Top Ten Things To Know

1. Mechanical circulatory support (MCS) has evolved to become an important therapy for patients who have advanced heart failure with the advent of more durable, implantable ventricular assist devices.

2. The regulatory oversight of these new technologies has been difficult owing to the complexities of these devices, associated adverse event profile, and severity of illness of the intended patient population.

3. Maintaining a regulatory environment to foster efficient introduction of safe and effective technologies is critical to the success of ventricular assist device therapy and the health of patients with advanced heart failure.

4. Physicians representing key surgical and cardiology societies, and representatives from the Food and Drug Administration (FDA), National Heart Lung Blood Institute, Centers for Medicare and Medicaid Services, Interagency Registry of Mechanically Assisted Circulatory Support, and industry partners gathered to discuss relevant issues regarding the current regulatory environment assessing ventricular assist devices.

5. The overarching goal of both the meeting and this document is to serve as a platform to launch next steps toward achieving a collaborative effort focused on bringing safe and effective MCS therapies to appropriate patients in an efficient, consistent, and economically responsible manner.

6. Five important areas of the regulatory process were examined for ways to improve predictability and efficiency of evaluation and assessments and standards of safety and efficacy.

7. These areas focused on the following:
   - innovative clinical trial designs;
   - the need for a new encompassing indication for therapy to facilitate device evaluation and reduce disparities in patient access;
   - assessing appropriateness of international standards for regulatory evaluation of MCS devices;
   - exploring methods for preclinical MCS device evaluation; and
   - development and regulatory oversight of MCS devices in the pediatric population.

8. The current regulatory evaluation of devices is lengthy owing to a number of critical factors, including lack of consensus on trial designs, meaningful outcomes for trials, and statistical methodologies to assess outcomes, lack of available and robust data to serve as comparator, multiple device indications, lack of uniform preclinical testing...
standards, and differing regulatory and reimbursement requirements.

9. The introduction of innovative methodologies to conduct the preclinical and clinical evaluation of MCS devices is necessary to foster an environment of device innovation and to improve assessments of safety and efficacy and efficiency of the regulatory process in the United States.

10. Professional societies may be uniquely positioned to provide a mechanism for bringing together a balanced group of experts (academic researchers and clinician leaders) who can engage with the FDA.

Reference:
http://circheartfailure.ahajournals.org/content/early/2012/11/12/HHF.0b013e318279f55d.full.pdf+html

ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: Full Text
http://circ.ahajournals.org/content/117/21/e350.full.pdf