Cancer is a disease of aging. U.S. census data show that 57% of all cancers and 71% of all cancer deaths are seen in persons over 65 years of age. Persons ages ≥65 years represent the fastest growing segment of the U.S. population. In the year 2030, it is estimated that 20% of the population, 70 million Americans, will be ages ≥65 years compared with 12% at present. Similar demographics are found in the European Union and other affluent nations. Moreover, during the latter half of the 20th century, life expectancy has also dramatically increased. The average life expectancy in the year 2000 for males and females in the United States was 79.9 and 74.2 years, respectively (2). Despite the well-documented increase in cancer incidence with age and the increasing proportion of elderly persons in the U.S. population, few elders were represented in clinical trials (3), including those sponsored by the National Cancer Institute (NCI)–funded cooperative groups (4, 5). Historically, older patients were excluded from trials, either categorically or due to age bias. Ironically, these large older trials, which have proven to be such a rich resource for defining the risks and benefits of the most widely used treatments, lack needed information on treating elders and are the major reason that now make it important to study elderly cancer patients. Barriers to elders participation in clinical trials continue to be a major problem (6) and have led to federal grant funding targeted for clinical research in elders (7). Such research will provide data that will help oncologists guide treatment selection for elderly patients.

In the mid-1990s the lack of information regarding appropriate cancer treatments for the elderly had begun to be apparent. Historically, the Cancer and Leukemia Group B (CALGB) had been quite interested in cancer in the elderly. For example, CALGB had initiated Protocol 9343 to explore the role of radiation therapy in older women ages ≥70 years with stage I cancer treated with lumpectomy and tamoxifen. However, in our group as in others, there was no specific organized focus of activities to deal with the issue of cancer in the elderly.

In December 1994, Dr. Richard Schilsky, Chair of CALGB, attended a Working Group on Pharmacology in Aging and Cancer sponsored by the National Institute on Aging, the NCI, and the Agency for Health Care Policy Research. This conference, attended by both oncologists and geriatricians, concluded that there was a great need for attention focused in this area. For example, they concluded that cancer in older patients was “underdiagnosed, underinvestigated, and undertreated.” They also noted that “there is an urgent need for useable guidelines for treatment.” They recommended that there was a need for prospective clinical trials specifically focused on and including sufficient numbers of older patients to provide meaningful data. In addition, they specifically cited the need for studies to address all phases of drug testing, to characterize trial enrollment of older subjects and the barriers to participation, to identify prognostic factors of importance in the elderly, and to determine the effects of therapy on performance and functional status and quality of life. Other members of CALGB had already shown interest in this area of inquiry. Dr. Hyman Muss as Vice Chair of the Breast Committee had been an active participant in Protocol 9343. Dr. Harvey Cohen had been one of the first investigators to address the issues of cancer in the elderly in the mid-1980s with studies done at Duke University with the Southeastern Cooperative Cancer study group.

Abstract Cancer is a disease of aging, and the majority of cancers occur in persons over 65 years of age. In spite of this, few elders have been represented in clinical trials, and the need for information regarding the treatment of elders with cancer remains great. Recognizing these needs, the Cancer and Leukemia Group B (CALGB) formed an elderly Working Group in 1995, and after initial success in developing clinical studies focused on elders, a Cancer in the Elderly Committee. The Committee's objective is to focus attention on issues specifically relevant to the treatment of cancer in the older patient. Two strategies were developed to achieve this objective: (a) to initiate projects and protocols within the Committee and (b) to foster the initiation of studies by other CALGB committees. The research themes of the Committee and the main thrust of committee's research activities are (a) understanding and overcoming barriers to clinical trials participation; (b) treatment efficacy and pharmacokinetic/pharmacologic issues related to chemotherapy and hormone therapy in the older cancer patient; and (c) improving the quality of life for older cancer patients. The Cancer in the Elderly Committee has been successful in developing, implementing, and completing trials in all these areas and serves as a major resource for clinical trials development for the CALGB.

