

**PREPARED STATEMENT OF BRUCE TROMBERG, PH.D.
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Ms. Chairwoman and Members of the Subcommittee: I am pleased to provide this statement highlighting the excellent programs of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) of the National Institutes of Health (NIH).

The mission of NIBIB is to improve human health by leading the development of biomedical technologies and accelerating their application. NIBIB supports research that integrates engineering with the physical and life sciences to develop new technologies that can be applied to a broad range of biomedical and health care problems. Building partnerships with industry, academia, and other federal agencies is a high priority for the institute. A few examples from the many exciting NIBIB-funded research efforts that are leading to better, faster, and less costly ways to advance public health are shared in this testimony.

ON THE SPOT FOOD ALLERGY TESTING

Eating out can be a challenge for people with allergies. Diners must rely on knowing what ingredients contain the allergens they must avoid, and on restaurants to serve dishes that exclude them. Recognizing this widespread public health problem, researchers have developed a system called integrated exogenous antigen testing (iEAT). The purpose of the iEAT system is to give those who suffer from food allergies a rapid, accurate device that allows them to personally test foods in less than 10 minutes. The device is small enough to fit on a keychain and can test for common allergens such as gluten, milk, or nuts. The device contains a disposable testing chamber, so once a test is completed the chamber can be replaced and the device used again. After developing and testing a prototype of the device, the research team

granted a license to a local start-up company to make iEAT commercially available. In the future the device could be adapted to test for other allergens or substances.

FOCUSED ULTRASOUND FOR SURGERY

Using a new ultrasound technique, researchers have developed an entirely non-invasive toll for brain surgery. This new approach uses targeted sound waves to manipulate the brain without opening the skull. This technique offers the potential to treat essential tremors—a symptom of Parkinson’s disease--and other movements disorders. Other applications include opening the blood brain barrier without damaging tissue to allow medications used to treat brain tumors or other neurological diseases to enter the brain.

CLEARING OUT BLOOD CLOTS

A blood clot that forms in the deep veins of the legs is called deep vein thrombosis and can be quite painful, and even fatal if a clot dislodges from the wall of the vein and travels to the heart or lungs. Currently, intravascular treatments use devices inserted into the vein to trap clots, but they have limitations including damage to the blood vessel wall. In some patients, clot thinning medication is required, which can have a range of side effects. A new approach to overcome these limitations uses a surgical tool that is inserted into a vein and directs ultrasound waves directly at clots to break them up into tiny pieces. It is targeted and therefore minimizes damage to blood vessels; and because the broken pieces are tiny, patients do not need to use blood thinning medication following the procedure. In addition to using ultrasound, researchers are adding injectable microbubbles that vibrate when exposed to the ultrasound waves. This helps to further break up the clot. This tool is portable and is estimated to cut the declotting

procedure time by more than half, from 10 hours to four hours. So far, the tool has only been tested in synthetic blood vessels, and more study is needed to bring this treatment to patients.

NANOVACCINES WEAPONIZED TO BATTLE TUMORS

A new vaccine designed to stimulate a multi-pronged immune response can stimulate the immune system to specifically attack a tumor, while simultaneously inhibiting the suppression of the immune system, which often occurs in people with cancer. The researchers also developed a way to shrink the vaccine molecule so that it can more easily reach the parts of the immune system to activate it. Using colon cancer that had spread to the lungs as a test case for this approach, the nanovaccine successfully blocked lung tumor growth in a mouse model. Further testing revealed that mice receiving the nanovaccine had a significant increase in a type of immune cell that can target cancerous cells. Another potential benefit of this approach is that it mounts an anti-tumor immune response that circulates through the system, and therefore is particularly valuable for finding and inhibiting metastatic tumors growing throughout the body.

SOLVING A COMMON HEART DISEASE WITH ENGINEERING

Ischemic cardiovascular disease is a result of impaired blood circulation to tissues and organs and is the leading cause of death and disability in the U.S. Damage to small blood vessels is difficult to treat and can result in heart failure, stroke, or other arterial diseases. To address this problem, researchers developed a way to grow new blood vessels using 3D printed patches. The specially designed patches are seeded with cells and implanted into damaged areas. Once implanted, the patches induced the growth of new blood vessels. This early stage, basic research

is an example of interdisciplinary teams including engineers, biologists, and clinicians combining their expertise and collaborating to solve health problems.

ADVANCES FROM NIBIB LABORATORIES

NIBIB's growing Intramural Research Program (IRP) supports a range of discovery including investigators working to create optical imaging technologies that provide unprecedented high resolution and speed to study living cells in real time. Others create "theranostic" imaging probes—based on nanomaterials—that combine therapeutic and diagnostic capabilities to improve early diagnosis, monitor therapeutic responses, and guide drug discovery and development.

In one example, researchers developed a new radiotracer to help diagnose prostate cancer. Prostate cancer is the fifth leading cause of death worldwide and is especially difficult to diagnose, particularly early on. While prostate cancer is relatively easy to treat in its initial stages, it is prone to metastasis and can quickly become deadly. The research team developed a radiotracer that could identify prostate cancer at all stages. This new tracer is one of the first dual-receptor target tracers, which target more than one biomarker, to be studied in humans. This new method improves on the current practice that can lead to many false positive results and cause the patient to undergo unnecessary treatments or painful biopsies. A successful Phase I clinical trial with a small group of patients to establish safety and identify any possible side effects was recently completed.

CONCLUSION

Advances in technology are catalyzing the development of solutions to

previously intractable disorders and improved approaches to biomedical research. As these examples illustrate, this type of research requires many disciplines to work together. This integration of disciplines is what defines NIBIB's approach. NIBIB is Engineering the Future of Health to solve major biomedical challenges that will improve the health of all Americans.