New Clinical Drug Evaluation Unit (NCDEU) Annual Meeting: A Great Opportunity for Early Career Psychiatrists

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When the Early Clinical Drug Evaluation Unit meeting was first held over a half century ago, psychopharmacology and indeed modern-day psychiatry were in their infancy, yet there was enormous excitement surrounding the introduction of new medications that appeared to have a profound impact on major psychiatric illnesses. Perhaps the most publicized effect was the control of the florid symptoms of psychosis that was used as a basis for moving the majority of patients with schizophrenia to outpatient settings as an alternative to long-term hospitalizations. Even then, it was realized that much more needed to be done and that it was in the public interest for government to invest in methods for developing effective treatments for serious mental illnesses.

At that time, the recently established psychopharmacology research program at the National Institute of Mental Health (NIMH) under the leadership of Jonathan O. Cole, MD, one of the remarkable pioneers of that era, was sponsoring a network of research "units" in academic centers that became known as the Early Clinical Drug Evaluation Units. These units had annual gatherings to exchange data and discuss the new ideas, challenges, and opportunities in this nascent field—these sessions came to be known as the ECDEU meeting. From that start in 1959 and subsequently under the name New Clinical Drug Evaluation Unit (NCDEU), this event has expanded and added new features to become the key meeting in this domain, bringing together academic investigators; industry scientists; US and international regulators from the US Food and Drug Administration (FDA) and the European Medicines Authority; National Institutes of Health (NIH) components including the NIMH, National Institute on Drug Abuse, and National Institute on Alcohol Abuse and Alcoholism; and many other professionals working in various aspects of drug development and clinical trials. The meeting has played a historic role in the evolution of treatment research, the development of new treatments and treatment strategies, biostatistics, psychiatric diagnosis, and many other aspects of our field. With over 1,200 annual attendees, the meeting has also become a key opportunity for networking, planning, and the training of young investigators.

The NCDEU New Investigator Award (NIA) program began in 1992. The program provides an opportunity for investigators who have not yet been a principal investigator of an RO1 grant to participate in an intensive training experience and develop a network of peers and senior mentors who can help him/her with career focus and development. The signature event of the NIA program is a closed, 1-day workshop wherein new investigator awardees hear presentations from established investigators, experienced mentors, and subject matter experts, as well as representatives from the federal government and private industry whose work involves scientific research. The informal, small-group format fosters an engaging and lively exchange of questions, answers, and ideas among the awardees and workshop faculty. Workshop didactic presentations are designed to provide practicable information about interacting with the FDA and the NIH; career opportunities in academia and industry; practical statistics, design, and methods tips for clinical trials; mentoring; scholarly writing; and work-life balance. Awardees also present posters in the general poster sessions that provide an opportunity for interaction with the broader NCDEU community. A recent addition to the NIA program is "Breakfast Roundtables," which provide more personalized opportunities for advising and networking with senior leaders in the field. The NCDEU NIA program is competitive and selective. Awardees are chosen based on their potential to become successful independent investigators; a major criterion is evidence of a passion and curiosity for scientific research that is apparent in their applications. New investigators come from the disciplines of medicine, psychology, pharmacology, and other fields. This program has involved over 250 new investigators, many of whom have become leaders in the field.

In 2011, after 5 years of partnership sponsoring NCDEU, the NIMH asked the American Society of Clinical Psychopharmacology (ASCP) to take full responsibility for the meeting. Since its founding in 1992, the ASCP has had the missions of advancing research and knowledge in psychopharmacology, facilitating implementation of best practices, and, especially, enhancing training efforts on all levels from medical students and primary care physicians to psychiatric residents, fellows, attending psychiatrists, psychologists, and other professionals. The ASCP produces a curriculum widely used in residency training programs for the teaching of psychopharmacology, provides annual updates on the state-of-the-art, and sponsors an annual 3-day workshop in New York City on the design and conduct of clinical trials for early investigators and trainees in relevant disciplines.

The training of new generations of investigators to carry forward the promise of research in psychopharmacology

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and related domains has always been a high priority, but, at this moment in time, the opportunities are both uniquely exciting and especially challenging. As our knowledge of basic mechanisms continues to advance and pharmacogenetics emerges as a critical field, health care reform, cost-effectiveness concerns, and constrained resources add to the issues that need to be addressed in developing and testing new treatments. This gathering of academic, industry, and public service thought leaders at NCDEU provides those just beginning or contemplating a career in clinical research the unique opportunity to "see the moving parts" that advance new treatments from the laboratory to patients and to experience the encouragement that this community openly provides. The annual NCDEU conference should be the meeting of choice for early career psychiatrists who are contemplating such careers.

As we prepare for the 52nd annual NCDEU meeting in Scottsdale, Arizona, on May 29–June 1, 2012, we note the continuities from early beginnings but also highlight changes that have been introduced in the past 2 years. The meeting now includes the broader community of NIH institutes involved with central nervous system disorders and the National Center for Advancing Translational Sciences. The regulatory perspective has been expanded to include the European Medicines Authority, as well as the FDA. The commitment to inclusion of pharmaceutical industry scientists has generated a Pharma Pipeline session for presentation of new compounds relatively early in development. The Scientific Program Committee's membership has been expanded to include senior representatives from academia, the NIH, regulatory bodies, and industry. As such, the meeting is unique in covering the core disciplines and structures involved in central nervous system drug development. The goal is to integrate the latest means of translating molecular science into new treatments with traditional approaches to clinical trials and modifying the latter as needed. Thus, NCDEU is both a proud tradition and a work in progress that offers the most comprehensive annual meeting focused on the state-of-the-art in central nervous system drug development.

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Potential conflicts of interest: **Dr Kane** is president of the American Society of Clinical Psychopharmacology (ASCP); has served as a consultant to Alkermes, Amgen, Boehringer Ingelheim, Bristol-Myers Squibb, Cephalon, Eisai, Eli Lilly, Intracellular Therapies, Janssen, Johnson & Johnson, Lundbeck, Merck, Novartis, Otsuka, Pfizer, Pierre Fabre, Proteus, Roche, Sunovion, and Targacept; and is a stock shareholder in MedAvante. **Dr Kinon** is an employee of Eli Lilly. **Dr Potter** is on the ASCP board of directors; has served as a consultant to Agebio, Amgen, Astellas, AstraZeneca, Bristol-Myers Squibb, Envoy, InVivo, Johnson & Johnson, MedAvante, Orasi, Pfizer, and Theravance; and is a stock shareholder in Eli Lilly and Merck. **Dr Rapaport** is on the ASCP board of directors; has served as a consultant to National Center for Complementary and Alternative Medicine, National Institute of Mental Health, and National Institute on Drug Abuse; and has served on speakers or advisory boards of PAX (unpaid). **Dr Schooler** has received grant/research support from AstraZeneca, Bristol-Meyers Squibb, Eli Lilly, Ortho-McNeil Janssen, and Pfizer; has received honoraria from H. Lundbeck; and has served on speakers or advisory boards of Abbott, H. Lundbeck, Janssen Psychiatry, Johnson & Johnson, Merck, NuPathe, and Shire. **Dr Hill** reports no conflicts of interest related to the subject of this article.

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