The Cancer and Leukemia Group B Cancer in the Elderly Committee: Addressing a Major Cancer Need

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In May 1995, Dr. Cohen proposed to Dr. Schilsky the concept of a working group to focus attention, ideas, and planning for studies of the elderly cancer patient. Given the background, Dr. Schilsky initially authorized the Working Group to make a proposal to the CALGB Executive Committee regarding what such a group might contribute to CALGB. In November 1995, it was proposed that such a group would serve as an important catalyst for investigative work on cancer in the elderly. It would interface well with the other activities in the CALGB and would concentrate on areas in which the Group already had great strengths. For example, it was proposed that The Working Group would develop a protocol to assess barriers to participation in research trials, phase II studies to specifically determine pharmacokinetics of drugs in the elderly in conjunction with the Pharmacology and Experimental Therapeutics committee, and specific disease trials for the elderly in areas of strong participation by CALGB (e.g., lymphoma, lung cancer, and breast cancer). Moreover, it was proposed that data from previously completed CALGB studies be reviewed focusing on age-related outcomes and patterns of response that could serve as clues for the development of new trials.

The charge of the Working Group was to provide a forum for CALGB members interested in cancer in the elderly to share ideas; to transform the most promising and innovative ideas into concepts and, ultimately, protocols; and to provide input to other CALGB committees about opportunities for developing clinical trials focused on cancer in the elderly. Committee members were selected based on their interest in older individuals. Dr. Schilsky appointed Drs. Harvey Cohen and Hyman Muss to Co-Chair this Working Group. Other members included Alice Kornblith, Ph.D., Drs. Stuart Lichtman, Merrill Egorin, Margaret Kemeny, and Richard Stone. CALGB staff members appointed to the Working Group were Gini Fleming, M.D., Executive Officer; Bercedis Peterson, Ph.D., Statistician; Judith Wheeler, Data Coordinator; and Michael Kelly, Protocol Editor.

**Evolution and Structure of the CALGB Cancer in the Elderly Committee**

The Committee’s objective was to focus attention on issues specifically relevant to the treatment of cancer in the older patient. It has focused and has continued to focus on two strategies to achieve this objective: (a) to initiate projects and protocols within the Committee and (b) to foster the initiation of studies by other CALGB committees. The research themes of the Committee and the main thrust of our research activities are:

1. Understanding and overcoming barriers to clinical trials participation;
2. Treatment Issues
   (a) Treatment efficacy in the older cancer patient
   (b) Pharmacokinetic/pharmacologic issues related to chemotherapy and hormone therapy in the older cancer patient;
3. Improving quality of life for older patients with cancer.

The working group held its first meeting in November 1995 and was formally accepted as a working group by CALGB in January 1996. It was included in the formal structure of the group for the first time in the 1997 CALGB renewal application to the NCI. The working group was reviewed quite positively at that time and launched its initiatives. In 1997, members of the working group actively participated in the Geriatric Education Retreat in Oncology sponsored by the Hartford Foundation and The American Geriatrics Society. Dr. Cohen chaired the retreat that brought together 40 influential leaders in oncology and geriatrics in an attempt to sketch an agenda by which training and research at the interface of aging and cancer could be enhanced. CALGB participants included Drs. Cohen, Muss, Schilsky, Peterson, Mayer, and Green. This conference helped set an agenda that subsequently resulted in a series of National Institute on Aging and NCI Program Announcements and Requests for Proposals, including initiatives for the Cooperative Groups in which CALBG has successful participated. In addition, other initiatives for individual investigators and Comprehensive Cancer Centers, in which many of our investigators and institutions have participated, were also begun.

