June 13, 2013

Stephen Seidel
Acting Director, Office of Policy
National Center for Advancing Translational Sciences
National Institutes of Health
6701 Democracy Blvd, Suite 900
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Email: comment@ncats.nih.gov

Re: NCATS’ Request for Comment on Proposed Methods for Avoiding Duplication, Redundancy and Competition with Industry Activities, 78 FR 28601

Dear Mr. Seidel,

The Association of American Medical Colleges (AAMC) is pleased to respond to the request for comments on proposed methods to avoid risk of duplication, redundancy, and competition of NCATS’s sponsored research with industry activities, published in the Federal Register on May 15, 2013. The AAMC is a not-for-profit organization representing all 141 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 128,000 faculty members, 75,000 medical students, and 110,000 resident physicians.

The Association supports the mission of NCATS to “catalyze generation of innovative methods and technologies”1 that will further the development of new diagnostics and therapeutics. The new center was established in part to better understand and overcome a systemic difficulty in pharmaceutical and biotechnology R&D by which many promising fundamental and clinical discoveries, which are most typically made in academic settings, fail to translate effectively to commercial or industry development (the so-called valley of death). NCATS provides a center within NIH to develop new scientific means for effecting or stimulating such translation, and in one sense to treat the drug discovery and development pipeline as a research problem itself, i.e., open to making and testing hypotheses about improving the development process. Much of the important research undertaken by NCATS is complementary, not competitive or redundant to industry. This is especially true in areas of precompetitive research, including platform technologies, such as much of the genomic research of the last several decades that has made possible new industries. The issues raised in this request for comment are critical not only to industry, but to the academic institutions and the public who are investing resources to advance discovery.

The AAMC appreciates the concerns reflected in the request. In a time of severe budgetary constraints and now unprecedented—and entirely unwarranted—cuts to the nation’s medical research budget, we wish to ensure that public funds are not further diminished by unnecessarily diverting them to areas of research better supported by private capital. A second concern is that federal initiatives in drug or other development—if they in fact were to encroach on activities more appropriately left to industry or venture capital—could disrupt or distort vital market signals that private firms use to manage their own investment and development. Although, here again, we note that

the recent and sudden curtailing of federal commitments to medical research, including clinical trials and small business innovation awards, also disrupt business plans and investors’ expectations; our point is that the hypothetical concerns implicit in the notice would, if realized, only compound actual harms that the government has already unilaterally inflicted.

In any event, complementary and precompetitive research engender inherent risks for some overlap with industry or other sector activities, and the issue of avoiding potential duplication or competition is fundamentally one of managing this risk. NIH and NCATS could help avoid or manage risk through effective communication among all sectors involved in this research, and by providing to the best extent possible for transparency in the agency’s rigorous processes for merit review, priority setting, and decision making. Our recommendations for reducing the potential for redundancy are as follows:

1. Involve broad public input from across industry, academia, voluntary health organizations, patient advocates, and philanthropic foundations in the NCATS advisory process. Diverse input would help inform and guide decisions and priority setting, and increase the likelihood that potentially overlapping projects would be identified. Broad input would allow for diversity of views and better reliability of information, and also would help avoid the risk of research being captured by more narrow interests. The current composition of the Cures Acceleration Network (CAN) board and NCATS’ advisory council already includes a breadth of such perspectives.

2. Continue to provide for rigorous peer/merit review, priority setting, and decision making process, and maintain transparency in this process.

3. NCATS should consult closely with other NIH institutes and centers that have a history of working in industry collaborations and on platform technologies, including the institutes for Cancer, Human Genome, Biomedical Imaging and Bioengineering, the Intramural Program, among many. NCATS should also seek advice from other federal agencies, including DARPA (Defense Advanced Research Projects Agency, a model for CAN) and the National Science Foundation. Among other experience, DARPA and the NSF for example successfully managed initial expansion of the Internet until it could be transferred to private providers.

4. NIH and NCATS should continue to focus intently on research in areas that address important public health priorities and in which private industry has historically under-invested. These areas include, for example, research addressing health disparities, underserved populations, and “orphan diseases”, among others. Such a focus also helps to mitigate potential redundancy with industry, although we hope at the same time that advances in these areas will encourage private firms to reconsider potential business models that do serve these populations.

5. NCATS’ programs in training and workforce development, such as through the Clinical and Translational Science Awards consortia, exemplify activities that complement and enable research across many sectors, and should remain a vital part of the Center’s portfolio.

6. It is likely that in the course of successful NCATS initiatives, research projects that originally had not posed concerns for overlap with industry may reach a point where they should be transferred to the private sector. This could happen for example, with certain proof of concept research. NIH and NCATS should evaluate the agency’s already remarkable capacity for tech transfer and licensing to ensure that it is
adequately supported, and is innovative and flexible in handling new arrangements. The NIH already has extensive experience relative to all federal agencies in its tech transfer capacity, as do many academic institutions.

In closing, we note that in the biological sciences discoveries from fundamental science can, when fortune permits, lead almost immediately and directly to new applications. Similarly, knowledge generated in the clinic or in commercial R&D can also generate immediate revelations for treatment or new applications (for example, the development of antibiotic therapy for peptic ulcers originated from clinical observations). The immediacy of fundamental biological research with potential application has been referred to as Pasteur’s quadrant, reminiscent of the scientist whose career notably embraced basic research and application to such an extent that he himself disdained any distinctions between them. If anything, this effect is amplified in contemporary biotechnology research. If such “eureka moments” occur in the course of NCATS or any other NIH sponsored research, we should be careful not to retrospectively judge whether that research was inappropriately competitive with any other sector, but should move prospectively in the best way to apply the invention.

AAMC is willing to provide additional input that would be helpful to NCATS in developing its recommendations. For assistance or more information, please contact Heather Pierce, Senior Director for Science Policy and Regulatory Counsel, (hpierce@aamc.org; 202-478-9926) or Stephen Heinig, Director, Science Policy (sheinig@aamc.org; 202-828-0488).

Sincerely,

Ann C. Bonham, Ph.D.
Chief Scientific Officer