clinical trials are being conducted in academic health centers and cancer centers (40%) and in the community hospital environment (60%) (3,4). Fleming (5) recently reviewed the outcome of various clinical trials with emphasis on reimbursement problems and their potential solutions. The increasing emphasis on cost control, managed cancer care, and health care reform has provided increasing resistance and even denial by third-party insurance carriers for the usual cancer care com-

pleted within prescribed guidelines of cancer clinical trials.

Several sources for costs and the mechanisms for reimbursement are involved in the delivery of protocols for cancer trials. First is the *"usual and customary care" cost* for therapy of patients, which is generated regardless of whether or not the patient participates in a clinical trial. This cost has historically been remunerated by third-party carriers such as indemnity insurance and Medicaid/Medicare. Second is the *administrative cost* associated with the conduct of the study, which includes biostatistical studies, travel, meeting expenses, and data acquisitions. These costs are typically borne by the sponsoring organization (e.g., NCI/NIH, CALGB, and NSABP). The third cost, which is real but sometimes was hidden in studies of the past, is the *extra cost of patient care* in trials generated specifically by the cancer clinical protocol, including medications, diagnostic imaging, and basic and extensive laboratory studies. These costs are often denied reimbursement because they may be substantial, especially when advanced methodologies with imaging and technology are essential for evaluations (e.g., MRI, CT scans, radionuclide imaging, or monoclonal antibodies). Moreover, these costs usually are not fully reimbursed by the sponsor of the clinical cancer trial. By virtue of the increasing TNM stage and the difficulty in management of the cancer patients approved for participation in these protocols, the trials generate additional laboratory and imaging studies and operative procedures designed to identify or enhance disease-free and overall survival. However, as a consequence of these diagnostic measures and additive approaches, cancer clinical trials typically generate these extra studies, which are cost ineffective and add to prolongation of hospitalization, while increasing toxic side effects and costs for expensive drugs not otherwise used in patient management. Third-party payors, as well as case managers in the hospitals in which these trials are conducted, increasingly scrutinize the conduct of patient care expectantly, and commonly deny these additional therapies unless preapproved by the indemnity insurance carrier, Medicaid/Medicare, and the Institutional Review Board (IRB) of the center in which the protocol is being conducted. Additionally, prolongation of these trials within the context of approved IRB studies may result in patients being denied reentry into protocol assessment, denial of further therapeutic intervention because of increasing costs, or both. These patients may be further denied reimbursement for "usual cancer care." These changes in care reimbursement are seen as barriers to cancer clinical trials, because there are: (1) a decrease in cost reimbursement; (2) an increase in capitation and diagnostic related groups (DRG) payments; (3) an increase in "discounting"; and (4) the presumptive advancement into "managed competition" (5).

As noted earlier, hospitals have historically funded cancer clinical trials and research via third-party indemnity insurance payments of approved "usual care costs," and through supplemental funding for the costs of special studies in treatment related to the protocol. In many academic health centers, foundations and philanthropy have contributed to clinical trial support via fund-raising, or internal decisions have been made for "cost-shifting" from other income sources. Furthermore, academic health centers and cancer centers may also have core or program project grants that support these cancer clinical trials.

The negative impact of managed care and cost containment on oncology clinical trials was recently made evident by Mortenson (6) of the Association of Community Cancer Centers (ACCCs) at a meeting of the Collaborative Research Group (CRG). A survey by the ACCC of 856 oncologists in 20 states involved in CRG clinical investigations confirmed that 3361 patients had been unable to enter clinical trials because of insurance denials. As a way of providing measures to counteract the increased difficulty faced by community-based investigators in conducting these trials and accruing patients to cancer research studies, the CRG agreed to vigorously pursue, with high priority, pharmaceutical and biotechnology industry support for these studies.

Of interest, the now-defunct Clinton health plan, which originally proposed the concept of managed competition for support of cancer clinical research, suggested that hospitals should compete for health contracts on the basis of lowest cost. However, any additional expense for clinical studies would have significant negative impact, perhaps eliminating the majority of cancer research in community hospitals, unless additional funding was provided (5). Indeed, this plan was to have clinical trials supported by third-party reimbursement for the "usual care" of patients, but only if patients participated in an approved clinical trial conducted by a national trials review organization (e.g., NCI/NIH, VA, or FDA) and approved by the Medical Review Board. The Clinton plan earmarked additional funds for research; the bulk of these funds were appropriated for studies of the reimbursement mechanisms, however, rather than being specifically designed for scientific clinical research.

## Barriers to Enrollment in Clinical Trials

Multiple factors contribute to the inability of academic medical centers, the NIH, and community trial groups to enroll in clinical trials all patients who may benefit from

participating in these studies. These issues were recently discussed in the President's Cancer Panel held at Brown University in October 1996 (7). Despite efforts by the NIH to increase these accruals to CCOP and CGOP and other trials, well-intentioned outcomes have met with mixed results, as follows: (1) greater time commitments and administrative burdens on physicians who are experiencing simultaneous decreases in their fiscal incentives for participation in these trials (8); (2) fear and confusion among eligible patients who are concerned about selection of the most appropriate therapy; (3) the inherent competition between opening clinical trials to the general community and, perhaps, losing valuable data generated from center-sponsored trials; (4) a shift toward provision of care by generalists rather than specialists; (5) patient resistance to entering clinical trials when the option exists for state-of-the-art therapy by their oncologists (7); (6) the stringent requirements for protocol review by members of the participating medical staff and IRBs (8); (7) physician opposition to randomization of patients required in phase III trials (8); (8) difficulties in securing reimbursement from managed care companies and other third-party payors; and (9) the increased patient-care costs associated with tertiary care facilities provided in academic medical centers. These barriers to accruing eligible patients to clinical trials become more evident because the academic medical centers, where research is an integral portion of patient care and medical education, treat only a small portion of cancer patients (10–15%) (7–9).

## CONTEMPORARY TRENDS TO ENHANCE PARTICIPATION IN CLINICAL TRIALS

In contrast, there are forces in operation that encourage participation in cancer clinical trials and basic research:

1. Well-informed patient advocacy groups that educate cancer patients about the benefits of clinical trials and actively lobby for their support have evolved. These successful groups were modeled on the successes of the AIDS advocacy community, which has promulgated a rapid approval process for promising new drugs and has continued to serve as a model for other disease advocacy groups.
2. An explosion of cancer information is readily available to patients and their families on the information superhighway, most commonly via the Internet (10). This rapid and comprehensive source of cancer information is also available to physicians/specialists (e.g., PDQ, Silver Platter).
3. There continues to be increased support of clinical cancer research by the NCI and the pharmaceutical and technology industries for both community- and hospital-based cancer research. In addition, with direct marketing to consumers, the FDA's efforts to expedite its approval times and to secure reimbursement for "off-label" uses of approved drugs have fostered a greater appreciation among the public of the importance of the drug development process and the availability of promising new products.
4. The legislative efforts by medical oncologists to mandate coverage of "off-label" drugs in cancer care further encourage participation in clinical cancer research trials (11).
5. Finally, the threat of litigation and the adverse publicity generated by competitive managed care environments and HMOs are forcing third-party insurers to consider coverage of certain cancer chemotherapies and technologies (e.g., autologous bone marrow transplantation [ABMT] for breast cancer) (12). The 1996 GAO study of reimbursement for ABMT/stem cell transplant for breast cancer revealed that many insurers are covering the procedures despite unanswered questions about the clinical efficacy of the procedure. Managed care organizations (MCOs) have great trepidation regarding litigation and the ensuing unfavorable publicity, and this fear remains a major factor in these companies' decisions (12).