In the years following its initiation, the working group successfully pursued projects related to its core missions (as described below) and in recognition of its accomplishments was elevated to full committee status by the executive committee in 2002. With this evolution, the committee has been able to further broaden its multidisciplinary participation by adding other interested investigators to the core cadre and as liaisons to other key committees. This dual thrust membership has allowed the committee to be tightly integrated with group activities; in addition to ideas emanating from the committee, our liaisons foster ideas and concepts emanating from other disease and modality committees. The purpose and conceptual framework of the Committee is presented in Fig. 1.

**Accomplishments in Cancer in the Elderly Research**

The accomplishments of the committee are described below and follow from our research themes. Major trials are listed in Table 1. Some of these trials represent "joint ventures" of the Cancer in the Elderly Committee and other CALGB site and modality committees.
Understanding and overcoming barriers to clinical trials participation. CALGB 9670 ("Barriers to The Participation of Older Women with Breast Cancer in Clinical Trials: A Pilot Study") was the first protocol initiated under the direct auspices of the Working Group. This study was considered unique for a cooperative group because it addressed the issues of barriers to enrollment rather than treatment outcome and was developed and funded in response to a specific RFA for Cancer in the Elderly Trials. The study showed that age bias played an major role in offering clinical trials to patients even in major CALGB institutions and identified barriers to trials participation for both patients (6) and physicians (8). Patients ages ≥65 years were only offered trials participation 35% of the time, whereas younger patients were offered participation 50% of the time. Of note, when a trial was offered, both older and younger patients had similar rates of participation averaging about 50%.

CALGB 36001 ("The Effect of an Educational Program for Health Care Providers on Accrual of Older Persons to Cancer Treatment Protocols or "IOPEN"—Increase Older Persons Enrollment Now") was a randomized trial that compared an educational intervention [an educational session and case discussion seminar, educational materials (a notebook, slide sets, and a videotape of the educational symposium), protocol checklists for use on patient charts, and monthly e-mail and mailed reminders for 1 year] with standard group procedures (CALGB web site access and periodic information on trials). The trial found that ~36% of patients entered on to CALGB clinical trials were ages ≥65 years, a percentage higher than noted by other cooperative groups several years earlier. However, the educational intervention did not increase accrual of older patients to trials within the time period of the study (5). Current efforts are focused on developing an automated process for identifying elders with cancer shortly after diagnosis and alerting their physicians as to their eligibility for clinical trial participation.

CALGB 369901 ("An Observational Cohort Study: Chemotherapy Outcomes for Elderly Breast Cancer Patients Treated Outside of Clinical Trials") is a registry trial now in progress with a current accrual of 225 patients. This trial parallels CALGB 49907 (see below) and will compare patients in 49907 with patients treated with adjuvant systemic therapy outside of a protocol. CALGB 369901 will establish an observational cohort registry to study chemotherapy outcomes of elderly women who are treated off clinical trials and will assess reasons for treatment selection, comorbidity, functional status, quality of life, and outcome using identical instruments as CALGB 49907. This latter strategy will allow us to compare treatment issues among patients on a clinical trial with those not on trial. These studies will provide much needed

