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Heart Failure Society News

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7th Annual Scientific Meeting to Feature Enhanced Program

Registration for the 7th Annual Scientific Meeting scheduled for September 21-24, 2003 at the Mandalay Bay Resort & Casino in Las Vegas is running ahead of last year's pace, and organizers expect record attendance.

A wide range of symposia will highlight exciting developments in the field of heart failure including new treatments for heart failure, cell therapy, genomics and genetics, models for heart failure therapy delivery, heart failure management guidelines, and health care policy for heart failure.

In addition to the symposia, the scientific program will provide a variety of formats including debates, workshops, "lunch and learn" sessions, and poster presentations.

New this year: An added feature of the 7th Annual Scientific Meeting will be a Basic Science Workshop on Sunday, Sept. 21st. The morning will be devoted to didactic lectures revolving around a central theme: basic mechanisms of cardiac disease. This year's session will focus on modifiers of transcription regulation and their role in cardiac growth, development, and disease. The afternoon session will focus on

proteomics and the recently established centers around the country. The National Heart, Lung, and Blood Institute (NHLBI) will participate in this session.

To complement the Sunday Basic Science Workshop, one-hour Basic Science Seminars will be held on Monday, September 22 (molecular imaging) and Tuesday, September 23 (proteomics). Translational research on topics such as gene therapy and myocardial remodeling will also be addressed throughout the Annual Scientific Meeting. These sessions are designed to be of interest to clinicians as well as those involved in basic science.

Also new this year will be a presentation called "Court is in Session". HFSA President Marvin A. Konstam, MD will preside. On trial is "The term diastolic heart failure as it is currently applied to patients with heart failure and a normal EF." Milton Packer, MD, will lead the prosecuting team, and Michael R. Zile, MD, will lead the defense team. You, the audience, will serve as the jury. The presentation will take place Tuesday afternoon.

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Workshop Focuses on Clinical Trials for HF Devices

Inclusion and exclusion criteria, design, endpoints, reliability standards, performance targets, and reimbursement were among the topics addressed at the HFSA sponsored workshop, "Key Issues in Trial Design for Devices in Heart Failure", held in Washington, D.C. on February 26-27, 2003.

This workshop, hosted by the HFSA, involved representatives from the U.S. Food and Drug Administration (FDA), Centers for Medicare and Medicaid Services (CMS), and National Institutes of Health (NIH), physicians with an expertise in heart failure, statisticians, economists, and representatives from industry that had an interest in or are developing devices for use in treating heart failure.

"The goal of the meeting is not to settle all questions and solve all problems. We could not do that in two days or in even two weeks. The goal is to establish a forum for on-going progress," said HFSA President Marvin A. Konstam, MD in his opening remarks.

The 1.5-day workshop focused on three areas: Ventricular Assist Devices (VADs), resynchronization devices, and the economics of device development and utilization. Topics covered in moderated panel discussions included: lessons learned from clinical trials; safe and effective versus reasonable and necessary; current and new

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7th Annual Scientific Meeting to Feature Enhanced Program

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Two joint sessions with other societies which also have an interest in heart failure are planned for this year's program: the European Society of Cardiology (ESC) will focus on "Innovative Concepts in Heart Failure", and the International Society for Heart and Lung Transplantation (ISHLT) will cover "Surgery and Device Therapy in Heart Failure".

Nineteen industry-supported satellite programs will be held at this year's Annual Scientific Meeting. These programs will provide information on new drugs, therapies, and devices used in heart failure. The agenda for each of these

programs can be found on the HFSA web site, www.hfsa.org, under Annual Scientific Meeting. The final program for the 7th Annual Scientific Meeting, as well as registration and lodging information can also be viewed at the web site.

Continuing Medical Education (CME) credits are available for both the main scientific program and the satellite symposia.

The University of Minnesota has designated the Main Scientific Program for a maximum of 18 category 1 credits towards the AMA Physician's Recognition Award, and the Basic Science Workshop on Sunday for a maximum of 6 category 1 credits. Each physician should claim only those hours of credit actually spent in the activity. The scientific program is CME accredited for physicians, nurses, and pharmacists. Details will be provided in the final program book.