### Regional Impact

Throughout the United States and Canada, legislatures are becoming active on the subject of clinical trials reimbursement. Rhode Island was the first state that required health insurance companies to pay for Phase III/IV clinical trials for cancer patients. This legislative mandate followed action (January 1994) to pass "an Act relating to health care insurance policies for new cancer therapies" (State RI 27-18-35.2). In this statute, coverage is provided for Phase III and IV clinical trials that are still under investigation when the following circumstances prevail: "Treatment is being provided pursuant to a Phase III or IV clinical trial which has been approved by the NIH in cooperation with the NCI, Community Clinical Oncology Programs, the Food and Drug Administration in the form of an IND exemption, the Department of Veterans Affairs, or a qualified nongovernmental research entity as identified in guidelines for NCI cancer center support grants."

After 24 months of experience, two of the major insurers in Rhode Island indicated that they have experienced no negative financial impact as a result of this legislation. Because only 5% of eligible patients enter

clinical trials, and because insurance companies have to provide coverage for standard ("usual") health care, it is unlikely that significant financial impact would be expected when patients enter these studies. The academic oncology physicians at Brown University consider that entering these patients on randomized trials offers our patients the potential benefits of the newest developments in oncology management.

The Rhode Island legislature is now introducing legislation to extend the Rhode Island statute to include Phase II trials, in which "cutting-edge" translational research in oncology is expected. In the fall of 1996, a survey of the impact of managed care on clinical trials disclosed that 88% of Rhode Island oncologists consider extending current law to fund Phase II trials "highly important"; 100% of surgical oncologists agreed with extending current legislation. In February 1997, my oncology colleagues testified before the Rhode Island legislature for introduction of these measures. The passage of this important legislation to extend coverage to Phase II (and possibly Phase I) trials would provide the citizens of our state the maximum opportunity to participate in state-of-the-art oncologic clinical trials research.

Bill 27-18-40, introduced in January 1997 for the General Laws entitled "Accident and Health Insurance Policies," also positions Rhode Island as the first state to regulate insurance coverage for genetic testing. Under this bill, health insurers subject to the provisions of this section are forbidden to:

1. "Use a genetic test or the results of a genetic test to reject, deny, limit, cancel, refuse to renew, increase the rates of, affect the terms or conditions of, or otherwise affect a health insurance policy or contract;
2. Request or require a genetic test for the purposes of determining whether or not to issue or renew health benefits coverage; or
3. Release the results of a genetic test without the prior written authorization of the individual from whom the test was obtained."

This proposed law applies to health insurers in general, nonprofit health service corporations, and HMOs. This act, therefore, prohibits insurers from using genetic testing to make negative decisions regarding insurability, risk, or outcome in any aspect of coverage when applied under current policies and contracts. It is hoped that other states will use a similar approach when genetic testing becomes more widely applied for various oncologic and disease states, because it is highly probable that this methodology will also be integrated into clinical trials. The medical community and patient advocacy groups in Rhode Island are working to ensure that all phases of cancer clinical trials will be covered by third-party payors or MCOs in the near future.

## THE EFFECTS OF MANAGED CARE ON THE PERFORMANCE OF CLINICAL TRIALS

Clinical investigators and translational researchers who design and implement cancer clinical trials must have insight into the economic design of a proposed study, as well as its scientific merit. Concomitant with the ethical and fiscal responsibilities expected of the clinical scientist who designs such a trial is the obligation of the managed care organization to operate in the interest of its patient-clients and the communities that it serves. This industry would prefer to "legislate away" disease and reimbursement for patient care to gain in the "risk-sharing" profits of managed care. The egregious and aggressive posture currently taken by for-profit hospitals, HMOs, and MCOs will necessitate regional and national legislation to address their oversight and the lack of the ethical responsibility that is incumbent upon health care insurers and the research community.

My colleague, Dr. Arvin Glicksman, serves as Director of the Quality Assurance Review Center (QARC) at Brown University for central review services of radiotherapy components for clinical trials of national cooperative groups. Currently, QARC services the CALGB, POG, RSG, and a component of CCG. Investigators of over 500 cancer management facilities in the United States were recently surveyed by the QARC regarding the current environment in clinical trials and the impact of managed care on their clinical research. One fourth of respondents noted a change in their institution's policy and its attitude regarding participation in cancer clinical trials. Approximately two thirds, particularly respondents in the East, stated that they receive subsidies to cover overhead expenses, such as travel, personnel, and supplies; however, only 30% (principally in the Northeast) receive support for patient costs incurred in these clinical trials. These subsidies are garnered from practice plan funds (47%) and from indirect costs (18%); over one half of respondents did not identify the source of subsidies they received.

The QARC survey by Glicksman (13) found that 77% of respondents, including 93% of medical oncologists and 66% of surgeons, participated in clinical trials other than those sponsored by the national trial groups (Table 1). Phase I trials had the lowest participation rates (34% in NCI-sponsored trials; 39% in cancer center trials; and 41% in industry-sponsored trials). Participation in Phase II trials included 48% in NCI-sponsored trials; 52% in

**TABLE 1.** *The influence of managed care on clinical trials: participation in clinical trials other than group trials*[a]

| Physician participation (%) | Medical oncologists 93 | Pediatric oncologists 72 | Radiation oncologists 86 | Surgeons 66 | Overall 77 |
|---|---|---|---|---|---|
| **NCI-sponsored** | | | | | |
| Phase I | 46 | 29 | 38 | 26 | 34 |
| Phase II | 73 | 32 | 52 | 40 | 48 |
| Phase III | 62 | 43 | 56 | 53 | 54 |
| **Cancer center trials** | | | | | |
| Phase I | 11 | 7 | 24 | 14 | 39 |
| Phase II | 19 | 8 | 27 | 21 | 52 |
| Phase III | 13 | 5 | 30 | 17 | 45 |
| **Industry-sponsored** | | | | | |
| Phase I | 46 | 39 | 22 | 35 | 41 |
| Phase II | 85 | 46 | 28 | 56 | 60 |
| Phase III | 62 | 43 | 25 | 44 | 50 |
| **Other trials** | | | | | |
| Phase I | 12 | 18 | 10 | 14 | 13 |
| Phase II | 8 | 29 | 19 | 14 | 17 |
| Phase III | 4 | 18 | 15 | 14 | 13 |

[a] According to Glickman (13).

cancer center trials; and 60% in industry-sponsored trials (see Table 1). A similar distribution was evident for Phase III trials in this survey: 54% in NCI-sponsored trials; 45% in cancer center trials; and 50% in industry-sponsored trials (see Table 1). This survey identified no major differences with regard to geographic region or discipline of oncology.

An important finding of the QARC survey was that one half of respondents reported a decrease in the availability of patients for Phase II and Phase III trials, as a consequence of the entry of MCOs into the health care environment (Table 2) (13). The loss of available patients for these studies was most commonly related to the emphasis on cost containment, markedly fewer referrals, an increase in fragmented care, limitations on care rendered outside of a network, and reduction of patient availability for newer (FDA, NCI-approved) therapies. Only 22% of respondents indicated that the decreased availability of patients affected which trials they chose to participate in as investigators. Over one fifth of respondents indicated that patient willingness to participate had been impacted by managed care; common concerns included randomization and loss of reimbursement. Major financial anxieties were greatest among oncologists in the West, where MCOs have achieved maximum penetration of the health care market (13).