<table>
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<tr>
<th>CALGB no.</th>
<th>Title</th>
<th>PI</th>
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<td>Barriers to the Participation of Older Women with Breast Cancer in</td>
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<td>Refs. (6, 8)</td>
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<td>Clinical Trials: a Pilot Study</td>
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<td>119801</td>
<td>Telephone Monitoring: Early Identification of Psychological Distress</td>
<td>Kornblith</td>
<td>Patients accrued.</td>
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<td></td>
<td>in Cancer Patients 65 or more years old during Active Treatment</td>
<td></td>
<td>Publication in preparation</td>
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<td>36001</td>
<td>The Effect of an Educational Program for Health Care Providers on Accrual of Older Persons to Cancer Treatment Protocols or &quot;IOPEN&quot;—Increase Older Persons Enrollment Now</td>
<td>Kimmick</td>
<td>Ref. (5)</td>
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<td>369901</td>
<td>An Observational Cohort Study: Chemotherapy Outcomes for Elderly</td>
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<td>Breast Cancer Patients Treated Outside of Clinical Trials</td>
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<td>Clinical Pharmacology of Paclitaxel in Relation to Patient Age</td>
<td>Lichtman</td>
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<td>49907</td>
<td>A Randomized Trial of Adjuvant Chemotherapy with Standard Regimens,</td>
<td>Muss Mauer Theodoulou</td>
<td>Active and Accruing patients</td>
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<td>Cyclophosphamide, Methotrexate and Fluorouracil (CMF) or Doxorubicin</td>
<td>Kornblith Partridge Dressler</td>
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<td>and Cyclophosphamide (AC) versus Capecitabine in Women 65 Years and</td>
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<td>Older with Early Stage Breast Cancer</td>
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<td>9343</td>
<td>The Evaluation of Lumpectomy, Tamoxifen, and Irradiation of the Breast</td>
<td>Hughes Schnapper</td>
<td>Ref. (14)</td>
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<td>Compared with Lumpectomy plus Tamoxifen in Women 70 Years of Age or</td>
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<td>Older Who Have Carcinoma of the Breast ≤2 cm and Clinically Negative</td>
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<td>Axillary Nodes</td>
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<td>9793</td>
<td>A Phase III trial of CHOP vs. CHOP and Rituximab in Older Patients</td>
<td>Morrison</td>
<td>Final publication in preparation</td>
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<td>with Diffuse Mixed, Diffuse Large Cell, and Immunoblastic Large Cell</td>
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<td>Histology Non-Hodgkin’s Lymphoma</td>
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Table 1. Cancer in the Elderly Committee Trials

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Information concerning reasons for declining trial participation, treatment toxicity, outcome, quality of life, and comorbidity in older women with early-stage breast cancer given chemotherapy outside of the clinical trials setting. The three trials outlined above have all helped to identify barriers to trial participation and are likely to provide leads for more effective interventions.

Assessing the effects of comorbidity and function on treatment outcome for elders with cancer remains a major challenge for all oncologists. Comprehensive geriatric assessment consists of medical, functional, affective, social, spiritual, and environmental assessment, including nutrition, vision, hearing, continence, gait and balance, and cognition evaluation. A substantial amount of research has shown the value of geriatric assessment in detecting impairment and in leading to meaningful interventions to improve functional status and quality of life (9, 10). Dr. Arti Hurria and her CALGB colleagues have completed a pilot study of 43 patients that explored the use of a short, mostly self-administered geriatric assessment instrument (11). Medical personnel were only required to help with a “get up and go” test and with a brief assessment of cognitive function. The instrument explored all domains, took an average of 27 minutes to complete, and has led to the development of a new protocol (CALGB 360401: “Development of a Geriatric Assessment Measure for Older Patients with Cancer”) that will formally evaluate this instrument in a variety of disease settings. This protocol is currently under review at the NCI. It is believed that this simple, user-friendly instrument will provide data that will help oncologists estimate the toxicity of specific treatments in individual patients.

**Treatment issues.** Because there have been few prospective studies of the pharmacokinetics and pharmacodynamics of chemotherapy drugs in older cancer patients, CALGB 9762 (“Clinical Pharmacology of Paclitaxel in Relation to Patient Age”) was initiated to provide prospective data on the effects of aging on pharmacokinetic variables and tolerance of paclitaxel given at a dose of 175 mg/m² over 3 hours. This was also the first study in the development of a CALGB pharmacology program focused on elderly patients. A limited sampling strategy (on the day of treatment only) was devised to simplify acquisition of pharmacokinetic data. Three age cohorts (55-64, 65-74, and ≥75 years) were evaluated. Of the 158 patients accrued on this trial, increased age was associated with a statistically significant decline in total body paclitaxel clearance, an increase in ATIC, and a lower WBC and neutrophil nadir (12). A similar trial was designed to explore irinotecan toxicity in older patients but was stopped for poor accrual. Future studies exploring the pharmacokinetics and pharmacogenetics of newer agents in older patients are in the planning stages, including a study of capecitabine pharmacology in the elderly. These trials have been planned and developed in partnership with the Pharmacology and Experimental Therapeutics Committee.

