DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
35th CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE (CTAC) MEETING

Summary of Meeting
March 7, 2018

Webinar

CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE
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The 35th meeting of the Clinical Trials and Translational Research Advisory Committee (CTAC) of the National Cancer Institute (NCI) was held by webinar on Wednesday, March 7, 2018, at 11:00 a.m. The CTAC chair, Dr. Nancy E. Davidson, presided.[1] The meeting was adjourned at 12:59 p.m.

Chair
Nancy E. Davidson

CTAC Members
David F. Arons
Debra L. Barton
Walter J. Curran, Jr.
Janet Ellen Dancey
Timothy J. Eberlein
Howard J. Fingert
David M. Gershenson
Paul A. Godley
Anne-Marie R. Langevin
Michael L. LeBlanc
Patrick J. Loehrer, Sr.
David A. Mankoff
Lynn M. Matrisian
Neal J. Meropol
Edith P. Mitchell
Nikhil C. Munshi
Augusto C. Ochoa
Roman Perez-Soler
Gloria M. Petersen
Steven T. Rosen (absent)
Dan Theodorescu
Louis M. Weiner

***Ex Officio* Members**
William L. Dahut, NCI (absent)
James H. Doroshow, NCI
Paulette S. Gray, NCI
Rosemarie Hakim, Centers for Medicare & Medicaid Services
Michael J. Kelley, U.S. Department of Veterans Affairs
Anthony Kerlavage, NCI
Richard Pazdur, U.S. Food and Drug Administration (absent)

Executive Secretary
Sheila A. Prindiville, NCI

Presenters
Nancy E. Davidson, MD, Senior Vice President, Director, and Full Member, Clinical Research Division, Fred Hutchinson Cancer Research Center; President & Executive Director, Seattle Cancer Care Alliance; Head, Division of Medical Oncology, Department of Medicine, University of Washington
Andrea Denicoff, RN, MS, ANP, Nurse Consultant, Cancer Therapy Evaluation Program (CTEP), Division of Cancer Treatment and Diagnosis (DCTD), NCI
James H. Doroshow, MD, Deputy Director, Clinical and Translational Research; Director, DCTD, NCI
Holly A. Massett, PhD, Senior Behavioral Science Analyst, Clinical Trials Operations and Informatics Branch, CTEP, DCTD, NCI
Meg Mooney, MD, MBA, Branch Chief, Clinical Investigations Branch, CTEP, DCTD, NCI
Sheila A. Prindiville, MD, MPH, Director, Coordinating Center for Clinical Trials, Office of the Director, NCI
Norman E. Sharpless, MD, Director, NCI

[1]A roster of CTAC members and their affiliations is included as an appendix.

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WEDNESDAY, MARCH 7, 2018

I. Call to Order and Opening Remarks

Nancy E. Davidson, MD

Dr. Davidson called the 35th meeting of CTAC to order and welcomed participants to the meeting.

Dr. Davidson reviewed the confidentiality and conflict-of-interest practices required of CTAC members during their deliberations. She invited members of the public to send written comments on issues discussed during the meeting to Dr. Prindiville within 10 days of the meeting. National Institutes of Health Events Management was videocasting the meeting, and the videocast would be available for viewing following the meeting at http://videocast.nih.gov.

Motion. A motion to accept the minutes of the 34th CTAC meeting held on November 1, 2017, was approved.

II. NCI Director's Update

Norman E. Sharpless, MD

Budget. Dr. Sharpless reported that Congress has not yet approved the Fiscal Year 2018 budget for the National Institutes of Health (NIH) or NCI. The federal government is operating under a continuing resolution that expires on March 23, 2018. The hope is that Congress will pass an omnibus bill that includes NCI's budget before that date.

Intergovernmental Affairs. NCI is working with several other federal agencies. For example, discussions with the Food and Drug Administration (FDA) are focusing on training new investigators, data sharing, and cell manufacturing for cellular immunotherapy. For the Centers for Medicare & Medicaid Services (CMS), topics of mutual interest include use of Medicare claims data, coverage for clinical trials, and next-generation sequencing (NGS). Dr. Sharpless described his recent outreach to Congress and the Department of Health and Human Services, including a meeting with the new secretary, Alex M. Azar, II, and the delivery to the White House of the President's Cancer Panel report, *Promoting Value, Affordability, and Innovation in Cancer Drug Treatment*.

