DUKE UNIVERSITY MEDICAL CENTER

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Statement to the Senate Health, Education, Labor and Pensions Committee on Medical Innovation

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Thank you for the introduction Senator Burr and good morning Chairman Alexander, Ranking Member Murray and other Committee Members. I would like to thank you for the opportunity to share with this Committee my perspective as an academic biomedical researcher working on the front lines of medical innovation. In addition to being an innovator and entrepreneur, I help other faculty at Duke University apply their medical innovations to human health in my role as Director of the Duke Translational Research Institute. This Institute provides preclinical and early stage clinical trial seed funding and project management support to build collaborative, translational research teams (https://www.dtmi.duke.edu/about-us/organization/duke-translational-research-institute/pilot-program/leadership).

I was trained as a basic scientist in one of the pre-eminent biochemistry laboratories in the world, Dr. Cech's lab at the University of Colorado with a goal of pursuing knowledge for the sake of knowledge. However in 1994, I a sought a new scientific path and focused on what came to be known as "translational research". I joined the faculty in the Department of Surgery at Duke so I could work closely with physicians and surgeons to develop new approaches to effectively and safely treat the patients they saw every day. During the past two decades, this unorthodox career path has been enormously rewarding. Unfortunately, it has also has become increasingly challenging.

With cardiologists, cardiothoracic surgeons and neurosurgeons, we invented new ways to deliver reversible anticoagulants for the potential treatment of cardiovascular disease and stroke patients. I also worked with surgical and medical oncologists to develop new classes of compounds that precisely deliver cytotoxic and immune-modulatory medicines to prostate, pancreatic and other types of cancer cells. Most recently working with rheumatologists we invented a novel anti-inflammatory drug for the treatment of lupus, arthritis and other chronic inflammatory disorders without serious side effects.

We have been busy but there is so much more we could be doing. Creativity and ingenuity is not in short supply. What is preventing these ideas from becoming realities are ever dwindling resources. All of the preclinical work leading to the medical innovations I described was possible because of funding by the NIH and its associated Institutes. With a 20% decline in the purchasing powers of the NIH budget over the past decade, it has become increasingly challenging to create a path to move these inventions from the bench top to the clinic. And moving these inventions from an academic setting to the private sector has become even more challenging and rate limiting. It is extremely difficult to obtain investments from the private sector for IND (Investigational New Drug) enabling work such as compound

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optimization, preclinical pharmacology and toxicology studies and manufacturing. I applaud the NIH and Congress for recognizing this translational bottleneck and for establishing the Clinical and Translational Science Award (CTSA) program and the National Center for Advancing Translational Sciences (NCATS) to begin to address this critical issue. In addition, the NHLBI, NCI and other institutes at the NIH have established some programs such as the NHLBI national network of Translational Research Centers for Thrombotic and Hemostatic Disorders that supports the translation of basic sciences into clinical applications. These new initiatives are critical for our success and will be essential if the United States is to remain the international leader in medical innovation.

Finally, precision medicine- the future of medicine- is a major challenge to all of us who translate basic research into health care. This new frontier in medicine combines the information age with personalized genomics to collect unparalleled intelligence as to what makes us sick and what therapies can be tailored to each of us. To meet these challenges- and opportunities- head on, we will need to reposition and train a new generation of the biomedical researchers. This next generation will look very different form the one we have today: Engineers, physicians, mathematicians, and biologists will need to come together to effectively combat disease, disability, aging and death.

To prepare for the coming challenges, I would encourage this Senate Committee to work with the NIH, FDA, academic community and private sector to consider four tractable issues:

1.) How to train and expand a biomedical research workforce that is ready to utilize and act upon the genomic and informatics revolution;
2.) How to rebalance and right size support for all phases of biomedical research as we transition from gathering intelligence on health and disease (basic research) to rationally using the large amounts of information to combat disease (translational and clinical research);
3.) How to reduce the administrative and compliance burdens placed upon investigators and academic institutions to reduce costs and improve productivity; and
4.) How to further encourage academic institutions to more effectively engage with the private sector and clarify the NIH conflict of interest policy to facilitate such endeavors without restricting innovation.

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Some references regarding these considerations.

1.) How training should be expanded to create a biomedical research workforce that is ready to utilize and act upon this emerging information;

References describing strategies to revise the training of the biomedical work force and how team science will be important for translational medicine.

https://www.aau.edu/WorkArea/DownloadAsset.aspx?id=15491

http://www.hhmi.org/programs/med-into-grad-initiative

https://www.dtmi.duke.edu/about-us/organization/duke-translational-research-institute/pilot-program/leadership

http://www.pnas.org/content/111/16/5773

2.) How to rebalance and right size support for all phases of biomedical research as we transition from gathering intelligence on health and disease (basic research) and move toward rationally applying the large amounts of information being amassed to combat disease (translational and clinical research);

Breakdown in basic versus applied funding from the NINDS: http://blog.ninds.nih.gov/2014/03/27/back-to-basics/

3.) How to reduce the administrative and grant writing burden upon translational investigators and academic institutions to reduce costs and improve productivity; and

Link to DTRI Project Management and Consultation Office which offers professions trained in the private sector to act as faculty extenders and facilitate translational team builders.

https://www.dtmi.duke.edu/research-facilities-and-support/duke-translational-research-institute-dtri/project-management

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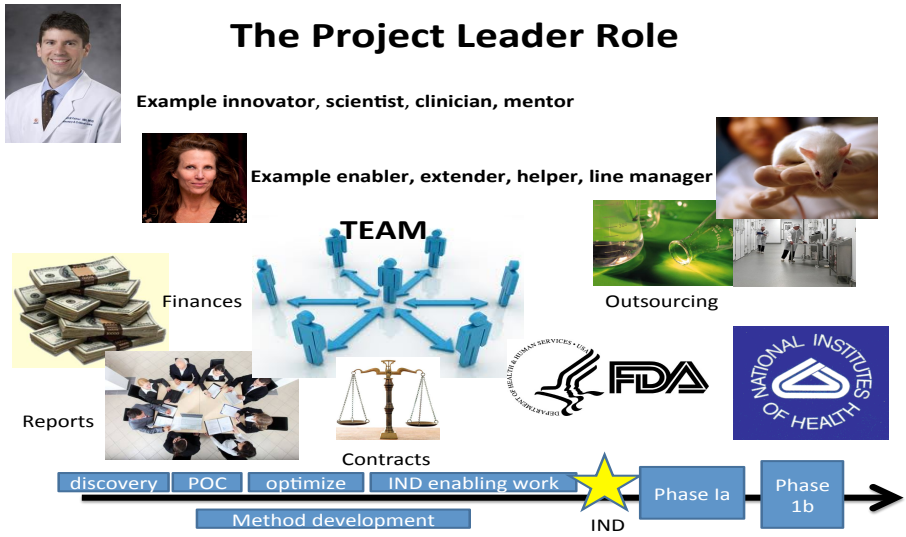

4.) How to further encourage academic institutions to more effectively engage with the private sector and clarify the NIH conflict of interest (COI) policy to facilitate such endeavors without restricting innovation.

Links to NIH COI policy and the Duke's approach to complying with the policy

http://grants.nih.gov/archive/grants/policy/coi/tutorial/fcoi.htm

http://duke.edu/services/ethicscompliance/coi/fcoi/index.php

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