The Society for Cardiovascular Angiography and Interventions

9111 Old Georgetown Road, Bethesda MD USA 20814-1699
(800) 992-7224 Fax (301) 581-3408 e-mail: info@scai.org http://www.scai.org

INTERVENTIONAL CARDIOLOGISTS' PROFESSIONAL SOCIETY SUPPORTS FDA ADVISORY ON DRUG-ELUTING STENTS (DES)

SCAI Urges Physicians to Follow Instructions for Use, Report Adverse Events to FDA

(BETHESDA, MD, October 30, 2003) – The Society for Cardiovascular Angiography and Interventions (SCAI), today issued a statement commenting on the U.S. Food and Drug Administration (FDA) *Public Health Web Notification: Information for Physicians on Sub-acute Thromboses (SAT) and Hypersensitivity Reactions with Use of the Cordis CYPHER™ Coronary Stent.* SCAI's statement strongly supports FDA and manufacturer efforts to determine the cause of these events.

In its Notification, FDA reported 290 cases of subacute thrombosis – SAT – clotting of the device one to 30 days following implantation in the coronary arteries. The FDA did not make any specific recommendations, but urged physicians to report any adverse events and follow instructions for use of the stent.

SCAI President Dr. John McB. Hodgson (MetroHealth Medical Center, Cleveland) commended the FDA for its Notification. Dr. Hodgson urged all SCAI members (3,000 interventional cardiologists) to report all adverse events to the FDA promptly. Dr. Hodgson said, "we view the FDA as our partner in providing quality care to our patients. The function served by the FDA -- as data collector and disseminator -- is invaluable to the medical community. The FDA performs a vital service by informing us of trends, thereby enabling us to modify our care protocols in a data-driven and appropriate manner. The result -- improved patient care."

Dr. Hodgson added, "The clinical benefit of drug-eluting stents is very high, and we should remember that the incidence of SAT both in controlled clinical trials and in wide-scale use has been low. In fact, the incidence of SAT since FDA approval is extremely low (290 reported cases out of approximately 400,000 stents used, or 0.07%), although underreporting is likely. What is important is that physicians follow sound medical practice, follow the instructions for use, and report any adverse events to the FDA."

SCAI is the only medical specialty association to take a stand on how and when DES should be used, in its formal Position Statement earlier this year: http://www.scai.org/public/pages/DESpositionstatement.pdf This

statement was in response to an October 2002 survey of SCAI members (prior to FDA approval of DES), who overwhelmingly expressed excitement about this new technology but were deeply concerned about high initial costs and potential legal ramifications of not using DES in every patient. SCAI repeated the survey this month, to gauge experience based on six months' experience with these stents. Results will be reported in November.

In its Position Statement, SCAI recommends an evidence-based adoption strategy recognizing that physicians are concerned about offering the best possible patient care: *"Intervention should be employed only after documentation of the clinical and/or physiologic significance of individual lesions. The patient's physician should make this assessment based on objective evidence. A large spectrum of the coronary disease population will have benefit from reduced recurrence rates after treatment with DES. However, there remain patients for whom this therapy requires further study."*

Dr. Hodgson noted that, based on the data reported thus far, SCAI believes that the guidance in its Position Statement still is valid: physicians should use DES according to the scientific evidence reported to date.

Dr. Hodgson noted that developing a national database of patient outcomes (a patient registry) will be vital, and applauded the FDA and the manufacturer, Cordis Corporation, for initiating such a database as recommended by SCAI earlier this year.

This summer, SCAI also formed a multidisciplinary task force to address the thorny financial and medicolegal consequences surrounding DES use. The task force includes physicians, health economists, policy experts, industry, insurers and others. The task force report will be released in November, with recommendations addressing these non-clinical areas.

Headquartered in Bethesda, MD, The Society for Cardiovascular Angiography and Interventions is a 3,000-member professional organization of invasive and interventional cardiologists. SCAI's mission is to promote excellence in invasive and interventional cardiovascular medicine through physician education and representation, and advancement of quality standards to enhance patient care. SCAI was organized in 1976 by Drs. F. Mason Sones and Melvin P. Judkins. SCAI's next annual meeting will be April 28 – May 1, 2004 in San Diego.