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February 22, 2011

The Honorable Fred Upton  
Chair, Energy and Commerce Committee  
2125 Rayburn House Office Building  
Washington, D.C. 20515

Dear Chairman Upton,

The American College of Cardiology (ACC) is pleased to submit comments regarding the Energy and Commerce Committee hearing on the “Impact of Medical Device Regulation on Jobs and Patients.” The ACC is a professional medical society and teaching institution made up of 39,000 cardiovascular professionals from around the world – including 90 percent of practicing cardiologists in the United States and a growing number of registered nurses, clinical nurse specialists, nurse practitioners, physician assistants and clinical pharmacists.

On a daily basis, cardiovascular professionals rely on medical devices and pharmaceuticals approved by the Food and Drug Administration (FDA) to furnish high quality care to patients. The ACC is a strong supporter of innovations in care and treatments for cardiovascular conditions. The ACC understands the government must strike a balance between protecting the public health and encouraging creativity and scientific advancement.

The College has a strong commitment to evidence-based medicine, and this applies to approvals for medical devices as well. Science must be the foundation of all approved medical devices. Any changes to the medical device approval process must not stray from this fundamental principle. Medical devices unsupported by scientific evidence should not be approved, and the approval process must protect against that. The ACC urges the FDA to ensure that any changes to the approval process are supported by science and that any decisions made through the approval process will also be required to be supported by science. Transparency is also critical to this process.

*The mission of the American College of Cardiology is to advocate for quality cardiovascular care — through education, research promotion, development and application of standards and guidelines — and to influence health care policy.*

The ACC encourages the FDA to ensure that the medical device approval process is clear and predictable and that the path for navigating it is publicly available and easily understood. This will allow medical device manufacturers to understand their objectives in the early stages of product development. It will also prevent delays in the approval process that create additional work for both the FDA and industry when requirements are misunderstood, causing the submission of incomplete applications. Ultimately, unnecessary resource usage is minimized when all parties understand initially what is expected of them, benefiting all concerned.

The College is willing to work with FDA on post-market surveillance of cardiovascular products. Through clinical data registries, such as the ACC's National Cardiovascular Data Registry (NCDR®), patient outcomes can be tracked and provide critical information on device effectiveness and safety. The ACC NCDR includes several registries that focus on common cardiovascular diseases and interventions, including diagnostic cardiac catheterizations and percutaneous coronary interventions, ICD implantations, carotid artery stenting and endarterectomy and in addition congenital heart disease interventional procedures. The ACC also appreciate FDA's support in developing the data set definitions for an atrial fibrillation ablation registry.

Overall, the ACC supports efforts by the FDA to find the appropriate balance between fostering innovation and ingenuity and protecting the public health and patient safety. Changes to current processes must strive to maintain innovation in the United States and not inadvertently drive device related research and development offshore. In order to carry out this important work and ensure that cardiovascular patients benefit from needed technology, innovation, and health care improvements, the ACC urges Congress to provide adequate funding to the FDA.

The College looks forward to working with Congress and the FDA on this and other related issues.

Sincerely,

A handwritten signature in blue ink that reads "Ralph Brindis". The signature is written in a cursive, flowing style.

Ralph G. Brindis, MD, MPH, FACC  
President, American College of Cardiology