All satellite symposia have been approved for AMA category 1 credit by the University of Minnesota for an hour for hour basis. All have been designed in accordance with Accreditation Council for Continuing Medical Education (ACCME) guidelines. Individuals must register for the Annual Scientific Meeting to attend the satellite symposia. No additional registration fee is required to attend the satellite meetings. Delegates should register electronically at each satellite

symposium attended to receive the appropriate CME credits.

The Mandalay Bay Casino & Resort meeting venue is located on the south end of the Las Vegas Strip and features a tropical motif and environment. The scientific meeting and satellite programs will be held in the North Convention Center contiguous to the hotel. The venue provides state-of-the-art meeting rooms with full audio-visual support.

A wide variety of recreational activities are available on-site or near by. The resort itself has an 11-acre beach and shark reef stocked with 100 types of fish and marine animals. Golf, a spa, fitness center, and gaming are also among the possibilities.

Future Annual Scientific Meeting Dates

2004: September 12-15,
Toronto, ON, Canada

2005: September 18-21, Boca Raton, FL

2006 September 10-13, Seattle, WA

2007: September 16-19, Washington, DC

2008: September 21-14, Boca Raton, FL

Travel Arrangements for the Annual Scientific Meeting

Travel arrangements, including discounted airfares, may be arranged through Stratton Travel Management at:

(888) 387-5435,

(201) 405-1999;

fax (801) 729-2032.

HFSA Awards First Research Fellowships

Ahmed S. Hinan, MD of the Medical University of South Carolina in Charleston and David Mathew Fiss, MD of Temple University in Philadelphia have been named recipients of the 2003 HFSA Research Fellowships.

The title of Dr. Hinan's research is "Matrix Metalloproteinase Dysregulation in Diastolic Heart Failure". This project will test the central hypothesis that the balance between matrix metalloproteinases and their tissue inhibitors is dysregulated in various forms of ventricular overload. The goal is to identify novel therapeutic agents against diastolic heart failure. Michael R. Zile, MD, Professor of Medicine at the Medical University of South Carolina, will provide direct supervision of this research project.

The title of Dr. Fiss's research is "Diastolic Dysfunction and Relaxation Reserve". The main objective is to determine whether

frequency-dependent relaxation reserve is abnormal among patients with a history of diastolic heart failure. Secondly, the project is to determine whether frequency-dependent relaxation reserve is abnormal among patients with moderate concentric left ventricular hypertrophy but no clinical history of diastolic heart failure. The study will help determine whether examining relaxation reserve across a range of heart rates using existing noninvasive techniques will provide greater clarity about the nature and severity of relaxation abnormalities than the current static approaches used for assessing diastolic function in clinical settings. Kenneth B. Margulies, MD, Associate Professor of Medicine at Temple University, will provide direct supervision of this research project.

The HFSA established the one-year research fellowship program to develop

clinician-investigators in the field of heart failure. The fellowship program is open to applicants with a doctoral degree in medicine, osteopathy, or nursing. Preference is given to those whose research is a bridge or can be translated into the clinical care of patients with heart failure. Candidates shall be – and shall intend to continue to be – directly involved in patient care.

The deadline to apply for 2004 HFSA Research Fellowships is February 2, 2004. Application information will be available on the web site, www.hfsa.org, in November 2003.

The HFSA Research Fellowship has been funded by educational grants from: AstraZeneca, GlaxoSmithKline, Guidant Foundation, Merck, Scios Inc., and Vasomedical, Inc.

Workshop Focuses on Clinical Trials for HF Devices

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technologies; opportunities and obstacles for development; use of devices as bridges versus destination therapy; statistical obstacles; and the cost effectiveness of device therapy for heart failure patients.

The panels included a cross section of the invited attendees to assure a balanced discussion. Audience discussion was encouraged with ample time for comments and questions. The discussion raised many thought provoking issues which could not be resolved at this meeting. Future meetings will be planned to continue to address the issues surrounding the use of devices in treating heart failure.

"We are relying on the FDA to help guide us on what the key questions are," said Dr. Konstam, who noted that collaboration with the FDA on a workshop was a first for the HFSA.

The issues covered at the workshop have become increasingly important, as clinicians look to devices as another form of therapy for heart failure patients. "If the last decade was a decade of advancement in drug therapy for heart failure, then this decade seems to be measuring up as a decade of devices," said Dr. Konstam. However, Dr. Konstam noted that the ascendancy of devices for heart failure poses clinical, regulatory, and economic challenges not present with drugs.