## FUTURE TRENDS INFLUENCING CANCER CLINICAL TRIALS

Nationally, the majority of privately insured individuals are enrolled in some variant of managed care; Medicare and Medicaid are the next major markets for the managed care industry. Both Medicaid and Medicare patients are increasingly being served their medical care via MCOs. Over 61 million poor, aged, and chronically ill Americans are affected by these public insurance programs; this transformation has profound implications for

**TABLE 2.** *The influence of managed care on clinical trials: Impact of managed care in the community*[a]

| | Medical oncologists | Pediatric oncologists | Radiation oncologists | Surgeons | Overall |
|---|---|---|---|---|---|
| **Patient availability for study (%)** | 67 | 59 | 65 | 71 | 66 |
| Phase I | 37 | 29 | 40 | 35 | 35 |
| Phase II | 56 | 41 | 47 | 49 | 48 |
| Phase III | 63 | 39 | 67 | 54 | 56 |

[a] According to Glicksman (13).

academic medical institutions and the training of surgical oncologists, should these funds be significantly reduced (14). Within calendar year 1995, Medicare enrollment in risk-bearing HMOs grew in excess of 26%. Currently, over 5 million Medicare beneficiaries are enrolled in managed care plans. Enrollment in HMOs is growing by more than 80,000 per month and currently accounts for 13% of the more than 38 million Medicare beneficiaries (15). Health Care Financing Administration (HCFA) administers the Medicare program, contracting with more than 280 MCOs, of which nearly 200 are on a risk basis (14). The transformation of Medicaid is even more dramatic: Medicaid managed care enrollment grew over 50%, reaching nearly 12 million individuals—representing one third of all program beneficiaries. Forty-nine states now employ managed care in their Medicaid programs, 46 of them through waivers approved by HCFA (16).

As the leading purchaser of managed health care, HCFA will demand far greater accountability of MCOs on a national scale, affecting both private and academic physicians. Differences in quality among the MCOs will be measured and disseminated among the health agencies, giving beneficiaries a basis for choice among competing MCOs. Thereafter, HCFA will demand continuous improvement in outcomes from all providers; clinical and functional status outcomes will be the principal measures of quality (12,16).

### Current Congressional Actions and The Impact on Research-Related Patient Care Costs

Future trends that impact cancer clinical trials are those that involve Congressional action to mandate MCO coverage of research-related costs for patient care. Current law suggests that Medicare generally does *not* pay patient care costs incurred during a clinical trial. An exception adopted last year allows Medicare coverage of investigational medical devices used in clinical trials, and of the associated medical care, if the FDA determines that the investigational device is similar to a previously approved or cleared device. In 1996 Senators Jay Rockefeller (D-WV) and Connie Mack (R-FL) sponsored the "Medicare Cancer Clinical Trial Coverage Act of 1996" (S. 1963). This bill was introduced "to establish a demonstration project to study and provide coverage of routine patient care costs for Medicare beneficiaries with cancer who are enrolled in an approved clinical trial program" (16). This important legislation did not pass in the 104th Congress, due to the uproar that occurred as a consequence of efforts at balancing the federal budget by reducing Medicare and Medicaid. Both Senators Rockefeller and Mack plan to introduce a similar bill in the 1997 105th Congress (16). Although this legislation requires Medicare coverage for patient care costs when associated with a beneficiary's participation in a clinical trial, additional components of this bill will require that added costs associated with coverage be quantified.

Increasing attention will also be focused on the real and perceived bottlenecks in the new drugs/device approval process, with impetus from emerging coalitions of patient advocacy groups and physician professional societies. An additional stipulation proposes that the Secretary of Health and Human Services (HHS) conduct a demonstration project to study the feasibility of covering patient costs for beneficiaries diagnosed with cancer and enrolled in certain approved clinical trials. Eligibility for coverage would depend on approval of the trial design by one of several high-quality peer-review organizations, including the NIH, the FDA, the Department of Defense, and the Department of Veterans Affairs. Further, no later than January 2001, the Secretary of HHS would be required to report to Congress the audited concerns of any incremental costs of such coverage and the advisability of covering other diagnoses under the same circumstances.

This proposed legislation has been supported by multiple patient advocacy groups and professional societies, including the SSO, the American Cancer Society, the American Society of Clinical Oncology, and the National Coalition for Cancer Survivorship, among others. These advocates for both consumer and professional groups have become active at the agency level as well. For example, these groups have forced the FDA to address its regulatory review for new products, in order to shorten the 10 to 12 years it often takes to bring a product to market. This lengthy and arduous process results in slow patient accruals, unnecessary delays, and reimbursement denials; this laborious process also allows the emergence of ethical questions regarding the best course of therapy for patients who are involved in these studies. With regard to pharmaceutical evaluations, these ethical issues require reevaluation of Phase I and II research design, essential to achieve maximal benefit through the best methods of drug dosing (7). Thus, the growing availability of new therapeutic biological agents/technological advances will challenge the traditional models of cytotherapeutic agents and result in greater variability among reimbursement policies (7,17).

## THE NATION'S INVESTMENT IN BASIC AND TRANSLATIONAL CANCER RESEARCH

Progress in oncologic research and innovations is unprecedented. The Human Genome Project is ahead of

schedule in identifying a complete human genetic blueprint. This is the result of our nation's investment in biomedical molecular genetic research. Genetic tests are commercially available for many diseases, including hereditary breast–ovarian cancer (BRCA1, BRCA2), hereditary nonpolyposis colon cancer (MSH2, MLH1), familial adenomatous polyposis (APC), familial melanoma (p16), and medullary thyroid cancer (RET), as well as various other protooncogenes and tumor suppressor genes used in oncologic practice. Additionally, medical oncologists and surgeons may use new approaches to the therapy of solid organ malignancies that include cell cycle regulation and biologicals to induce programmed cell death by apoptosis. Antiangiogenesis research continues to build on the clinical evidence linking observed levels of angiogenesis in a primary tumor to metastasis and overall survival. Clinical strategies are aimed at inhibiting angiogenesis by interfering with several pathways: TNP-470, thalidomide, and PDGF products (e.g., SU-101) will soon enter Phase I and Phase II trials. Use of tissue inhibitors for proteases and the application of genetic therapy to restore aberrations of protein loss or mutation of genetic constructs are exciting translational research developments.

The Society has an unparalleled opportunity to apply to our practice of oncology the knowledge gained from basic research studies. The common denominator that bridges basic science to progress in cancer prevention, care and outcomes is *translational research.* The latter research rapidly moves our basic methodologies into technological refinements that thereafter initiate clinical cancer trials. Translational research is, therefore, conducted by the physician-scientist and his or her coinvestigators, who are comprised of laboratory personnel, technicians, data managers, nurses, and the supporting infrastructure of epidemiology and clinical oncology. With the ability to recognize the potential of promising new therapies, the translational researcher is in the unique position of designing and implementing cancer clinical trials for Phase I and Phase II studies. Thereafter, these developmental studies are advanced and tested in prospective large-scale Phase III efficacy trials. The Phase III randomized trials that are conducted by national clinical trials cooperative groups, the NCI, CCOPs, cancer centers, and industry are the final pathways for assessment of the effectiveness and merit for widespread application of these preventive or therapeutic interventions and techniques.