Method to Extend Research in Time (MERIT) R37 Awards for Early-Stage Investigators (ESIs). ESIs are applicants who have received their terminal research degree or completed their clinical training within the past 10 years and have not yet received an independent NIH research award. ESIs who apply for their first R01 and receive a score within the NIH payline will now receive a MERIT R37 award instead of an R01. The MERIT award will offer up to 2 additional years of funding, giving ESIs more time to establish their careers before applying for a renewal award. The MERIT award responds to a call in the 21st Century Cures Act for increasing NIH support for ESIs. ESIs do not need to apply for the MERIT award separately from the R01. ESIs whose applications do not score within the payline will not receive a MERIT award, but they might receive a traditional R01 grant through the selective pay process.

Applied Proteogenomics OrganizationaL Learning and Outcomes (APOLLO) Network. The APOLLO Network is a collaboration among NCI, the Department of Defense, and the Department of Veterans Affairs. APOLLO is analyzing the DNA, RNA, and protein expression of 8,000 clinically annotated human tissue specimens from active-duty military servicemembers and veterans.

National Cancer Advisory Board Working Groups. The Global Health Working Group, led by Deborah Bruner, RN, PhD, Emory University, and Satish Gopal, MD, University of North Carolina at

Chapel Hill, will provide general guidance to NCI regarding strategic opportunities to enhance NCI's contributions to global cancer research. It may address such topics as the balance of functions for NCI's Center for Global Health, the Center for Global Health research portfolio, and how to identify priorities for NCI given the tremendous international burden of cancer.

The Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Working Group is assessing the SBIR/STTR award sizes for different phases of funding, the review process, possible resources in addition to funding, how to deliver funds more quickly to small companies, and other topics. This group is chaired by Elizabeth Jaffee, MD, Johns Hopkins University, and Mel Billingsley, PhD, Pennsylvania State University.

The Informatics Working Group provides general guidance to NCI regarding utilization of new developments in informatics and computational science to serve all components of the institute. They will be asked for input on the role of the director of Center for Bioinformatics & Information Technology compared to that of a chief information officer, expanding funding opportunities for data science and bioinformatics research, and improving data sharing to maximize the impact of cancer research on patients. The group's co-chairs are Mia Levy, MD, Vanderbilt University, and Charles Sawyers, MD, Memorial Sloan Kettering Cancer Center.

Cancer Moonshot. The Blue Ribbon Panel (a working group of the National Cancer Advisory Board) provided 10 recommendations in its 2017 report (https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/blue-ribbon-panel#ui-id-3) for accelerating progress against cancer. NCI formed several implementation teams to expand on these recommendations and has now issued Cancer Moonshot funding opportunities (https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/funding) to address the Blue Ribbon Panel's recommendations.

One of these funding opportunities is for the Partnership for Accelerating Cancer Therapies (PACT), a collaboration between NCI and 12 large pharmaceutical partners. PACT will identify, develop, and validate robust biomarkers to advance new immunotherapy treatments for cancer. The Cancer Immunologic Data Commons and four Cancer Immune Monitoring and Analysis Centers will support PACT immunotherapy trials.

The Cancer Moonshot is also supporting the new Immuno-Oncology Translational Network to foster collaborative team science approaches to accelerate the discovery of new immune targets and evaluate novel immune-based therapies and combination approaches that eliminate established cancers in adults or prevent cancers. The Pediatric Immunotherapy Discovery and Development Network will identify and advance research opportunities for translating immunotherapy concepts for children and adolescents with cancer toward clinical applications.

NCI Experimental Therapeutics Program (NExT). The mission of the NExT program is to advance clinical practice and bring improved therapies to patients with cancer by supporting the most promising new drug discovery and development projects. The NExT pipeline spans the continuum from early discovery to full development through partnerships with academic institutions, biotechnology companies, and pharmaceutical companies. NExT is assessing several targets and agents at different points in the continuum.

