

# SVS advocacy efforts help spark landmark change in research effort requirements

BY EDITH TZENG, MD

The recent decision from the National Heart, Lung, and Blood Institute (NHLBI) to reduce the dedicated research effort from 75 to 50% for K awards is a landmark change and will have a tremendous impact on vascular surgeons.

## THE DECISION AFFECTS THE JUNE 2021

submission date and applies to vascular, cardiothoracic and trauma surgeons, as well as interventional.

The change is a result both of advocacy from the Society for Vascular Surgery (SVS), among other entities, and the resulting responsiveness from the National Institutes of Health to the surgical community and the National Cancer Institute, which had sought out information from the surgical community.

The National Institutes of Health (NIH) has a long tradition of supporting early-career physician researchers through the K08 and K23 Mentored Clinical Scientist Development Award mechanisms that fund protected time for intensive, mentored research. This pathway to independence has been adopted by clinician-scientists, but surgeon-scientists are reluctant to take advantage of these awards because of the requirement for a significant 75% dedicated research effort and a level of compensation that is not commensurate with the level of training and specialization of surgeon-scientists.

Surgical specialists, such as vascular surgeons, have significant clinical demands and highly developed technical skills that make this level of time commitment unrealistic. The limited salary support offered by K08 and K23 awards for 75% of dedicated effort results in a financial burden on the surgical departments and divisions supporting these early-career faculty. Thus, many institutions are often not able or are unwilling to support that level of effort, especially in the current state of medical economics.

The SVS has been a longstanding advocate for developing vascular surgeon-scientists. To offset the financial burden of supporting young vascular surgeon-scientists, the SVS Foundation in 1999 created a supplemental award that provides additional funds to select K08 and K23 awardees to offset research costs. These SVS Foundation awards, in part co-sponsored by the American College of Surgeons, have supported 39 vascular surgeon-scientists to date and yielded a nearly eight-fold return on

investments in the form of independent national funding.

Despite the great success of this program, there were years where only a single K08 or K23 application was submitted to the NIH. This problem is not unique to the vascular surgery community, with similarly low numbers of K08/K23 applications by other surgical specialties.

In response to these concerns, the National Cancer Institute (NCI) issued a Request for Information (RFI, NOT-CA-21-027) in January 2021 to invite comments and suggestions in regard to the surgeon-scientist effort requirement for K08 awards. The SVS responded that these awards are a missed opportunity in the career development of vascular surgeon-scientists due to the 75% effort requirement. It has been roundly agreed within the surgical community that 50% effort is sufficient time commitment for active surgeon-scientists to succeed in research and for career development. In the SVS response, we highlighted that the 75% effort requirement was a deterrent for young surgeons to pursue research-intensive careers because they do not want to sacrifice that much of their clinical time, with patient care the driving motivation behind both their career path and desire to conduct research.

This effort requirement reduces clinical productivity and results in lower financial compensation for surgeon-scientists compared to their peers. As a result, fewer

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surgeons are pursuing research-intensive careers. Regardless of the level of specialized skills and clinical commitment, all surgical specialties have been impacted with a progressive decline in the number of surgeon-scientists applying for K awards. While the RFI was issued by the NCI, we indicated that all NIH institutes should consider

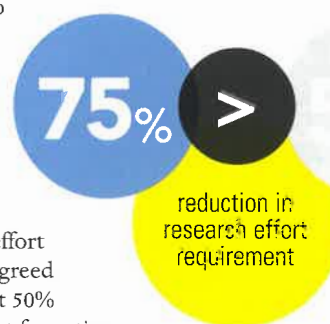
reducing the effort requirement for K awards and this should apply to all surgeons.

In response to an overwhelming response to the Request for Information, the NCI announced that it will allow the reduction in research effort for surgeon-scientists applying for K08 awards to 50%. On March 22, the NHLBI announced that, as of the June 2021 submission date, vascular, cardiothoracic and trauma surgeons, as well as interventional cardiologists, will also be able to reduce research effort to 50% for K08 and K23 applications. This is a landmark change and highlights the responsiveness of the NIH to the needs of the surgical community.

Unfortunately, this change does not appear to be NIH-wide, with other institutes with high levels of surgical investigators, such as National Institute of General Medical Studies (NIGMS), not yet adopting the reduced effort requirement. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) allows only urologic surgeons to request 50% effort. We hope that the reduction in effort requirement for some surgeon-scientists at NCI and NHLBI will be adopted by all NIH institutes and will broadly apply to all surgical specialties.

This reduction in K award effort requirements by NHLBI will have a tremendous impact on vascular surgeons. It is now the time to act and for departments of surgery and divisions of vascular surgery to support our early-career faculty by encouraging them to apply for these awards. We strongly voiced that this change would be pivotal in the training of vascular surgeon-scientists—now we must show the NIH that it is. Finally, we must continue to advocate for uniform application of reduced effort requirements at all institutes and for all surgeon-scientists.

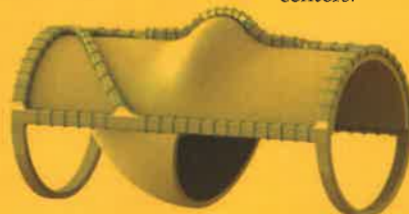
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## VenoValve: Chronic venous insufficiency device gains brisk double of first US patent, IDE approval

BY BRYAN KAY AND JOCELYN HUDSON

Hancock Jaffe Laboratories recently revealed that the United States Patent and Trademark Office (USPTO) issued the first patent covering the company's VenoValve. The patent is entitled Implantable Vein Frame and is U.S. patent number 10,959,841.



THE COMPANY RECENTLY announced that only 28 days after filing, the Food and Drug Administration (FDA) approved the company's Investigational Device Exemption (IDE) application to begin the U.S. pivotal trial for the VenoValve. Known as the SAVVE study, the trial is a prospective, non-blinded, single-arm, multicenter study of 75 chronic venous insufficiency (CVI) patients to be enrolled at up to 20 U.S. centers.

"We will continue to work with agencies like the FDA and USPTO, and other regulatory authorities throughout the world towards our ultimate goal of reaching the millions

of patients suffering from CVI", said Hancock Jaffe CEO, Robert Berman. "We believe that the VenoValve will set a new standard of care for CVI patients and will establish Hancock Jaffe as a leading provider of innovative medical devices for peripheral vascular disease".

Leading hospitals and top vascular surgeons throughout the U.S. have expressed interest in participating in the SAVVE study. The company has begun the process of fulfilling conditions for study initiation outlined by the FDA and seeking Institutional Review Board (IRB) and other necessary approvals from potential SAVVE sites. The company expects to begin patient enrollment in the third quarter of 2021 and will provide periodic updates.