However, the translational researcher represents an endangered species in all disciplines of medicine, especially surgery, because this individual has the greatest difficulty competing for research support. These clinical scientists are critical to the success of Phase I and II trials, and, because of their knowledge of scientific query and clinical medicine, provide design and implementation of Phase III trials. This important bridge to clinical trials research is often characterized as too clinical and applied for the basic scientist, whereas it is considered too basic as an inquiry for the clinical investigator and industry. As a consequence of this paradox, translational scientists undergo prolonged training, commonly combining fellowships in their medical or surgical oncology training with 2 to 3 years in bench research. Thus, the young surgical investigator or general surgical resident considering a career in surgical oncology translational research may conclude that this pathway is "academic suicide."

The NCAB has recognized the need to balance "concept-targeted" and "disease-targeted" translational and clinical research (18). Further, a subcommittee of the NCAB has made strong recommendations for preservation of translational and basic cancer research (18). Recommendations to the National Cancer Program by the NCAB, chaired by Dr. Paul Calabresi of Brown University, further emphasize the importance of an enhanced relationship between industry and government to balance our return on investment for both partners to ensure the development of new clinical modalities. Chief among these processes that can be improved is a reduction in the time for new drug and technological testing to enhance the commitment of pharmaceutical and biotechnology companies to develop new agents and technologies for use in Phase I and II trials.

## Patient-Oriented Translational Research

Evaluation of the NCI budget for fiscal year 1994 suggests that investigator-initiated, patient-oriented research received little funding relative to the total budget. For fiscal year 1994, of the total NCI funds of $2.076 billion, 21.3% ($442.2 million) was directed to clinical trials and clinical treatment research programs. However, investigator-initiated R01 clinical research received only 1% ($21.5 million) of the total NCI budget (19). The actual NCI budget for fiscal year 1996 was $2.255 billion dollars; $1.035 billion (45.9%) is dedicated to research project grants (Table 3). The investigator-initiated R01s in clinical research (R03, R21, R29, R35, R37, and R55) are essential for development and maintenance of translational research. These investigators will receive 9.3% of fiscal year 1996 total NCI budget ($210,299 million of $2.255 billion). This increased allocation for patient-oriented research project grants (RPGs) is 20.3% of the total NCI investigator-initiated grants funded (Table 4). Moreover, the fiscal year 1997 budget (estimated) pro-

**TABLE 3.** *National Cancer Institute Budget: fiscal years 1995–1998 (dollars in thousands)*

| | 1995 (Actual) | 1996 (Actual) | 1997 (Estimate) | 1998 (President's budget) |
|---|---|---|---|---|
| Research project grants | $977,561 | $1,034,530 | $1,119,267 | $1,163,288 |
| Cancer centers | 156,766 | 163,073 | 168,135 | 171,135 |
| Clinical cooperative groups | 75,192 | 89,244 | 91,160 | 92,960 |
| Other research grants | 30,850 | 33,680 | 42,165 | 39,965 |
| Subtotal, grants | 1,240,369 | 1,320,527 | 1,420,727 | 1,467,348 |
| National research training awards | 38,571 | 41,170 | 43,669 | 44,419 |
| R&D contracts | 152,544 | 166,334 | 171,052 | 173,452 |
| Intramural research | 391,084 | 406,891 | 403,805 | 412,805 |
| Research management & support | 108,059 | 100,831 | 100,793 | 100,793 |
| Cancer prevention and control | 192,275 | 216,187 | 238,103 | 240,348 |
| Construction | 8,000 | 3,000 | 3,000 | 2,573 |
| **Total, NCI** | **$2,130,902** | **$2,254,940** | **$2,381,149** | **$2,441,738** |

From Financial Management Branch, NCI. Analysis: February 1997.

jects that the total RPGs and Clinical Trials Infrastructure Budget will be $1.421 billion—59.7% of the total NCI budget. At present, 20.7% of all RPGs are patient oriented as a result of the effort of the director of the NCI to enlarge the commitment to translational research. The President's fiscal year 1998 budget includes $1.163 million for RPGs, $93.0 million for Clinical Cooperative Trial Groups, $171.1 million for Cancer Centers, and $40.0 million for additional grants (see Table 3) (personal communication, NCI, February 1997). Currently, nine NCI-sponsored cooperative groups place approximately 20,000 new patients per year into cancer treatment protocols, principally large, randomized Phase III clinical trials. More than 1400 institutions and 8500 investigators participate in these national cooperative group trials. Translational investigators who participate in these clinical trials programs are also responsible for the development and initiation of new anticancer agents being tested for the first time in patients entered into Phase I and II clinical trials, most of which are conducted under NCI investigational new drug (IND) sponsorships that are funded by NCI cooperative agreements (20).

**TABLE 4.** *Investigator-initiated, patient (clinical)–oriented research funding by NCI: fiscal years 1996 and 1997 (dollars in thousands)*

| Budget | Fiscal year 1996 (Actual) | Fiscal year 1997 (Estimate) |
|---|---|---|
| **Total NCI** | **$2,254,940** | **$2,381,149** |
| Research project grants (RPGs) | $1,034,530 | $1,119,267 |
| Percentage of NCI budget | 45.9% | 47.0% |
| **Patient-oriented funding** | **$677,857** | **$722,265** |
| Percentage of NCI Budget | 30.1% | 30.3% |
| **1. Patient-oriented RPGs**[a] | **$210,299** | **$231,329** |
| Percentage of NCI budget | 9.3% | 9.7% |
| Percentage of RPGs | 20.3% | 20.7% |
| **2. Other clinical funding** | | |
| Clinical cooperative trials, cancer centers, cancer prevention and control, intramural research | **$467,558** | **$490,936** |
| Percentage of NCI budget | 20.7% | 20.6% |
| Percentage of patient-oriented funding | 69.0% | 68.0% |

[a] R01, R29, R35, R37, R55, P01

From Financial Management Branch, NCI. Analysis: February 1997.

Funding support for cancer clinical trials is derived principally from the NCI for research project grants, cancer trials infrastructure, and research support grants. For fiscal year 1997, patient-oriented research will comprise 30.3% of the NCI budget (see Table 4); RPGs for translational research represent 20.7% of RPG funding, whereas 68.0% of patient-oriented funding is directed to cooperative trials, cancer centers, prevention/control, and intramural research (see Table 4). It would appear that the efforts of the SSO to enhance these awards in translational research have been acknowledged by the NCI leadership to maintain the nation's investment in the conduct of quality cancer clinical trials. Collectively, RPGs that span the entire spectrum of cancer clinical research should be enhanced, with emphasis on funding of the R01-type translational grant in clinical research. In fiscal year 1996, at a total cost approximating $500 million, the NCI funded over 1900 R01 grants. At least 600 were new awards, which will undergo intense competition; almost three out of four meritorious applications failed to receive this funding.

As a result of the emphasis of the leadership of the SSO and ASCO on the importance of investment in R01 clinically-oriented (translational) grants, the NCI initiated the Accelerated Executive Review (AER) Process.

