



Helping Cardiovascular Professionals  
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May 7, 2012

Chairman Fred Upton  
Energy and Commerce Committee  
2125 Rayburn  
Washington, DC 20515

Ranking Member Henry Waxman  
Energy and Commerce Committee  
2322A Rayburn  
Washington, DC 20515

Dear Chairman Upton and Ranking Member Waxman:

On behalf of the American College of Cardiology (ACC), I am pleased to provide comments on the user fee proposals that are moving through your committee and the impact they will have on care for cardiovascular patients. The ACC commends your bipartisan work on these proposals and commitment to enact them in a timely manner.

The ACC is a 40,000-member nonprofit medical society comprised of physicians, surgeons, nurses, physician assistants, pharmacists and practice managers, and bestows credentials upon cardiovascular specialists who meet its stringent qualifications. The College is a leader in the formulation of health policy, standards and guidelines, and cardiovascular research. The ACC provides professional education and operates national registries for the measurement and improvement of quality care.

In the past decade, mortality related to cardiovascular disease has dropped by 30 percent in part due to innovations in pharmaceutical and device therapies that have come through the Food and Drug Administration (FDA) approval process. ACC members rely on products approved by the FDA to furnish high quality cardiovascular care to patients on a daily basis.

Nearly 1 in 3 adults in the United States (US) suffers from heart disease. Given the aging of the population, people are living longer with forms of heart disease. To keep up the strides we are making, medical science and innovation and the FDA's capabilities must continue to advance.

The College strongly supports innovation in treatments for cardiovascular conditions and understands the FDA must find the appropriate balance between protecting the public health and patient safety and fostering innovation and scientific advancement.

#### FDA Resources

To help FDA carry out its important mission and ensure that cardiovascular patients benefit from needed innovations, the College urges Congress to provide adequate resources to the FDA. In the era of increasingly promising but complex cardiovascular technologies, the ability of the FDA to evaluate drugs and devices must be appropriately supported.

*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.*

### *Post Market Surveillance*

The College strongly encourages Congress to require the FDA to improve its post-market surveillance capabilities by incorporating clinical data registries into its infrastructure and increasing support for existing surveillance systems. This would help decrease the time from signal detection of a problem to action, decreasing the number of affected patients and the costs of their care.

Clinical data registries offer enormous potential to perform longitudinal research, tracking patients over time to determine long-term and short-term effects and outcomes, as well as monitor device effectiveness and safety.

Clinical data registries are an ideal mechanism for collecting information for post market surveillance activities. They can facilitate patient-centered research, comparative effectiveness research, adverse event and signal reporting, identifying device performance trends, inappropriate off-label use and hypotheses for follow-up studies.

For instance, through collaboration with the FDA and Edwards Lifesciences, Inc., the TVT Registry™, created by The Society of Thoracic Surgeons (STS) and the ACC, tracks patient safety and real-world outcomes related to the newly introduced transcatheter aortic valve replacement (TAVR) procedure for the treatment of aortic stenosis. Through the capture and reporting of patient demographics, procedure details, and other information, the TVT Registry provides a data repository capable of monitoring the safety and efficacy of this new procedure and delivering insight into patient outcomes.

Improving FDA's post market surveillance infrastructure through the use of clinical data registries will help provide the confidence in safety and effectiveness necessary to provide patients with timely access to critical advances in medical device and pharmaceutical technology.

### *Sentinel*

The College encourages the FDA to expand the Sentinel Initiative to medical devices as well as drugs and to make the program more robust and timely in detecting and evaluating safety issues.

### *Conflict of Interest*

The ACC is concerned about the vacancy rate on FDA advisory committees due to the currently overly restrictive conflicts of interest policy. The College supports efforts to improve the conflict of interest rules in order to allow appointments to advisory bodies that promote scientific and technical expertise while minimizing potential conflicts of interest.

### *Guidance*

The ACC supports efforts to improve the transparency and public input into the development of FDA guidance documents.

### *Prescription Drug Shortages*

Cardiovascular specialists are increasingly aware of and concerned about shortages of critical drugs. This is a critical patient safety issue. The College supports proposals that require drug manufacturers to notify the FDA as soon as possible about any discontinuance or interruption in manufacturing that is likely to produce a shortage. The ACC also supports efforts to encourage communication about shortages with stakeholders and to allow FDA to expedite changes in manufacturing and inspections of facilities for drugs in shortage.

Chairman and Ranking Member  
Energy and Commerce Committee  
April 23, 2012  
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*Humanitarian Device Exemption*

The College supports the inclusion of provisions to allow the humanitarian device exemption (HDE) for both adult and pediatric patients. This will help ensure access to needed treatments for cardiovascular patients.

*Unique Device Identifier*

The College supports enactment of the unique device identifier (UDI) as soon as possible. The UDI is an important component in tracking the safety and effectiveness of medical treatments.

*Conclusion*

On behalf of cardiovascular specialists and the patients they serve, the ACC appreciates this opportunity to comment on the prescription drug and medical device user fee acts moving through your committee and offers the College and its members as a resource to you.

As Congress looks ahead to the next reauthorization of the medical device and prescription drug user fee acts, the ACC encourages you to require the FDA to involve cardiovascular specialists and other physician specialties in the process in order to take advantage of their expertise.

Thank you for your consideration.

Sincerely,



William A. Zoghbi, MD, FACC  
President

cc: Thomas E. Arend, Jr, Esq, CAE  
*Interim Chief Staff Officer*

Jim Fasules, MD, FACC  
*SVP, Advocacy and Health Policy*