One example is the development of a high-affinity inhibitor of myeloid cell leukemia 1, an antiapoptotic protein. The new inhibitor has subnanomolar potency and favorable pharmacokinetic properties. An industry partner has licensed this agent.

Research on Low-Intensity Smokers. A research team from NCI and the FDA's Center for Tobacco Products published a study in *JAMA Internal Medicine* showing that low-intensity smoking (no more than 10 cigarettes, on average, a week) over a lifetime was associated with a significantly higher risk of all-cause mortality, including death from lung cancer and cardiovascular disease, than never-smokers (https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2588812). Furthermore, quitting low-intensity smoking earlier reduces the risk of these effects. The findings show that there is no safe level of exposure to inhaled tobacco.

Rural Cancer Control. Up to 19 percent of the U.S. population lives in rural counties. Challenges for this population include higher poverty levels as well as lower educational attainment and access to health care. To address the needs of rural populations, NCI is conducting a series of rural cancer control workshops and a conference, Accelerating Research in Rural Cancer Control, on the NIH campus on May 30–31, 2018. NCI will use the lessons from these events to develop funding announcements.

NCI Molecular Analysis for Therapy Choice (MATCH). NCI-MATCH has enrolled patients at almost 1,100 sites throughout the United States. Dr. Sharpless characterized the establishment of the NCI-MATCH infrastructure as a *tour de force*. Although many components of NCI-MATCH are no longer enrolling patients, the Rare Variant Initiative continues to accrue patients whose tumors are tested for molecular alterations outside the study and found to harbor low-frequency genetic mutations for which well-qualified drugs and targets are available in the study. The results are being verified centrally by the NCI-MATCH Oncomine® assay.

Dr. Sharpless shared some summary statistics from NCI-MATCH showing that the trial enrolled more than 6,000 patients in record time. Approximately 15 percent of tumors tested were found to contain a genetic mutation targeted by drugs being tested in one of the 30 trial arms; thus, NGS is clearly helping patients find personalized treatments that may benefit them. The first NCI-MATCH efficacy data have come from the nivolumab (Opdivo) arm for microsatellite instability–high cancers. The 6-month progression-free survival rate was 49 percent, and the median duration of response was not reached at the time of data cutoff. More efficacy data from NCI-MATCH will be released soon.

Vision for NCI. Dr. Sharpless continues to meet with various stakeholders to deepen his understanding of NCI. He has divided the challenges for NCI into three categories: things that NCI must do, things that NCI would like to do if new funding becomes available, and things that NCI is already doing but require ongoing investment.

Questions and Discussion

Dr. Loehrer suggested that Dr. Sharpless add a fourth category of NCI challenges to his list: things that NCI should not be doing. Dr. Sharpless said that it is difficult to find examples of activities that belong in this category. Most NCI programs are strong, well justified, and excellent investments of public resources. However, some activities that are wrapping up do not need to continue or should be transferred to another agency.

Dr. Curran asked how to better align clinical trials in cancer centers with NCI initiatives, including those of the National Clinical Trials Network. Dr. Sharpless replied that one of the top three challenges facing NCI is the difficulty of accruing patients to clinical trials across the country. The institute is therefore eager to find ways of increasing accrual to well-designed clinical trials. Many cancer centers and clinical trial sites are colocated, and NCI hopes to use its investments for multiple kinds of trials at these institutions. He also believes that some clinical trials need to be open outside cancer centers and the National Clinical Trials Network to obtain the desired accrual numbers.

Dr. Sharpless added that cancer centers can help NCI implement programs very quickly. Furthermore, NCI can use administrative supplements to enable much more rapid progress in high-priority areas than the traditional request for application process. Dr. Doroshow commented that NCI constantly considers how to enable cancer centers to achieve their clinical trials mission, given the limited resources provided through the Cancer Center Support Grants.

Dr. Davidson wondered whether anything had greatly surprised Dr. Sharpless when he arrived at NCI. Dr. Sharpless said what surprised him, but should not have, were the scope and scale of NCI programs as well as the excellence of its staff. Working for the federal government can be challenging, but NCI's personnel have a strong commitment to the institute's mission and a passion for their work.