This review mechanism enables investigators who fall just outside the funding payline to submit additional information for consideration by the NCI Executive Committee. Many grants are then funded after resubmission, allowing research to proceed more rapidly.

**Policy Issues for the Preservation of Phase I/II Clinical Cancer Trials**

The Washington Cancer Trials Conference (July 1995) invited academia, industry, government, contract research organizations, and patient advocacy groups to discuss clinical trials in patients with cancer (21). This conference identified current issues that threaten the conduct of these trials for the next decade. Participants concluded that there existed considerable dissatisfaction with the status quo in cancer clinical trials and confirmed the deeply held conviction that all concerned parties would benefit from changes. The expansion of managed care, if it continues to operate as at present, can only worsen what is considered a serious, and deteriorating, situation (22).

Major recommendations promulgated by the Washington Cancer Trials Conference (21) include the following:

1. Phase I trials should be required to demonstrate "reasonable (but not exhaustive)" preclinical information and should be designed to more aggressively investigate appropriate dosages.
2. Phase I trial designs should be flexible, to encourage creativity by investigators and maximize potential benefits to patients.
3. Phase I trials should not only address toxicity but also yield information regarding efficacy. These approaches will become more evident as new agents move from cytotoxic drugs to biologicals and those with other mechanisms of cytotherapeutic benefit.
4. Community oncologists should be better informed regarding the "utility and importance of Phase I trials" via training and ongoing CME and outreach mechanisms.
5. Time-consuming IRB review for Phase I trials should be reevaluated, given the scope and setting of the typical Phase I trial and other safeguards which protect human subjects.
6. The time frame of Phase II and III trials should be shortened.
7. Third-party payors should cover the expenses of cancer patients enrolled in all phases of clinical trials involved with new uses of approved drugs.
8. HMOs should encourage their patient-clients to participate in clinical cancer trials with therapeutic intent (21).

This conference produced a new agenda for cancer clinical trials and research, and follow-up to this meeting is mandated and encouraged to maximize the possibility of acceptance and implementation of these proposed changes. The proposed changes could have a major impact on oncologic care in two respects: (1) rapid development of sorely needed new agents to treat advanced neoplastic diseases; and (2) expeditious implementation of currently available drugs to patients potentially deprived of these agents by ill-founded and capricious reimbursement policies.

In assessing the reimbursement policy for future clinical trials, we must acknowledge the current reality for trends in national cancer care:

*Fact 1.* Often, cancer chemotherapy and technical approaches administered for cancer care, especially in the non–peer-reviewed community practice setting, consist of the empirical "off-label" use of multiple toxic agents and unproven technical measures.

*Fact 2.* These multiple-drug agents and surgical/technical approaches are commonly administered *outside* a properly designed, scientifically conducted clinical trial.

*Fact 3.* Third-party payors supporting this nonscientific approach are unaware that these agents or procedures are not designed to advance knowledge of appropriate cancer treatment.

Thus, much of the potential empirical benefit and related data that could be gained from today's care are lost, except for circumstances in which data and outcomes, disease-free survival, and quality of life are captured by regional cancer registries or community cancer centers. Important to the global financial impact is the cost to payors for reimbursement of these therapies, which have not undergone rigorous scientific query for evaluation of therapeutic effectiveness and patient-related therapeutic outcomes. Therefore, a paradigm emerges as a question for payors and MCOs: *Are we not best served by systematically evaluating truly promising new therapies that are conducted within a well-designed, peer-reviewed, randomized, prospective clinical cancer trial?*

I would propose the following suggestions to third-party payors, MCOs, and HMOs:

1. Encouragement of eligible patients to participate in clinical cancer trials
2. Appropriate reimbursement of patient care providers and researchers for their design, implementation, and participation in these trials
3. Enlargement of the support systems for analysis of

outcomes research to advance potential control/cure of neoplastic diseases.

Surely this approach would represent an enhancement and improvement over the current system, which penalizes the well-designed clinical trial by diverting potential funds to unproven regimens of questionable scientific validity for cancer patients. Thus, members of the academic community must have the motivation and the ethical responsibility to obtain outcomes research data that are obtained only from well-designed, prospective, peer-reviewed clinical oncology trials. Moreover, we should remove incentives for regimens of dubious value administered outside the conduct of well-designed trials by individuals whose motivation is other than scientific query. This year, under the leadership of Dr. Samuel Wells, the American College of Surgeons submitted a grant proposal to the NIH/NCI for the support of clinical cancer trials to be conducted by Fellows of the College for various solid organ malignancies. The American College of Surgeons Oncology Group (ACSOG) has the potential to become the major surgical cooperative clinical trials group for the organization, implementation, and analysis of clinical research outcomes and to answer important questions related to surgical procedures that may not be answerable by the 11 active cooperative clinical trials groups. The SSO membership is strongly encouraged to be major participants and leaders in the ACSOG clinical trial efforts.

## THE SOCIETY AND RESEARCH: BASIC AND CLINICAL

The 1996–1997 SSO Membership Survey developed by the Issues Committee revealed important concerns of the Society for the investment in clinical trials research. Of interest, the great majority (88% of 651 respondents) agree or strongly agree that "the SSO should promote, support, and assume a leadership role in national cancer clinical trials." Furthermore, 457 respondents (71%) consider that the SSO should be the responsible agency for the conduct and completion of these cancer trials. The SSO should be optimistic, because the 105th Congress will consider the mandated payment by Medicare of clinical research–related patient care costs as proposed by Senators Mack and Rockefeller (S. 1963) in the spring of 1997.

The Membership Survey also identified the concern of the majority of our membership that the SSO should play a more active role in Washington and the NIH/NCI by identifying key members who support the goals of the Society (81%) and the Society's investment in clinical cancer trials (92%). Moreover, the Issues Committee's Membership Survey identified the prevailing concern that the "SSO should assume a more aggressive role in informing government officials of issues that relate to the care of the patient with oncological disease:

With Congress (89% agree or strongly agree)
With State officials (80% agree or strongly agree)
With City officials (60% agree or strongly agree)."

The efforts of the SSO to inform key Washington congressmen and NIH/NCI leadership of our concerns regarding graduate medical education (GME), clinical trials research, and access of cancer patients to qualified specialists in oncology continues. SSO members further consider that "reduction in GME funding (direct/indirect) by Congress following reductions in Medicare appropriations will have the following effects for surgical oncology practice and/or oncology research":

Quality and operative experience of surgical oncology fellows will be reduced (55% agree/strongly agree).

Competency of surgical oncology fellows relative to clinical practice will be diminished (44% agree/strongly agree).

Quality of basic research experience of SSO fellows will be diminished (73% agree/strongly agree).

Productivity of future leadership of academic surgical oncologists will be reduced (57% agree/strongly agree).

Of preeminent concern to the Society has been the preservation of clinical research–related trials by the membership. Table 5 identifies the sources of clinical and basic research support for 664 SSO members in the academic or community environment. Of interest, 415 members (62.5%) have no funding support for research. Departments of surgery and extramural noncompetitive support (e.g., contracts, grants, and philanthropy) provided the major sources of research funding, at 37.5% and 34.9%, respectively. NIH/NCI grants and contracts for fiscal year 1995 totaled $56,256,686 among 201 surgical oncology principal investigators—30.3% of the funding source for research support.