CALGB/Clinical Trials Support Unit 49907 [“A Randomized Trial of Adjuvant Chemotherapy with Standard Regimens, Cyclophosphamide, Methotrexate and Fluorouracil (CMF) or Doxorubicin and Cyclophosphamide (AC) versus Capecitabine in Women 65 Years and Older with Early Stage Breast Cancer”], funded through an National Institute on Aging/NCI grant, includes a randomized phase III trial of adjuvant chemotherapy that compares standard regimens (cyclophosphamide/methotrexate/fluorouracil or doxorubicin/cyclophosphamide) with the oral agent capecitabine. The trial is designed to show noninferiority of the capecitabine arm compared with the standard regimens (cyclophosphamide/methotrexate/fluorouracil and doxorubicin/cyclophosphamide) for relapse-free survival. In addition to determining the effects of chemotherapy on relapse-free survival, there are four other major components of the trial, including (a) a detailed quality of life study nested within the trial, (b) a study of drug adherence for the oral capecitabine arm using a computerized medication dispenser, (c) an extensive assessment of functional status and comorbidity, and (d) a correlation of outcome and toxicity with tumor biological characteristics for all patients and, for capecitabine-treated patients, a correlation of outcome with thymidine phosphorylase levels. This last translational part of the trial is separately funded through an NCI grant [“Tumor Markers to Predict Treatment Response” (CA# 1 U10 Ca 85790-01-A1)]. This trial has strong Intergroup support through the NCI Clinical Trials Support Unit with appointment of coinvestigators from all major Intergroup members. To date, >450 patients have been accrued, and the trial has recently been amended to allow entry of patients with breast cancers larger than 1 cm, irrespective of nodal status. There has been excellent accrual to the quality of life, compliance, and translational research companion trials.

The Cancer in the Elderly committee along with members of the Breast Committee analyzed four clinical trials of “higher” versus “lower” doses of chemotherapy in women with node-positive breast cancer to examine the effect of such treatments in women over age 65 years (13). The analysis showed that women ages ≥65 years had the same significant proportional reductions in risk of relapse and dying of breast cancer as did younger women. Treatment related mortality was higher in older patients but did not negate the benefits of higher-dose therapy. The results of this trial drew national attention and have supported efforts to provide appropriate treatment options for older women with high-risk early breast cancer.

Together with the breast and lymphoma committee, Cancer in the Elderly Committee members played major roles in two CALGB trials. CALGB 9343 (“The Evaluation of Lumpectomy, Tamoxifen, and Irradiation of the Breast Compared with Lumpectomy plus Tamoxifen in Women 70 Years of Age or Older Who Have Carcinoma of the Breast ≤2 cm and Clinically Negative Axillary Nodes”) was a randomized trial in 647 patients that compared post-lumpectomy breast radiation or not in patients with small hormone receptor–positive breast cancers (14). Most of the patients died of non-breast cancer–related causes, and there were no significant difference in the frequency of metastases among the groups. Patients who received breast radiation had a significantly lower rate of loco-regional recurrence. Tissue blocks collected on this trial are being analyzed in a companion trial (CALGB 159805: PI Dr. William Cance) to determine the relationship of molecular markers and recurrence for patients on this trial and to evaluate histologic characteristics and molecular markers in older patients with early-stage breast cancer. CALGB 9793 (“A Phase III trial of CHOP versus CHOP and Rituximab in Older Patients with Diffuse Mixed, Diffuse Large Cell, and Immunoblastic Large Cell Histology Non-Hodgkin’s Lymphoma”) was an
intergroup trial conducted in conjunction with Eastern Cooperative Oncology Group and Southwest Oncology Group with a final accrual of 632 (CALGB-174). The data have been analyzed and presented at the American Society of Hematology meetings in 2004 (15) and at the 2005 International Lymphoma meeting. In this study of patients ages ≥60 years, we found that the addition of Rituximab to cyclophosphamide-Adriamycin-vincristine-prednisone (CHOP) as induction therapy as a maintenance therapy improves the time to treatment failure, and RCHOP induction improved overall survival compared with CHOP alone in these older patients. Our committee has also stimulated other disease sites committees to assess age relationships in the malignancies under their purview. An example of this is an analysis of age and prostate cancer outcomes by members of the GU committee, showing that the hazard ratio for death and prostate death for octogenarians was 1.3 compared with men ages 70 to 79 years (16, 17).