"A device is not a drug," said Dr. Konstam. "With a drug, we can assume that the clinical effect seen in a randomized double-blind clinical trial is imparted by the molecular structure of the compound and the particular degree of bioavailability. If the compound is changed even slightly, the clinical effect may be altered."

Devices, however, evolve progressively. For example, if a new valve is incorporated into a VAD, it is unlikely outcomes will be affected as long as the mechanical performance and reliability of the new valve are adequate.

Similarly, the clinical effect of a drug is not prescriber dependent. However, the clinical success achieved with a device may be highly dependent on the skill of the implanting physician.

"We need to balance the realities of what it takes to develop a device with the imperative that if we do a study and get a device approved, the device needs to do what we think it does. That is the balance. Both of those goals need to be achieved."

The wide-ranging discussions during the workshop left many questions unanswered and identified areas requiring additional work. But participants reached consensus on some issues and drew boundaries around others.

"We in the HFSA have been really thrilled to host the symposium. It has been a great two days," said Dr. Konstam. "We have moved the field forward, opened lines of communication, and defined targets for future consensus documents."

The HFSA hopes to use some of the information provided in the workshop for development of consensus documents or other forms of rapid communication. "We are certainly going to hold additional workshops with the FDA and work closely with sister professional organizations," said Dr. Konstam.

For further discussion of the challenges of conducting clinical investigations of devices, see: Konstam MA, Piña I, Lindenfield J, Packer M. A device is not a drug. *JCF* 2003;9:155-157.

HFSA Ethics Committee Addresses Conflict of Interest Concerns

The responsibility of the HFSA's Ad Hoc Ethics Committee is to respond to any issues regarding Society leadership that might appear to raise concerns about conflict of interest. Given the close involvement of the Society and its members in diagnostic and therapeutic products and concepts that impact on industry, government, and the health care system, concerns often surface (sometimes anonymously) that require Ethics Committee deliberation.

All Society members in leadership roles are requested to provide conflict of interest disclosures on an annual basis. The Committee's consideration of specific issues involving individuals is to determine whether disclosure is adequate to allay any appearance of conflict or whether additional action is necessary.

The most recent recommendation of the Committee is that individuals involved in

discussion or decision-making regarding issues in which they appear to have a conflict should recuse themselves from the deliberations.

The Ethics Committee was formed about three years ago to respond to any issues regarding Society leadership that might appear to raise concerns about conflict of interest – not to be a police force, said Committee Chair Jay N. Cohn, MD. The committee has focused its efforts on a case-by-case consideration of potential conflicts rather than develop a global ethics standard for the HFSA.

Other members of the Ethics Committee are: Richard A. Walsh, MD, Case Western Reserve University; Allen Farber, Esq.; and Cheryl Yano, HFSA Executive Director.

Any concerns received by the Ethics Committee are reviewed expeditiously on a confidential basis.



National
HEART
failure
AWARENESS
Week

February 8 - 14, 2004

www.abouthf.org

HFSA Small Group Meeting Addresses Financial Barriers to Quality HF Care

A small group of HFSA members with an interest in reimbursement and quality of care for heart failure patients recently joined representatives of Centers for Medicare and Medicaid Services (CMS), an economist, and a congressional advisor in a one-day meeting in Washington, D.C. to discuss "Aligning Quality and Payment for Heart Failure Care".

The attendees were asked to prepare short presentations, which were used to jump start discussions on the following topics: crafting novel payment mechanisms; overcoming professional parochialism (policy making from the policy maker's point of view); reimbursement for heart failure disease management; and next steps.

"We had very fruitful discussions. It was a very productive day, and we are

making progress. We would hope to make further progress using the same approach in a workshop next year," said Edward P. Havranek, MD, Chair of the HFSA Care Standards Committee.

"While a global scheme to restructure the reimbursement system to reward providers with the best heart failure outcomes is appealing in principle, incremental gains can be achieved through incentives of proven value," said Dr. Havranek.

Because a large percentage of heart failure patients are over 65 years old, it is important to understand the perspective of Medicare on the issue of quality of care. Policy makers were among the invited workshop guests, and the practical implications of reimbursement policy were discussed.