Table 6 lists the research grant/contract awards of the NCI for fiscal year 1990 through fiscal year 1995 to surgical oncology principal investigators. These data, provided by the Research Analysis and Evaluation Branch, Division of Extramural Activities of the NCI (personal communication, March 1997), confirmed that the total of $56,256,686 awarded for 367 grants and contracts in fiscal year 1995 to 201 investigators represents an 84.6% increase since fiscal year 1990 in NIH/NCI-funded competitive basic and clinical grants (R01, R03, R13, R21, R29, R35, R55; P01, P20, P30, P50; U-01, U-10). Efforts to increase NIH/NCI competitive research

**TABLE 5.** *Sources of clinical/basic research support for SSO membership, fiscal year 1996 (survey response n = 664)*

| Source of research support[a] | Percentage of total research support 1–25% | 26–50% | 51–75% | 76–100% | Total | Percentage |
|---|---|---|---|---|---|---|
| | No. SSO members | | | | | |
| National Cancer Institute | 83 | 43 | 39 | 36 | 201 | 30.3 |
| American Cancer Society | 77 | 17 | 2 | 2 | 98 | 14.8 |
| University/Institutional | 103 | 57 | 23 | 13 | 196 | 29.5 |
| Department of Surgery | 111 | 67 | 30 | 41 | 249 | 37.5 |
| Other | 108 | 56 | 30 | 38 | 232 | 34.9 |
| **Subtotal: Research Support** | | | | | **249** | **37.5** |
| **Subtotal: No Research Support** | | | | | **415** | **62.5** |
| **TOTAL** | | | | | **664** | **100.0** |

[a] Several SSO members had more than one research support grant or contract source.
Data from 1996 SSO membership survey

project grant funding for translational research increased further in fiscal year 1996 and fiscal year 1997 as the total NIH budget was increased 6.8% for fiscal year 1996.

Figure 1 illustrates the recommendations to the National Cancer Advisory Board (NCAB) by the Subcommittee to Evaluate the National Cancer Program for NCI funding (18). To stabilize and enhance basic cancer research, $977 million was expended for NCI investigator-initiated grants in fiscal year 1995, and $1.035 billion was expended in fiscal year 1996 (see Table 3). Considering the fact that nearly one third of SSO members are NIH-funded basic and clinical investigators, there has been only a modest increase in surgical oncology RPG total funding from fiscal year 1990 through fiscal year 1995 relative to the NCI budget. These data are further illustrated in Table 6. NCI surgical oncology RPG funding for fiscal year 1990 was 5.1% of the total RPGs and increased to only 5.8% in fiscal year 1995 (see Table 6). With yearly adjustments for inflation, this RPG amount should rise 3% annually for the next 5 years. As shown in Figure 1, the estimated investment from fiscal year 1989 through fiscal year 1994 is well *below* the desired (recommended) amounts for proper RPG support based upon 3% real annual growth (over inflation). However, it is favorable news for the Society's investigators that this funding gap closed substantially with the enlarged investment in fiscal year 1995 ($977 million) for investigator-initiated research. Real increases of 3% per annum in the 5 years through fiscal year 2000 will close this deficit in funding, and, it is hoped, avoid the crises of fiscal years 1989 through 1994. Nonetheless, SSO investigator-initiated NCI cancer RPGs still remain funded at <10% of total NCI-RPG funding. Because surgery remains the principal diagnostic and therapeutic modality for the therapy of solid organ malignancies, our efforts to increase funding awards for competitive SSO members must be implemented and ensured.

Table 7 depicts the number of RPGs held by surgeons as principal investigators. Except for 1993, a significant trend toward increased funding for surgical oncology research support is evident between fiscal year 1990 and fiscal year 1996—a 65.9% increase over this 6-year interval. Of the total $31.615 million in RPG funds held by surgical oncologists (Table 8), 2.0% ($20.818 million) of

**TABLE 6.** *NCI funding of surgery-related projects, fiscal years 1990–1996 (dollars in millions)*

| Fiscal year | Surgical research grants[a] | | Contracts for surgical research | | Total surgery contract/grant funding | | Change from fiscal year 1990 (%) | Total NCI extramural funding ($$) | Extramural surgery projects: % of NCI extramural funding |
|---|---|---|---|---|---|---|---|---|---|
| | No. | $$ | No. | $$ | No. | $$ | | | |
| 1990 | 282 | 29.4 | 25 | 1.00 | 307 | 30.5 | — | 1237 | 2.5 |
| 1991 | 285 | 32.0 | 33 | 1.99 | 318 | 33.9 | 11.2 | 1288 | 2.6 |
| 1992 | 273 | 35.1 | 33 | 2.10 | 306 | 37.2 | 22.0 | 1472 | 2.5 |
| 1993 | 315 | 40.7 | 49 | 2.70 | 364 | 43.5 | 42.6 | 1502 | 2.9 |
| 1994 | 337 | 47.2 | 28 | 2.20 | 365 | 49.4 | 62.0 | 1584 | 3.1 |
| 1995 | 339 | 52.4 | 28 | 3.80 | 367 | 56.3 | 84.6 | 1637 | 3.4 |
| 1996 | 333 | 71.7 | 25 | 1.54 | 358 | 73.3 | 140.3 | 1709 | 4.3 |

[a] R01, R03, R13, R21, R29, R35, R37, R55; P01, P20, P30, P50; U-01, U-10. Excludes Training Grants. From Division of Extramural Activities, Research Analysis & Evaluation Branch, NCI/NIH. Analysis: March, 1997

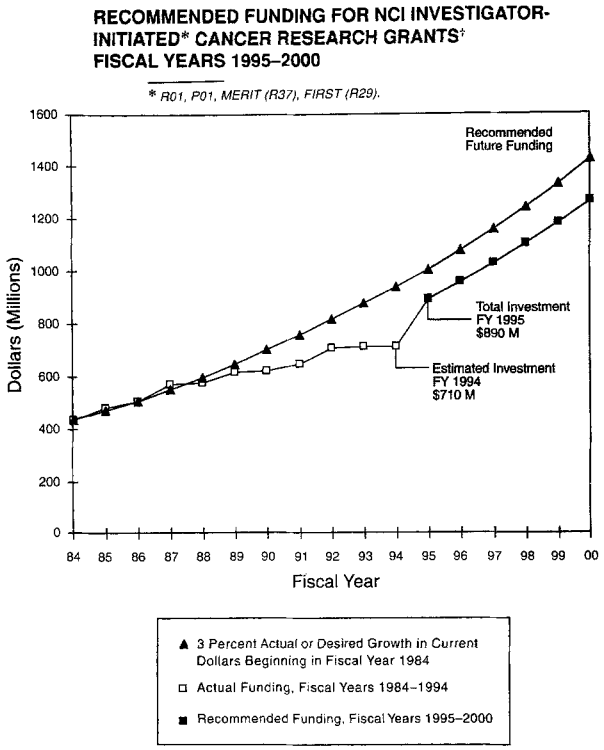


**FIG. 1.** Trends in NCI investigator-initiated funding of cancer research grants for all oncology disciplines, fiscal year 1984 to fiscal year 2000. (From National Cancer Advisory Board Subcommittee to Evaluate the National Cancer Program. Cancer at a Crossroads: A Report to Congress for the Nation. Bethesda, MD: National Cancer Institute.)

the NCI RPGs was funded by the newly created Division of Cancer Treatment, Diagnosis and Centers (DCTDC). Seventy RPGs held by surgical oncology principal investigators were funded by the DCTDC; the majority of these grants (41/70; 58.6%) were clinical and surgical oncology research projects (Table 9).

