How Creative FDA Regulation Led to First-in-the-World Approval of a Cutting-Edge Heart Valve

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— Jeffrey Shuren, M.D., J.D., Director of FDA's Center for Devices and Radiological Health

Nearly six years ago FDA approved an artificial transcatheter heart valve (THV) to treat patients having severe symptoms and life-threatening heart problems such as fainting, chest pain, heart failure, irregular heart rhythms, or cardiac arrest, because one of the valves in their heart (the aortic valve) was no longer working properly and they were too sick for surgery.

Transcatheter aortic valve replacement (TAVR) has revolutionized the treatment of these patients. But the U.S. wasn't the trendsetter – in fact, it was the 42nd country to approve the first TAVR device, the Edwards Sapien THV.

Since that approval, FDA has sharpened its focus on patient access to innovative medical devices. On June 5th, 2017, FDA became the first regulatory body in the world to approve the most recent iteration of the Sapien valve, the Sapien 3, to treat high-risk patients whose surgically-placed aortic or mitral bioprosthetic valves were old and worn out. The Sapien 3 is intended to slip into these valves using a so-called "valve-in-valve" option, a procedure that can be done without open heart surgery through a patient's blood vessel or a small cut in the chest.

— SAPIEN 3 Heart Valve Device

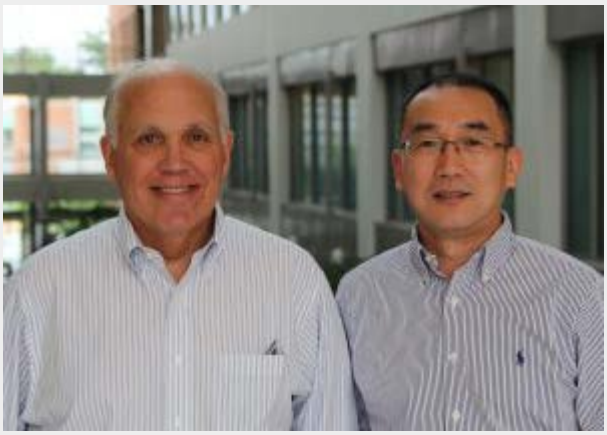
To narrow the gap from 42nd to first required creativity and commitment. The FDA Heart Valve Review Team first streamlined FDA's expectations for nonclinical testing – something that had been a huge rate-limiting factor for translating innovative TAVR devices from bench to bedside. We became more consistent, predictable, and transparent about our expectations, which helped significantly reduce the total time to initiating clinical studies. And we worked closely with the industry on creative clinical trial designs and the use of other sources of clinical evidence that could demonstrate that the device is safe and effective when used in the intended patient population.

— Bram Zuckerman, M.D., FDA's Director, Division of Cardiovascular Devices, Center for Devices and Radiological Health

This latest approval is the most recent example of our increasing use of real-world evidence, made possible in this case by the Transcatheter Valve Therapy (TVT) Registry, a partnership of the American College of Cardiology and the Society of Thoracic Surgeons. The TVT registry collects clinical data on the performance of transcatheter valve replacement procedures performed in the U.S. once a product goes to market – including both on-label and off-label uses – making it possible, under certain circumstances, to accumulate more data faster, without the need for costly and time-consuming formal clinical trials.

Some 100,000 patients have received TAVR since FDA's first approval in 2011, including more than 600 patients for what were then off-label, valve-in-valve uses. FDA relied on real-world evidence to evaluate the benefits and risks of this off-label use — such as the safety of the procedure, the function of the valve, and the improvement of patient symptoms – to approve the new indication for Sapien 3. This is a promising approach for the expansion of indications for other devices, provided robust registries are available. FDA is working to broaden and improve the opportunities to leverage real-world evidence for many types of devices through the establishment of the National Evaluation System for health Technology, or NEST,

which will integrate data from clinical registries, electronic health records, and medical billing claims to gather more comprehensive evidence of medical device safety and effectiveness.



— John C. Laschinger, M.D., Medical Officer, and Changfu Wu, Ph.D., Lead Reviewer, Members of FDA's Structural Heart Devices Branch

And we're not stopping here. U.S. medical device companies have long been accustomed to going overseas to conduct early feasibility studies (including first-in-human studies) for new heart valve devices, securing marketing authorization in other countries, and then returning to the U.S. for pivotal clinical trials before FDA approval. We're trying to break that model with a new program that encourages early feasibility studies for new medical devices in the United States. These studies allow for early clinical evaluation of devices to provide proof of principle and initial clinical safety data, and may be appropriate early in device development when clinical experience is necessary because nonclinical testing methods are not available or adequate to provide the information needed to advance the developmental process.

Many heart valve device companies have already responded. Rather than traveling to other countries, they're staying put in the U.S. for their early feasibility studies, saving on travel costs, enjoying more convenient communications with the investigators, and benefiting from early interactions with FDA.

These steps – along with our other reforms – will ensure that cutting-edge treatments get to U.S. patients as quickly as possible.

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