FROM PATENT TO PRODUCT: COMMERCIALIZING AN INNOVATION IN VASCULAR ACCESS FOR HEMODIALYSIS TREATMENT

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As End-Stage Renal Disease (ESRD) affects more than 500,000 patients every year and is currently increasing at a rate of 5-7%, the need for effective hemodialysis treatment remains an important issue in our society. Currently there are two vascular access devices widely accepted by the medical community, the arteriovenous graft (AVG) and arteriovenous fistula (AVF). Dr. Akingba's innovation, the modular anastomotic valve device (MAVD), would allow for selective shunting during hemodialysis treatment in turn increasing the patency by an expected six fold. The purpose of our research pertaining to this device was to assist Dr. Akingba in preparing the device for commercialization through an analysis of FDA regulations, licensing, technological considerations, and medical device competitors. With this is mind, preliminary research, bench top model, flow dynamic computer simulations, and key interviews were implemented as data sources. Research in hemodialysis techniques, flow dynamics, FDA approval process, and licensing considerations including the valuation of the intellectual property has provided us insight into the most effective pathway to bring the MAVD to market. As a result, a more direct licensing plan was developed for Dr. Akingba to streamline the commercialization process. With this research, Dr. Akingba will be able to obtain FDA clearance through animal testing and clinical trials. Once this device has been brought to market, it will shift preference in vascular access toward usage of the graft for hemodialysis with its increased patency and ultimately bring medical enhancements to patients, surgeons, hospitals, and the health-care industry in general.

References:

Akingba, Ajibola G. Modular Arterio-Venous Shunt Device and Methods for Establishing Hemodialytic Angioaccess. Indiana University Research and Technology Corporation (Indianapolis, IN), assignee. Patent 8057421 B2. 15 Nov. 2011. Print.