

**STATEMENT OF DR. DAVID SHULKIN
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DEPARTMENT OF VETERANS AFFAIRS (VA)
BEFORE THE
HOUSE COMMITTEE ON VETERANS' AFFAIRS**

FEBRUARY 3, 2016

Good morning, Chairman Miller, Ranking Member Brown, and Members of the Committee. Thank you for the opportunity to discuss the Technology Transfer Program at the Department of Veterans Affairs (VA). I am accompanied today by Dr. Kyong-Mi Chang, Acting Chief Research and Development Officer, and Dr. Marisue Cody, Director of Research Operations.

VA's Technology Transfer Program is housed within the Office of Research and Development, through which VA conducts a robust research program whose fundamental mission is to advance the healthcare of Veterans. VA research supports over 2,000 research projects at over 100 VA medical centers (VAMC) throughout the country, with an FY2016 direct appropriation of over \$620 million. The VA research program is further enhanced by private and federal grants awarded to VA researchers, meaning total resources available for VA researchers will exceed \$1.8 billion this year. VA research projects focus on VA-relevant biomedical laboratory, clinical, rehabilitation, and health services research through four research services, a Cooperative Studies Program for large clinical trials, and a quality improvement program that uses research evidence to improve clinical care. For over 90 years, VA research has worked to improve the lives of Veterans: performing the first successful liver transplants; developing high-performance prosthetic devices; establishing the value of aspirin therapy in improving heart health; showing the effectiveness of the Shingles vaccine; and developing the nicotine patch.

Established in 2000, VA's Technology Transfer Program reflects our research focus on the Veteran, ensuring that products and innovations created by VA researchers are accessible to all Veterans. Prior to the establishment of the Technology Transfer

Program, VA had no policy on intellectual property rights, and generally waived ownership rights to inventions, tasking the inventor and usually the academic partner with patenting, marketing, and licensing responsibilities.

The Technology Transfer Program has three main areas of focus: 1) protecting and commercializing of intellectual property; 2) facilitating technology transfer and cooperative research and development activities among academic partners, local VAMCs, and industry; and 3) educating researchers within VA about their rights and obligations regarding intellectual property management and cooperative research activities. Technology Transfer within VA involves multiple integral individuals and entities nationwide, including researchers within VAMCs, the Office of General Counsel, academic affiliates, Nonprofit Corporations, and commercial partners.

Enabling greater cooperation with academic and private institutions is one fundamental goal of the Technology Transfer Program. To support this, the program executes over 1000 new Cooperative Research and Development Agreements per year, most are for clinical studies, and these agreements represent over \$35 million in sponsored research dollars available to VA research centers.

The Technology Transfer Program's public mission requires aggressive dissemination of educational information to researchers, and of products to the market. It is also necessary that VA asserts an ownership interest in disclosed inventions whenever appropriate, so that discovery can be built upon. This ensures Veterans have access to these technologies. Often, as opposed to patenting inventions and delaying their availability in the public domain, the Technology Transfer Program works to ensure Veterans have immediate access to these technologies by releasing them publicly.

The Technology Transfer Program has had several recent successes, particularly in areas that are highly specialized. The program is crucial to the dissemination of products that are of limited commercial value to private institutions but can greatly improve Veterans' quality of life. This has included the development of several kinds of

prosthetic feet, such as a foot that allows Veterans with lower leg amputation to easily change shoes without experiencing balance issues (allowing, for example, easier wearing of high heels or cowboy boots). This is an important quality of life issue for Veterans with lower limb amputation, but is not particularly commercially valuable, and would likely not be available to Veterans without the Technology Transfer Program. Other examples include products that make it easier for Veterans to use wheelchairs, or prevent common injuries (pressure ulcer, carpal tunnel syndrome) related to use of wheelchairs.

Every year, VA researchers develop dozens of new health care-related technologies and other inventions that benefit VA's patients, other Veterans, and all Americans.

Unlike other Federal agencies, VA has no laboratories whose predominant function is research. VA includes research as part of the mission of each VAMC, although the primary mission of a VAMC is patient care for Veterans. In fact, the majority of VA researchers are active clinicians. This leads to a focus on research areas most likely to benefit Veterans. VA's research mission is entirely intramural. VA does not have authority to award grants to parties outside VA and all VA research funding is provided to VA-employed researchers.

Researchers work at more than 100 VAMCs conducting research. In addition, 124 VAMCs have formal affiliations with academic institutions and hospitals, and many full- and part-time VA employees also have academic appointments or are employed at an affiliated academic institution or hospital – they are dually appointed personnel. Many clinicians/researchers have laboratory access at both VA and the academic affiliate. Because of these arrangements, most VA inventions are jointly owned by VA and its academic affiliates, making technology transfer a collaborative effort. To better facilitate efficient technology transfer, the Technology Transfer Program has executed Cooperative Technology Administration Agreements on VA's behalf with many academic affiliates, allowing the affiliates to take the lead in the management of the co-owned inventions, while maintaining VA's joint ownership. This arrangement is

particularly beneficial to VA, as affiliates are typically better positioned to manage these co-owned inventions, having greater flexibility with licensing terms and greater access to private sector partners.

VA research relies on researchers self-reporting invention disclosures, and this process is very similar to the one used by our academic partners. Without proper filing of invention disclosures, VA is unable to review and appropriately make a determination of rights. Any suspicion of wrongdoing or evidence of impropriety in this or any other VHA program has, and will be, referred to the Office of the Inspector General.

Thank you for the opportunity to testify today and we look forward to your questions.