Improving quality of life for older patients with cancer. CALGB 119801 ("Telephone Monitoring: Early Identification of Psychological Distress in Cancer Patients 65 or more years old during Active Treatment") is a randomized trial designed to test the value of telephone monitoring in lowering emotional distress and social isolation in older cancer patients with advanced-stage disease on active treatment. Patients were randomized to receive either monthly centralized telephone monitoring by trained investigators for 6 months and educational materials or to educational materials alone. Telephone monitoring included a phone interview to identify those patients at high rates of distress using the Hospital Anxiety and Depression Scale, European Organization for Research and Treatment of Cancer (QLQ-C30), and the MOS Social Support Survey; such patients were referred back to their oncology nurse for further evaluation and referral. The hypothesis tested in this trial was that the older cancer patient in distress would be even more likely to have distress go unrecognized and undertreated, as is found with cancer patients in general. Accrual has been completed with 186 patients, including 131 who have had a 6-month follow-up interview. Patients randomized to the telephone monitoring arm had significantly less anxiety and depression at 6 months compared with the education arm alone (18).

Future Plans

The committee’s plans for the future include continuing its present role as both a source of ideas for new clinical trials involving elders and facilitating interactions among other sites and modality committees. To help identify older patients suitable for clinical trials, we are developing a process that would identify such patients in the office setting using computerized data capture. Electronically informing physicians of patient age and diagnosis might help busy clinicians consider offering trials to older eligible patients.

We are presently working with the surgery committee on a registry trial that will collect data on outcomes of older patients with early-stage lung cancer treated with several surgical techniques. We hope to incorporate our recently tested geriatric assessment tool into this trial to determine if geriatric assessment can predict survival, morbidity, and mortality. In addition, we hope to incorporate a correlative science study into this trial to determine if there are differences in tumor markers and tumor characteristics among younger and older patients. A concept for this trial has been developed, and this trial has been reviewed and endorsed by the Thoracic Surgery Subcommittee of the CALGB. We are also planning with the Radiation Oncology committee a study to explore the effects of cranial radiation on cognitive function in older patients with lung cancer. A concept in development will explore the potential benefit of erythropoietin in these patients as an intervention that may lower the probability of cognitive loss in these patients. Others on our committee are exploring CALGB databases of completed trials that included elders, for assessment of treatment effects and age-related toxicity. Older trials in several disease sites and which included large numbers of patients are currently being reviewed for this purpose.

In addition, we are in the process of developing a concept that will define the pharmacokinetics of capecitabine in elders. Expanding on the success of our telephone monitoring trial, we are developing a concept to expand this valuable intervention to older patients with earlier stage and potentially curable cancers. Last, we continue to evaluate all new large CALGB trails for the feasibility of incorporation of our geriatric assessment tool.

Cancer in the elderly is a major problem confronting all health care providers and will become an even more pressing problem as the population continues to age. The CALGB has recognized this and through the Cancer in the Elderly Committee is addressing the important need for research in this population. In the short period of time since the committee’s inception, its members have developed several important trials addressing cancer issues in elders. We plan to continue these efforts hope to enlist new investigators and health care providers to expand research efforts in this underserved and continually expanding segment of our population.

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Harvey Jay Cohen and Hyman B. Muss


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