In fiscal year 1996, 3.9% of the applicant pool for clinical oncology grants were surgeons, of whom 2 (0.7%) were successful in acquiring RPG support (Table 10). This success rate increased to 13.5% for surgeons who applied for grants in their discipline. The overall funding rates for new and competing renewal applications for MDs and surgeons were 21.9% and 2.2%, respectively (see Table 10).

## THE FUTURE OF SURGICAL ONCOLOGY

The many reasons for discontent among today's physicians and surgeons are perhaps understandable. They include decline in income—real or perceived; loss of autonomy; issues that impact quality, duration and type of specialization; and limitation of their choice of consultants. Thoughtful physicians express concern about the increasing commercialization of medicine and its overall meanings for the core values of what should be a "healing" profession. However, the profession and the discipline of surgical oncology remain viable in both the academic and the public sector. When I graduated from medical school in the late 1960s, spending for health care was 5% of the gross national product (GNP) of the United States; today, health care is an enormous industry that consumes approximately 16% of our national resources, or almost one sixth of the GNP. This rise in the cost of health care and its impact on citizens in terms of finding affordable health insurance have therefore spurred private industry to implement managed care, which negatively impacts the management of health care financing and its organization. MCOs have taken a number of measures to hold down health care costs, but the most evident one is the use of rigorous methodologies to control the price and use of health care services.

Despite the aforementioned concerns, a paradox exists in that applications to medical schools and to the surgical disciplines in general are at an all-time high. The AAMC notes that the number of medical school applications increased for the seventh straight year, albeit at a slower pace (23). Following the declines of 26% between the years 1984 and 1988, the applicant pool began its current ascent. The greatest increases in the applicant pool took place between 1991 and 1993, when they averaged 13.5% per year. Since 1988, the number of first-time applicants has increased by 56.3%, while the number of repeat applicants has increased by 130.8% (23). Medicine remains the most prestigious and respected profes-

**TABLE 7.** *Division of Cancer Treatment (DCT): number of research project grants (RPG) held by surgeons as principal investigators (active grants in fiscal year)*

| Fiscal year | BRMP[a] | CTEP | DTP | RRP | **Total DCT** | **% Change from fiscal year 1990** |
|---|---|---|---|---|---|---|
| 1990 | 8 | 19 | 2 | 12 | **41** | — |
| 1991 | 8 | 22 | 2 | 11 | **43** | **4.9** |
| 1992 | 12 | 23 | 2 | 10 | **47** | **14.6** |
| 1993 | 10 | 25 | 2 | 3 | **40** | **-2.5** |
| 1994 | 9 | 40 | 2 | 1 | **52** | **26.8** |
| 1995 | 9 | 41 | 1 | 2 | **53** | **29.3** |
| 1996[b] | 0 | 50 | 16 (2+14) | 2 | **68** | **65.9** |

[a] The NCI was reorganized in FY 1996. BRMP is no longer in existence; the grants program has been moved to DTP.

[b] In FY 1996, DTP number includes BRMP grants (DTP + BRMP)
BRMP, Biological Response Modifier Program; CTEP, Cancer Therapy Evaluation Program; DTP, Developmental Therapeutics Program; DCT, Division of Cancer Therapy; RRP, Radiation Research Program.

Data from Division of Extramural Activities, Research Analysis & Evaluation Branch, NCI/NIH. Analysis: March, 1997

**TABLE 8.** *National Cancer Institute Number of research project grants (RPG) held by surgeons as principal investigators (funded fiscal year 1996)*

| NCI division | Number | Total Cost ($$) | % NCI RPGs[a] |
|---|---|---|---|
| Cancer Biology (DCB) | 18 | $7,213,470 | 0.7 |
| Cancer Epidemiology and Genetics (DCEG) | 11 | $2,418,800 | 0.2 |
| Cancer Treatment, Diagnosis, and Centers (DCTDC) | 70 | $20,818,629 | 2.0 |
| Cancer Prevention and Control (DCPC) | 5 | $1,164,567 | 0.1 |
| **Total NCI** | **104** | **$31,615,466** | **3.1** |

[a] NCI-RPG total (fiscal year 1996) = $1.035 billion

Data from Division of Extramural Activities, Research Analysis & Evaluation Branch, NCI/NIH. Analysis: March, 1997

sion, together with the clergy. The principal reasons for entering the profession have changed little: today's eligible students consider their basic interest in medicine to be driven by their ethical and moral obligation to society, combined with their interpersonal and noncognitive skills and academic ability for potential success as students (23).

Data from the AAMC regarding interest in specialties among medical school graduates suggest that certification in a generalist specialty rose for the third consecutive year (23). Moreover, interest in general surgery and its subspecialties represented the fourth most-favored specialty among matriculating medical students in 1995, preceded by family practice, pediatrics, and internal medicine. There has been no statistical change in medical students' interest in general surgery or the surgical specialties since 1985, in sharp contrast to many other specialties in medicine. The number of graduates from all surgical education programs has increased only 2.1% since 1987—the year that information first became available to track trends for subspecialization within surgery. Kwakwa and Jonasson (24) recently performed a longitudinal study of surgical residents for the American College of Surgeons. Since 1983, there has been a 0.5% net increase in general surgery graduates of RRC-approved surgical residencies. Moreover, program consolidation has occurred, with a reduction in number of residency programs from 415 in 1975 to 271 in 1994.

**TABLE 9.** *National Cancer Institute, Division of Cancer Treatment, Diagnosis, and Centers, number of research project grants (RPG) held by surgeons as principal investigators (funded fiscal year 1996)*

| Grants Activity Code | Number | Dollars | % NCI RPGs[a] |
|---|---|---|---|
| Biological response modifiers | 14 | $2,178,654 | 0.21 |
| Radiation | 0 | 0 | 0 |
| Biochemistry and pharmacology | 2 | $999,660 | 0.10 |
| Diagnosis | 9 | $1,453,202 | 0.14 |
| Diagnostic imaging | 2 | $844,499 | 0.08 |
| Clinical oncology | 23 | $7,356,032 | 0.71 |
| Surgical oncology | 18 | $7,621,448 | 0.74 |
| Nutrition | 2 | $365,134 | 0.04 |
| **TOTAL** | **70** | **$20,818,629** | **2.0** |

[a] NCI-RPG funding total (FY 1996) = $1.035 billion

Data from Division of Extramural Activities, Research Analysis & Evaluation Branch, NCI/NIH. Analysis: March, 1997

In contrast, there has been an excess in subspecialization beyond general surgery since 1983 in plastic surgery, cardiothoracic surgery, and colon and rectal surgery of 40%, 12.4%, and 5.7%, respectively. Specialization in vascular surgery has remained stable since it was first accredited in 1984. Table 11 indicates the additional subspecialty training for 1994–1995 general surgery graduates continuing in ACGME-approved surgery-based residency programs. Of interest, 45.9% of general surgery graduates continued beyond general surgery to acquire additional surgical training. Of these residents, 429 sought certification by a specialty Board or discipline that offers a Certificate of Added Qualification (CAQ). In this same year, there were 11 SSO-approved programs for advanced training in surgical oncology. The 30 graduates of SSO programs represent 3.0% of the total 1001 general surgery graduates in the year. Only surgical critical care and pediatric surgery programs furnished fewer subspecialty graduates (see Table 11). Although it is unlikely that the discipline of surgical oncology will be granted a CAQ by the American Board of Surgery, it is probable that qualified academic institutions and cancer centers with a vested interest in high-quality surgical oncology education and adequate numbers of oncologic procedures for training will be increased. As of this writing, 32 Fellows are awarded certificates by 12 SSO-approved programs. At least two additional programs are currently in review by the Training Committee of the SSO.