Dr. Davidson gave Dr. Sharpless an opportunity to identify anything he would like from CTAC. Dr. Sharpless asked CTAC to send feedback to norman.sharpless@nih.gov on the impact of the upcoming CMS coverage decision on NGS and clinical trials at their institutions.

III. Accrual Performance of National Clinical Trials Network (NCTN) Trials

Meg Mooney, MD, MBA

NCI replaced the cooperative group system with the NCTN on March 1, 2014. At that time, the existing cooperative groups were consolidated into five U.S. groups, of which four focus on adult cancers and one on pediatric cancers. A sixth group in Canada is also part of the NCTN.

NCTN Structure. The NCTN's centralized functions (the Central Institutional Review Board, the Cancer Trials Support Unit, radiotherapy and imaging cores, and a common data management system with central hosting) ensure operational efficiency throughout the NCTN and with the 46 NCI Community Oncology Research Program (NCORP) sites throughout the country. Thirty Lead Academic Participating Sites (including 29 comprehensive cancer centers) provide leadership in development of, accrual to, and conduct of clinical trials. NCI Disease-Specific Steering Committees evaluate and prioritize large phase II and phase III clinical trial concepts. All sites and institutions in each group may participate in any other NCTN group's clinical trials.

Accrual. Dr. Mooney presented detailed data on NCTN accrual. Between March 1, 2014, and December 31, 2017, 72,536 unique patients were enrolled on NCTN trials. Of those, 22 percent of NCTN participants came from Lead Academic Participating sites, 28 percent from NCORP sites, and 41 percent from other U.S. sites. Another 7 percent came from full members of NCTN groups outside the United States, and 2 percent from nonmember collaborators. Almost 1,800 institutions participated in NCTN trials worldwide.

Approximately 15 percent of NCTN participants who reported their race are members of a racial minority group. Although NCI hopes to increase the proportion of trial participants from minority groups,

this rate does represent an increase in minority participation over the past decade. Of patients reporting their gender, 56 percent are female.

Accrual in Phase II/III and Phase III Trials. The Cancer Therapy Evaluation Program (CTEP) monitors NCTN trial accrual rates after activation to identify accrual problems early and intervene quickly to improve accrual when needed. If the accrual rate in quarter 5 or 6 is 20 percent or less of the projected rate, NCI stops the trial. If the accrual rate at this time is between 20 percent and 50 percent of the projected rate, the study team is given 6 months to improve accrual. If the rate in quarter 8 is less than 50 percent of the projected rate, the trial might be amended to reflect the actual accrual rate. Dr. Mooney provided data on the number of trials opened between January 1, 2014, and December 31, 2017, in each category. She also provided accrual rate data for the five trials that opened and completed accrual in this period.

Trials that close early for futility or superiority (and do not achieve 90 percent of their accrual goal) still are considered successful because they have answered their clinical question. In other cases, trials have inadequate accrual because the standard of care changes, a drug has unacceptable toxicity, the randomization scheme raises concern in patients or clinicians, sites have low interest in the treatment approach, competing studies are ongoing, or the trials need patients with rare cancers.

Approximately 12 percent to 22 percent of phase II/III and phase III NCTN trials are at risk of closure due to poor accrual rates. These trials typically do not perform well from the start, and most focus on rarer tumors (or rare molecular subsets of common tumors). However, rare tumor trials can accrue well with careful planning and commitment. CTEP plans to continue intervening in trials that might face accrual challenges.

Questions and Discussion

Dr. Munshi asked whether the participation rates of NCORP sites in NCTN trials have changed in recent years. Dr. Mooney replied that the NCORP site participation rate is typically 22 percent to 30 percent, and it continues to be robust. Non-NCORP sites (many of which are community sites) contribute 41 percent of accrued patients.

Dr. Munshi asked whether the reason some trials struggle with accrual is that their accrual targets are too high. Dr. Mooney said that many of the trials might not have established realistic accrual rate targets, but this does not fully explain these challenges.

