#### Dean's Newsletter

### **Special Edition**

February 23, 2009

## Important and Evolving Events Related to the NIH and Biomedical Research

I am sending this special newsletter to update you on some of the changes unfolding at the NIH as a result of President Barack Obama's signing the American Recovery and Reinvestment Act of 2009 (ARRA) into law on February 17, 2009. I know you have heard much about the economic stimulus over the past days and weeks, but there are notable impacts on the NIH that I want to call to your attention. The information we have at this point is still sketchy and over the next weeks I will amplify it as plans become codified in Bethesda.

As you also know the NIH budget has been flat (and below inflation) for the past six years, since the NIH doubling was completed in 2003. During the past several years we and many others have been working diligently to restore the NIH budget – one of our nation's most important investments. And while the news has been mostly gloomy, that has changed dramatically in the past week. As a result of the ARRA the NIH will receive \$10.4 billion – that must be spent by September 2010. The magnitude of the NIH investment is a result of the incredible advocacy and support of Senator Arlen Specter (R-PA) who has been an extraordinary proponent of biomedical research. Senator Specter teamed with Senator Tom Harkin (D-IO) to achieve this level of funding. We are also grateful to the enduring support of Congresswomen Nancy Pelosi (D-CA) and Anna Eshoo (D-CA). While we all recognize that this is an enormous investment and although we might have wished that it could be spent over several years rather than over the next 19 months, it is clear that the Congress sees biomedical research as an area that could help spark the economic recovery through the preservation and creation of new jobs, as well as the impact of science and technology on improving health and innovation at the local and national level.

Of course the immediate question is how this money will be allocated and spent so as to assure that the investment is wise and successful. This has been a topic of intense discussion during the past days and I want to give you an update on what we have learned to date. My information comes from a meeting this past week with the Administrative Board of the Council of Deans of the Association of American Medical Colleges (AAMC) in DC and a conference call led by Dr. Raynard Kington, Acting Director of the NIH. Here's what we have learned to date:

#### **General Issues**

• The \$10.4 billion for the NIH must be spent by September 2010. This must be viewed as part of the economic stimulus and there should be no expectation that this will reset the base budget of the NIH. Simply put, for FY11 the NIH allocation may be at the same level it is now. That said, it is certainly plausible

- that if the use of these funds is successful and wisely spent, that continued support for the NIH will be in the offing but this is not guaranteed.
- This funding cannot be viewed as "business as usual." Because funding (except for construction) cannot be carried over beyond September 2010, the NIH will only award it to projects that can be completed during this very tight timeline. And they will focus particularly on whether the funding will preserve or create jobs.
- There will be intense reporting requirements unlike anything we have had to do to date. Specifically, it is likely that recipients of ARRA funding (whether institutions or individuals) will be required to provide on line updates to a publicly searchable website Recovery.gov, as well as to the NIH. We were told that this will be at the level of the investigator and that an exquisite level of transparency is expected. Obviously, failure to spend the funds on the proscribed timelines will be a source of embarrassment (at least) for the individual and the institution.
- Accordingly, Dr. Kington was clear that individual and institutions should only apply for funding if they are sure that they will spend it.
- Continued efforts to support new investigators will continue and there may be support for post-doctoral fellows in recognition of the tight job market at this time. However it is not currently expected that training grants will be a priority.

#### Current allocations and expectations for spending the \$10.4 billion.

Dr. Kington was clear that the information he was sharing was subject to final approval by the Executive Branch – but that this was roughly how things are lining up.

#### • Support for construction and infrastructure

- \$1 billion is allocated for renovation, alternation and construction in the extramural program. As you know, there have been few to no construction dollars in recent years, so this is a major investment in the aging laboratories and facilities at universities, institutes and academic centers.
  - Of note is that construction funds can be spent over 5 years which is the only exception to the completion of spending by September 2010
- \$500 million is allocated for NIH facility renovation, repair and construction (in Bethesda or other NIH sites)
- \$300 million is for shared instrumentation and other capital equipment. This will be done through NCRR.
  - One important note is that the NIH and NCRR will likely suspend the usual rules for "institutional matching" for shared instrumentation – which is additional good news in light of the negative economic impact on most every university and research institution.

#### • Support for science and research

- \$8.2 billion is for science and research of which \$7.4 billion will go to the Institutes, Centers and Common Fund on a percentage formula and \$800 million will go the Office of the Director (in addition to the Common Fund noted above) to further support research activities that can be completed in two years and that create alignment to further foster the goals of ARRA.
  - According to Dr. Kington, Institutes and Centers will set their own priorities on how this money is spent – but each will be responsible for assuring that it is high priority science that can be completed prior to September 2010.
- O In addition, \$400 million will be transferred from the Agency for Healthcare Research and Quality (AHRQ) to fund research in health quality, effectiveness and outcomes. This will complement separate allocations to AHRQ and to the Office of the Secretary of HHS for health quality and outcomes research. Clearly the magnitude of this funding is way beyond what has occurred historically and is evidence of the Administration's intent to further impact health care reform through research on quality and effectiveness.
- *Mechanisms for funding*. At this point several mechanisms are planned and others will unfold
  - Funding of "recently peer reviewed, highly meritorious R01 and similar mechanisms capable of making significant advances in two years."
  - o NIH will also consider funding new R01 applications that have a reasonable expectation of making progress in two years.
    - Dr. Kington was specific in noting that certain types of research would not likely fulfill these criteria – specifically clinical trials that ordinarily require much longer time-lines for completion.
  - Targeted supplements to current grants will also be pursued (which can include equipment and infrastructure support) as well as "competitive supplements" where a new direction is proposed to an existing grant as long as the project can be completed in two years and is deemed a high priority.
  - o The NIH Challenge Grant Program. The details are being worked out and will likely have Institute/Center specificity and are expected to support novel projects that advance science and health and that are deemed a high priority and can be completed in the two-year time frame. Currently it is anticipated that these will be \$1 million (over two years) and that NIH may allocate between \$100-200 million to this new challenge grant program.

# What We Are Doing to Prepare for the ARRA and Increased NIH Support

Clearly the first priority is to make sure you are informed about what is going on since it is clear that decisions will be made very rapidly. With that in mind, I am putting together a School-wide planning effort that engages our Institutes and Centers and related

programs that map to NIH Institutes and Centers. Each area will have a planning group and we will use our Office of Institutional Planning to help create alignments and communication mechanisms to faculty. I am also exploring ways to delegate support from our Office of Medical Development, Communications and Planning so that we can assist faculty with proposals for science and infrastructure support. I will have more to say about this in coming days and weeks. I did want to share the information we have now and to underscore that this is a unique and special opportunity and we certainly want to do all we can to benefit our school, community and the nation.

It also bears underscoring that we will need to coordinate efforts – especially around submissions for equipment and infrastructure support. And we will need to be creative in fostering new public-private partnerships to further support our efforts – especially beyond the two years of NIH support. This is a unique time in so many ways – and we are now faced with a remarkable opportunity. We will do all we can to help make this opportunity as successful as can be – but ultimately that success rests on our faculty, whose efforts we want to support as best we can.