June 20, 2013

Roger J. Lewis, MD, PhD
Department of Emergency Medicine
Harbor-UCLA Medical Center
Los Angeles Biomedical Research Institute
David Geffen School of Medicine at UCLA
Berry Consultants, LLC

RE: Partnership for Academic Innovations in Regulatory Science (PAIRS)

Dear Dr. Lewis:

I am writing to express my support for your U01 proposal, Partnership for Academic Innovations in Regulatory Science (PAIRS). As the Director of the UCLA Clinical and Translational Science Institute (CTSI), and Senior Associate Dean for Translational Research at UCLA, I welcome the addition of the PAIRS project to our collaborating UCLA and University of Michigan (UM) Clinical and Translational Science Award (CTSA) supported research institutes. As you know, the national CTSA program is designed to speed translation of laboratory discoveries into treatments for patients, to engage communities in research, and to train the next generation of clinical and translational science investigators. The UCLA CTSI mission is to create a borderless clinical and translational research institute that brings UCLA innovations and resources to bear on the greatest health needs of Los Angeles. We look forward to extending this collaboration and outreach to include our colleagues at both the University of Michigan and the US Food and Drug Administration (FDA).

Regulatory science is now viewed as the rate-limiting step in translational science because the cost, time, and complexity of gaining regulatory approval has grown to the point that implementation of medical innovations in translational science have stalled. I have previously chaired the FDA advisory committee on Cell, Tissue and Gene Therapy and have also filed FDA INDs and presented to the NIH Recombinant Advisory Committee, thus I fully understand the complexities and challenges that are facing the FDA staff in evaluating and regulating advances in medical research and technological innovations. I applaud the progressive action the FDA has taken by creating the “Advancing Regulatory Science and Innovation” Initiative to better evaluate the performance of FDA regulated products.

The opportunities for collaboration and resource sharing between PAIRS project and the UCLA and UM CTSAs are many and will benefit both FDA personnel and our research scientists. As

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you know, the UCLA CTSI is a dynamic partnership among UCLA, Los Angeles Biomedical Institute at Harbor UCLA Medical Center, Charles Drew University of Medicine and Science, Cedars-Sinai Medical Center, and our Los Angeles community. Our research resources, investigator services, and expertise are accessible across the four partnered institutions and our network of community clinics and healthcare organizations.

Specifically related to the PAIRS project aims, the CTSI will provide the FDA access to: (a) bioinformatics, electronic health records, and clinical trials data systems expertise, and (b) applied learning opportunities in our research and development labs and incubators. Drs. Alex Bui and Doug Bell will work collaboratively with FDA personnel to develop a flexible and practical approach to post-approval surveillance, based on the use of data streams from social media and web traffic to identify potential safety signals, combined with the use of electronic health record data from both the University of California and University of Michigan healthcare systems to verify or validate initial safety signals. Dr. Bell is the CTSI-Bioinformatics Leader and in collaboration with our UCLA Health Chief Informatics Officer, Dr. Mohammed Mahbouba, and Chief Information Officer, Dr. Virginia McFerran, we will provide seamless access to de-identified electronic health records to build the proposed post-approval surveillance system and a strategy for evaluating FDA-regulated products in epidemic or pandemic settings.

Other CTSI programs will provide consultation and expertise to ensure the training and scientific exchange opportunities will be custom designed to meet the specific training needs and interests of FDA personnel. Relevant CTSI components and expertise include, for example: (1) Regulatory Knowledge and Support and Research Ethics Program, (2) Research Training, Education and Career Development, (3) Business of Science Center, (4) Pilot and Collaborative Grants Program, and (5) CTSI-Evaluation.

Regarding educational opportunities for FDA personnel, UCLA is one of the leading public universities in the world, consistently ranked nationally in the top five institutions for research funding. The University is particularly strong in basic and clinical education and research in the health sciences. Its broad education and research achievements are collaborative efforts of numerous academic centers. Trainees are supported through more than 50 NIH T-type training grants, 55 F-type fellowships, almost 100 K-type awards in addition to being supported through national and international research grants from governments and private foundations. Most of the current training is strongly focused on preparing graduate students and postdoctoral scholars for careers in an academic research environment. The PAIRS project will have access to the major PhD training entities on campus, including the Graduate Division, David Geffen School of Medicine, College of Letters and Science Division of Life Sciences, PhD Programs in the Biosciences, and the Clinical and Translational Science Institute. Thus, the CTSI is positioned to provide relevant consultation and expertise to custom design FDA training and scientific exchange opportunities.

The Business of Science Center offers consultation and on-going educational opportunities to train scientists through the Drug Development Series and emphasizes the building of organizational and scientific competencies in technology transfer. CTSI Pilot and Collaborative Grants will provide applied learning experiences for FDA personnel through scientific involvement in projects funded through programs such as, Novel Methods and Technology, and Business of Science Prototype Grants. In collaboration with the PIs and investigators, the CTSI-Evaluation office has developed the PAIRS implementation phases, milestones, and measureable outcomes to ensure the PAIRS project will be responsive to FDA training and development needs, meets FDA center performance expectations, and that the center will be integrated into the UCLA and UM CTSA infrastructure to sustain and continue to address

emerging FDA training and scientific exchange needs. Additionally, CTSI-Evaluation will interface with experts across the four CTSI partner institutions, UM, and FDA to identify relevant opportunities for the PAIRS scientific exchange program.

You have brought together a strong, transdisciplinary team that will work well to ensure the PAIRS project enjoys long term sustainability. We look forward to collaborating closely with your leadership to share research resources and expertise. You have my support and best wishes on this unique and exciting venture.

The PAIRS project will benefit greatly from collaboration with the CTSI.

Sincerely,

Steven M. Dubinett, M.D.
Director, Clinical and Translational Science Institute
Senior Associate Dean for Translational Research
Associate Vice Chancellor for Research