Dr. Gershenson was concerned about the accrual of women to gynecologic cancer trials. In 2011, before NCTN was created, almost 3,000 women joined CTEP gynecologic cancer trials. In 2017, this number was 1,000, and almost as many patients have been accrued to industry trials. Dr. Mooney said that CTEP continues to try to determine the most appropriate niche for NCTN versus industry in gynecologic cancer trials.

IV. Activities to Enhance Accrual to National Clinical Trials Network (NCTN) Trials

Andrea Denicoff, RN, MS, ANP
Holly Massett, PhD

Network Accrual Core Team (ACT). Dr. Massett explained that the Network ACT gives NCTN and the NCI Community Oncology Research Program (NCORP) sites a forum to maximize accrual through communication and collaboration across the network. Its approximately 30 members include representatives of NCI, network operations offices, NCTN and NCORP sites, the Cancer Trials Support Unit (CTSU), and patient advocates; members serve for 2 to 3 years. The group holds monthly roundtable WebEx protocol discussions with principal investigators (PIs) of trials that have accrual challenges.

The CTSU also holds national hour-long WebEx seminars periodically throughout the year; these seminars feature presentations of several NCTN trials by their PIs and question-and-answer sessions. These meetings are open to all NCTN and NCORP sites, and they typically draw 450 participants, on average. During each webinar, sites have opportunities to learn about the trials, share strategies, and talk directly to the PIs.

Recommendations that have resulted from the Network ACT include identifying investigators from each NCTN group who are not members of the study team to serve as study champions within their group for each protocol; creating trial-specific materials for health care professionals to enhance discussion with potential patients; requesting clarifications of the protocol (e.g., patient eligibility, funding for tests); and providing contacts to external groups that can help promote NCTN and NCORP trials.

Network ACT Task Forces. Ms. Denicoff described the activities of the two Network ACT task forces. The Eligibility Task Force promotes the use of thoughtful, less restrictive eligibility criteria in NCTN and NCORP trials. Two task force representatives (Andrea Denicoff and Paul Hesketh, MD, Lahey Hospital & Medical Center) participated in a collaborative effort of the American Society of Clinical Oncology and Friends of Cancer Research working to broaden eligibility in clinical trials. This led to a series of published manuscripts in the *Journal of Clinical Oncology* on broadening clinical trial eligibility (http://ascopubs.org/jco/specialseries/2017/broadening-eligibility-criteria-clinical-oncology-trials).

The Data Inventory Task Force identifies best practices to enhance accrual, collects existing accrual support tools, and develops new templates when needed. An accrual planning checklist, developed by the task force for use across groups, is currently being pilot tested.

Examples of Protocol Discussions. To date, the Network ACT has supported over 28 clinical trials across all network groups in 15 cancer types. Ms. Denicoff gave two examples of trials that have been discussed on Network ACT calls. The first was a randomized phase III trial of endocrine therapy plus entinostat or placebo in patients with hormone receptor-positive breast cancer. Trial accrual during the first 6 months was very slow. The Network ACT recommended that other clinical trial networks and patient advocacy groups promote the trial throughout their breast cancer communities, which increased the accrual rate.

An NCORP trial of eflornithine and sulindac to prevent recurrent high-risk colon adenomas and second primary colorectal cancers in patients with colon cancer had four arms initially. After consideration by the Network ACT to help the trial succeed, it was amended to include only two arms.

Questions and Discussion

Dr. Munshi asked about the strategy to improve accrual to the NCORP prevention study that Ms. Denicoff had described, noting that after 5 years, the study has not reached half of its accrual target. Ms. Denicoff said that this study underwent a major redesign and substantially reduced its accrual target. Whether this redesign is having the desired effect will be assessed after a predetermined period. Worta McCaskill-Stevens, MD, MS, Community Oncology and Prevention Trials Research Group, reported that accrual to this study was slow for many reasons, such as problems with drug supply and toxicity, but its accrual is now on target. Leslie Ford, MD, Division of Cancer Prevention, added that NCI carefully considers whether the findings of trials that accrue slowly will still be relevant once they finish. NCI has determined that the trial in question is likely to offer valuable insights if it can be completed successfully.