"A dilemma facing disease management for heart failure is how to improve quality of care, which we suspect will lower readmission rates, while at the same time allowing hospitals to recover costs for heart failure care from other revenue streams," said Dr. Havranek. An article recently published in the *Journal of Cardiac Failure* discusses this topic in greater depth and detail. See Havranek EP, Krumholz HM, Dudley AR, Adams K, Gregory D, Lindenfield J, et al. Aligning quality and payment for heart failure care: Defining the challenges. *JCF* 2003;9:147-52.

It is anticipated that additional small group meetings will be held to continue the discussion and to work with governmental agencies that have an interest in care for patients with heart failure.

Jay N. Cohn, MD, Named Co-Winner of the 2003 Recordati Prize

The HFSA is pleased to announce that its nominee, Jay N. Cohn, MD, is one of the joint winners of the 2003 Recordati Prize. Dr. Cohn will share the prize with John K. Kjekshus, MD, PhD, of the University of Oslo, Oslo, Norway.

The Recordati prize was established to honor Arrigo Recordati, an Italian pharmaceutical entrepreneur. It is awarded every two years to recognize a distinguished scientist for his/her commitment to and accomplishments in cardiology. The 2003 prize was earmarked for a prominent researcher whose contributions have helped improve understanding of heart failure.

The judging panel made the unusual decision of naming joint winners after a one-time amendment to the prize regulations in order to recognize excellence in heart failure on both sides of the Atlantic. The joint award recognizes the contributions of both a European and an American scientific researcher for their contributions in making fundamental mechanistic observations on the pathophysiology of heart failure and translating those observations into clinical practice for the benefit of all patients suffering from heart failure.

Dr. Cohn's role as the "father of contemporary management of heart failure" has been documented in a biography of the prizewinners compiled by competition organizers. The achievements recognized include: Dr. Cohn's leadership in designing and carrying out clinical trials to document efficacy of new interventions for heart failure including the V-HeFT study; his animal and clinical studies that established the



Jay N. Cohn, MD

importance of structural remodeling of the left ventricle as the basis for the progression of heart failure; the identification of the syndrome of right ventricular infarction; his role in identifying neurohormonal activation as a key contributor to the progression of heart failure; and his innovative efforts at early detection. He is a founder of the HFSA, served as the first HFSA president, and started the *Journal of Cardiac Failure* in 1994, which became the official scientific journal of the Society in 1997. He served as Editor-in-Chief of the journal from 1994-2001.

The Recordati competition is open to scientists from all nations. Nominations were solicited from scientific societies and professional associations around the world.

Drs. Cohn and Kjekshus will be honored during a gala ceremony in Vienna, Austria on August 31 during the European Society of Cardiology Congress.

The award will be presented by the jury panel chaired by Douglas P. Zipes, MD, Distinguished Professor of Medicine, Pharmacology, and Toxicology, Director of the Cardiology Division and the Krannert Institute of Cardiology, Indiana University, Bloomington, Indiana. Other panel members were Peter Libby, MD, Chief of Cardiovascular Medicine, Brigham & Women's Hospital, Mallinckrodt Professor of Medicine, Harvard Medical School, Boston; and Karl B. Swedberg, MD, PhD, Professor of Medicine, Cardiovascular Institute, Göteborg University Department of Medicine, Göteborg, Sweden, and Senior Physician at the Department of Medicine at Sahlgrenska University Hospital/Ostra.

HFSA President Reflects on the First Year

"It's been thrilling. This Society has been doing so many great things, and there is so much potential for doing more. I am happy to be part of it," said Marvin A. Konstam, MD when asked to sum up his first year as the HFSA President.

Dr. Konstam also added that the HFSA has really kept him busy. The most surprising aspect of the president's job has been "how much work it is" but at the same time "how much fun it is. Aside from my professional work, what I enjoy doing most is working with the HFSA."

"We are a very special subspecialty medical organization. We are focused on a disease not a technical competency. We are centered on the heart failure patient. That is unique in cardiology."

"The role of the HFSA is to achieve better care and outcomes for patients with heart failure. That goal is served in many different ways, starting with facilitating research and communicating the results at scientific meetings, to developing consensus on patient management through guidelines, to improving the quality of care through education. What is exciting is that we have programs in every one of those areas."

Among the high points of the year, Dr. Konstam cited establishing the HFSA Research Fellowships; collaborating with the U.S. Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Centers for Medicare and Medicaid Services (CMS); and the Nursing Committee's work in developing patient education materials.

