Editorial

The first paper in this issue of CVET by Aguel et al. from the Center of Devices and Radiological Health at the FDA, addresses a very important regulatory matter: the role of the FDA in protecting human health while ushering in the latest healthcare technological advances. Heart valve surgery in the United States is at a cross roads with the clinical trials of the first percutaneous heart valve prostheses, namely the Edwards Sapien and Medtronic Core valves, and the standards and regulations that should govern these technologies. Surgical heart valve prostheses were first used clinically in 1960 with the introduction of the Starr-Edwards ball and cage valve, and have been regulated by the FDA since 1976 as a Class III (high risk) medical device. Surgical heart valve prostheses over the past five decades have saved millions of lives worldwide, and are one of the major success stories in the medical device field.

Now, we are experiencing the advent of percutaneous heart valve technologies. These prosthetic heart valves may be implanted by minimally invasive techniques, negating the use of open heart surgical procedures. Therefore, percutaneous heart valves, initially to be used in very sick, inoperable patients, pose significant regulatory challenges for the FDA and the medical device industry, specifically the introduction of randomized clinical trials. The FDA is rising to the challenge by working in cooperation with industry and academia to develop international standards documents for minimally invasive heart valve technologies.

As an academic researcher who has worked on prosthetic heart valves since 1975, I am fascinated by the new breakthroughs in heart valve technologies. However, I feel very strongly that percutaneous valves should be introduced slowly to the general patient population, since their long term safety and performance are currently unknown. Off-label use of these devices by interventional cardiologists and cardiac surgeons would be a tragic mistake. Haste would make waste; exposing patients to unnecessary risks, who could otherwise successfully be treated with a surgical heart valve prosthesis.

The FDA is taking a thoughtful approach in how to balance two juxtapositions of its purpose: protecting human health while expediting the availability of life-saving technologies. I look forward to the future of heart valve surgery: one that is made more effective through the thorough investigation and timely patient introduction of advancements in devices and procedures.

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