Dr. Fingert asked whether the data from trials with expanded eligibility criteria will change practice. He described a case in which a sponsor was unable to use the data from the site with the fastest accrual rate for its registration trial because the Food and Drug Administration determined that this site had deviated too far from the study protocol. Dr. Mooney replied that NCI monitors data quality carefully and systematically.

Dr. Loehrer wondered whether a central resource could help trials across NCI address accrual challenges or whether individualized solutions are typically required. Ms. Denicoff said that the recommendations of the Network ACT have already been integrated into group operations. The monthly calls give the study teams opportunities to share their approaches across the network, and the CTSU maintains a collaboration portal for the Network ACT to facilitate sharing of accrual tools and strategies.

V. Ongoing and New Business

Sheila A. Prindiville, MD, MPH

CTAC Working Groups and Subcommittees. The ongoing CTAC working groups are the Clinical Trials Informatics Working Group, Progress in Pancreatic Ductal Adenocarcinoma Research Working Group, and Progress in Small-Cell Lung Cancer Research Working Group. A fourth working group, the Clinical Trials Strategic Assessment Working Group, is being formed.

Dr. Prindiville asked CTAC to consider forming a fifth group, the Translational Research Strategy Subcommittee. CTAC discussed forming such a group at its March 2017 meeting after receiving a report on the National Cancer Advisory Board (NCAB) and Board of Scientific Advisors (BSA) Specialized Programs of Research Excellence (SPORE) Evaluation Working Group. This subcommittee will provide broad advice to CTAC, the NCAB, the BSA, and NCI leaders on enhancing and broadening NCI's translational research portfolio. It will be made up of CTAC, NCAB, and BSA members as well as ad hoc experts as needed.

Dr. Sharpless explained that this subcommittee is a response to an evaluation report suggesting that NCI enhance its efforts to identify topics that are ready for rapid translation. The issues that the new subcommittee addresses will include disease-based topics as well as new areas of technology, and its initial focus will be on glioma and radiation oncology. In the future, the subcommittee might consider

other diseases or other technologies, such as novel imaging modalities or next-generation sequencing. Working groups will also be established.

Dr. Davidson reported that she was part of the discussions of this subcommittee with Dr. Sharpless and NCAB and BSA members. She expressed her strong support for establishing the subcommittee.

Dr. Dancey asked whether the entire continuum of translational research is within CTAC's purview. Dr. Prindiville explained that CTAC's charter does include reviewing NCI's translational research portfolio. Dr. Sharpless said that reviewing the entire NCI translational research portfolio would be too much for a subcommittee, which is why working groups will focus on specific topics.

Motion. A motion to approve the formation of the Translational Research Strategy Subcommittee and subsequent working groups carried unanimously.

CTAC July Meeting Agenda. Proposed topics for discussion at CTAC's July 11 in-person meeting are as follows:

- Experimental therapeutics
    - Experimental Therapeutics Clinical Trials Network renewal
    - Investigational Drug Steering Committee update
    - Pediatric Early Phase Clinical Trials Network update
- Quantitative Imaging Network update
- Cancer Immune Monitoring and Analysis Centers update

Dr. Prindiville encouraged CTAC members to send her additional suggestions for the July 2018 meeting agenda. This meeting will be at the NCI at Shady Grove campus because the meeting rooms in Building 31 on the NIH campus are being renovated.

VI. Adjournment

Nancy E. Davidson, MD

There being no further business, the 35th meeting of CTAC was adjourned at 12:59 p.m. on Wednesday, March 7, 2018.

Appendix

National Institutes of Health
National Cancer Institute
Clinical Trials and Translational Research Advisory Committee

CHAIR

Nancy E. Davidson, MD **2018**
Senior Vice President, Director, and Full Member
Clinical Research Division
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President & Executive Director
Seattle Cancer Care Alliance
Head, Division of Medical Oncology
Department of Medicine
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MEMBERS

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Deputy Director
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Comprehensive Cancer Center and Beckman Research Institute
Irell & Manella Cancer Center Director's Distinguished Chair
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