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July 14, 2011

The Honorable Margaret A. Hamburg, MD
Commissioner
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD 20852

Re: Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting Announcement; Humanitarian Device Exemption Request for Berlin Heart EXCOR Pediatric Ventricular Assist Device

Dear Dr. Hamburg:

The American College of Cardiology (ACC) is pleased to submit comments in response to the request for a humanitarian device exemption of Berlin Heart, Inc. for its EXCOR Pediatric Ventricular Assist Device (VAD). The College is a 40,000-member nonprofit medical society composed of physicians, nurses, nurse practitioners, physician assistants, pharmacists and practice managers, and bestows credentials upon cardiovascular specialists who meet its stringent qualifications. The ACC is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research. The College provides professional education and operates national registries for the measurement and improvement of quality care. We appreciate the opportunity to furnish input to the Food and Drug Administration (FDA) and the Circulatory System Devices Panel of the Medical Devices Advisory Committee on this important new device.

As the FDA is well aware, the pediatric cardiovascular device industry is negligible at best. Pediatric cardiologists struggle to find devices that are specifically designed for infants and children. Frequently, they are forced to use products and devices designed for other purposes to ensure appropriate sizing. Children are not small adults. Their needs are unique, their sizes and proportions distinct, and their thresholds and body chemistries singular. This means that the devices used to treat their diseases and conditions must be unique, distinct and singular, as well.

The ACC is delighted to see device manufacturers venturing into the field of pediatric devices. For pediatric cardiology patients in need of a bridge to transplant, there are currently few, if any, treatment options. Both Extracorporeal Membrane Oxygenation (ECMO) and maximal medical therapy have severe limitations. ECMO carries with it time limits, in addition to high rates of infection. Maximal medical therapy has also time limits to its efficacy. Given the concerns regarding time and the 90-day average waiting period for an infant heart, these options are less than ideal. While the literature documents potential risks to the implantation of VADs in the pediatric population, it also indicates that VAD implantation offers the opportunity to extend the time limits of therapy beyond ECMO and maximal

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.

medical therapy as children wait for a new heart to become available. Adult VADs are simply not appropriate for the pediatric population, and there are no other devices that can be used as a substitute. We hope the FDA will encourage Berlin Heart and other device manufacturers to develop additional pediatric cardiology devices that appropriately treat the needs of this special population.

The ACC appreciates the opportunity to provide the FDA's Advisory Panel on Circulatory System Devices with input pertaining to the request of Berlin Heart, Inc. for a humanitarian device exemption for its EXCOR Pediatric Ventricular Assist Device and would welcome the opportunity to discuss this input further. We look forward to working with the FDA on this and future issues. Please direct any questions or concerns to Lisa P. Goldstein at (202) 375-6527 or lgoldstein@acc.org.

Sincerely,



David R. Holmes, Jr., M.D., F.A.C.C.
President

Cc: Jack Lewin, M.D. – CEO, ACC