The extraordinary investment in quality surgical sci-

**TABLE 10.** *Cancer Therapy Evaluation Program; DCTDC, NCI: New and competing renewal applications reviewed or funded in fiscal year 1996*

| | | No. applications | | No. awardees | | Success rate[a] | |
|---|---|---|---|---|---|---|---|
| Grant Activity Code | Total | MDs (% total) | Surgeons (% total) | MDs | Surgeons | **MDs** | **Surgeons** |
| Clinical oncology | 280 | 187 (66.8%) | 11 (3.9%) | 66 | 2 | **23.6%** | **0.7%** |
| Surgical oncology | 37 | 22 (59.5%) | 19 (51.4%) | 5 | 5 | **13.5%** | **13.5%** |
| Nutrition | 7 | 1 (14.3%) | 1 (14.3%) | 0 | 0 | **0%** | **0%** |
| **Total** | **324** | **210 (64.8%)** | **31 (9.6%)** | **71** | **7** | **21.9%** | **2.2%** |

[a] Defined as Number of awardees (MD, PhD, DVM, MS, BS)/Total number of applications
Data from Division of Extramural Activities, Research Analysis & Evaluation Branch, NCI/NIH.
Analysis: March, 1997

ence and oncology is evident in the academic surgical departments of the United States and Canada. Questions commonly asked by young surgical faculty and residents contemplating a career in surgical oncology are: "Will there be support for the discipline?" and "What do I consider the future of surgical oncology?" First, a reduction in GME funding (direct and indirect) by Congress following reductions in Medicare appropriations would have a global effect on hospitals and SSO-approved training programs, with a reduction in total revenues directed to this non-Boarded discipline. The 1996 Membership Survey suggested that the majority agree that this could affect quality and operative experience of surgical oncology Fellows as well as the quality of basic research, and may portend a reduction in productivity in future leadership of our discipline.

Only with mechanisms to sustain the current SSO-approved programs through clinical revenues, contracts or grants, and philanthropy, can we continue to support the educational training for these Fellows. However, it appears that Congress, as well as the public, has acquired a broader and more favorable understanding of the merits and outcomes of biomedical research and advanced training. The NIH budget has increased nearly 7% annually for the last 2 years (see Fig. 1), and if recommendations of the NCAB are approved on an annual basis, we should expect sustained and increased support beyond the year 2000 (20). Nonetheless, the membership should not be complacent, but, rather, should be vigorous contributors to the legislative and governmental committees of the regional, state, and national societies to ensure that Congress has an informed perception of the importance of high-quality surgical training and biomedical research. It is highly unlikely that we will see significant increases in direct funding for clinical training in oncology in the immediate future; thus, our attempts to educate legislators and the general public to the importance of quality surgical care and research must be maintained. However, it is probable that other surgical specialties will be further reduced as their respective RRCs ensure a balance of needs, as determined by practice trends and need outcomes in surgery and medicine. In contrast, it appears that the number of surgical oncology fellows finishing per annum is appropriate and should at least be maintained, or increased, relative to the available academic and private practice opportunities. Above all, the

**TABLE 11.** *General surgery graduates continuing in ACGME surgery-based residency programs, 1994–1995*

| General Surgery Graduates 1994-1995: | | | Total 1001 | Percentage (100%) |
|---|---|---|---|---|
| Surgical Subspecialty | 1994–95 Graduates | Prior graduates entering in 1994 | Total | Percentage total surgery graduates (100%) |
| Thoracic | 107 | 40 | 147 | 14.7 |
| Plastic | 107 | 0 | 107 | 10.7 |
| Vascular | 51 | 27 | 78 | 7.8 |
| Colorectal | 38 | 16 | 54 | 5.4 |
| **Surgical oncology (1994)[a]** | **30** | **0** | **30** | **3.0** |
| Surgical critical care | 22 | 0 | 22 | 2.2 |
| Pediatric surgery | 15 | 6 | 21 | 2.1 |
| Subtotal | | | 459 | 45.9 |

[a] 11 SSO-approved programs.
Modified from Kwakwa and Jonasson (24).

oversight provided by SSO Program Training Directors for the development of quality cognitive skills and the diversity of an operative oncologic experience are requisite to preserve the discipline and the Society's heritage. It is, therefore, the responsibility of our present and future leadership to see that this balance is appropriate to ensure adequate access to state-of-the-art oncology care in academic medical centers and cancer centers throughout the United States and Canada.

## MILESTONES AND IMPERATIVES FOR THE SOCIETY

Only 5 years ago, the Society had a total of 800 active, senior, and international corresponding members and attracted approximately 475 physicians to its annual convention. Decisions by the Executive Council to enhance our academic investment and improve our fiscal status have been amply rewarded: our membership has doubled to over 1600 members, and our scientific assembly registration will exceed 1000 physicians in 1997.

The Society has established its own journal, *The Annals of Surgical Oncology,* of which we are understandably proud as it moves to monthly publication. Further, we have received accreditation from the Accreditation Council for CME for our educational symposia. The SSO continues to provide a direct liaison with governmental regulation services and has developed contacts through the American College of Surgeons, with annual visits to our key congressmen to elucidate our specific concerns.

Other signal events in the Society include the acquisition of patron support via grants and contracts that allowed recovery of our fiscal status; this occurred with the development of a 5-year business plan in 1995, with the objective of accumulating net assets equivalent to one year's operating fund. SSO members have developed a website on the Internet, which positions us on the information superhighway and will provide the membership (and potential members) with a source of data for our oncologic specialty. The SSO website will thereafter become a forum for timely interchange of ideas, as well as function as an educational site. Of great importance has been the progress in the quality, diversity, and content of the SSO Annual Scientific Assembly, which attracts world leaders in the field to our annual forum. Finally, the imminent publication of SSO cancer clinical guidelines, developed by our members, is expected in 1997.

Despite these significant milestones of progress for the Society over the past 50 years, we must not be complacent, but rather have the obligation to continue the investment of our Society's founders. The SSO leadership and its members must continue the active support of national (i.e., cooperative trials) and institution-based cancer clinical trials. Moreover, we must enhance our commitment to the expeditious completion of these trials, to diminish the prolonged intervals between publication and implementation of the results of these trials.

As we enter the twenty-first century, the imperatives of the next generation will be to sustain and enlarge this investment in education, research, and camaraderie for the discipline. This can only be continued by the individual efforts of active contributors to the SSO committees of governance and legislative measures, and to the scientific and educational programs that continue to be the principal focus of the annual meeting. Above all, our commitment to patient care, with enhancement of overall survival and quality of life for the cancer patient, remains the principal tenet to which the Society owes its heritage and future.

It has been a privilege and honor to serve as your President the past year; I am grateful to the members for the opportunity to make these comments.

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