He also noted that three centerpiece HFSA efforts continue to grow and flourish: the *Journal of Cardiac Failure*, the Annual Scientific Meeting, and the Heart Failure Awareness program.

HFSA Research Fellowships Fill Unmet Need

"We are going to celebrate the first two winners of the HFSA Research Fellowships at the Annual Scientific Meeting in September. The fellowships fill an unmet need of helping young investigators working on research with clinical application to heart failure," said Dr. Konstam. "We would like to thank our industry supporters whose generous contributions made the fellowships possible: AstraZeneca, GlaxoSmithKline, Guidant Foundation, Merck, Scios Inc., and Vasomedical, Inc. With continued support, we expect to award more fellowships to help advance the careers of future investigators."

Governmental Relations

The HFSA collaborated with the FDA and CMS on workshops during the past year. In late February 2003, the HFSA sponsored a workshop on "Key Issues in Trial Design for Devices in Heart Failure". This workshop was attended by representatives of the FDA, NIH, and industry and by heart failure clinicians. In late May 2003, the HFSA held a small meeting with CMS on "Aligning Quality and Payment for Heart Failure Care". Both meetings were held in Washington, D.C.

This fall the HFSA will host a small workshop with the FDA. This will be followed by a larger workshop in the spring of 2004 focusing on the topic of developing rationale approaches to heart failure device and drug approvals.



Marvin A. Konstam, MD

HFSA committees are involved in on-going efforts to expand the Society's relationships with governmental agencies involved in heart failure. The Care Standards Committee, headed by Edward P. Havranek, MD, is working with CMS on reimbursement models for heart failure care. The recently formed Advocacy Committee headed by John E. Strobeck, MD, PhD, is communicating HFSA positions to agencies involved in setting policies affecting heart failure care. Another new committee, the Research Committee, headed by Wilson Colucci, MD, is overseeing the HFSA Research Fellowships as well as exploring ways to collaborate with the NIH.

Patient Education

The Nursing Committee has taken the lead on writing educational materials targeting patients, their families, and individuals at risk of developing heart failure. Debra Moser, RN, DNSc, former chair of the Nursing Committee, has spearheaded the effort to publish a series of 11 modules, each focusing on a different aspect of heart failure. Six of the modules have been completed to date. These modules can be viewed on the abouthf.org web site. Patients can order a complimentary copy, and multiple copies are now available for purchase. "I would like to thank all of the members of the Nursing Committee for their work on this important project."

What is Next for the HFSA

Next year marks the tenth anniversary of the HFSA. One of the biggest challenges facing the Society as it grows and matures is developing the next generation of leaders in the area of heart failure. "Great people have driven the HFSA through their passion, position, and excitement. Now we have to bring new people in." As part of the effort to develop the next generation of leaders, the HFSA will hold a Fellows Symposium in January to connect them with leaders in the field of heart failure. This one-day conference is being organized under the direction of Dr. Clyde W. Yancy, chair of the Membership Committee.

Additionally, HFSA committees and individuals are encouraged to take an active role in developing new ideas and projects that match the goals of the Society. "We are trying to empower committees and decentralize projects. To continue to grow and develop, we have to tap the ideas and efforts of all HFSA members."



Heart Failure Society
of America

2004 HFSA RESEARCH FELLOWSHIPS

The purpose of the research fellowship is to develop clinician-investigators in the field of heart failure.

Visit our web site to complete and download an application or call the HFSA for an application packet.

www.hfsa.org

Primary Care Symposium Proceedings Now On-line: No Pencils Required



Primary Care Symposium Now Online

Learn about heart failure and earn Continuing Medical Education (CME) credits at the same time by viewing the webcast from "Heart Failure 2003: Update for the Primary Care Physician" on www.hfsa.org.

The webcast consists of slides along with audio and a simultaneous written transcript of the symposium presentations. The on-demand program allows health care professionals to review the information presented at the symposium at their convenience.

The symposium, which was held on February 1 in New Orleans, provided a basic understanding of heart failure to professionals working in primary care who are taking care of heart failure patients. The goal was to help primary care physicians approach heart failure in their practice with increased confidence. The presentations focused on strategies for early recognition, prevention, and optimal management of heart failure and provided insight into the mechanism of disease and the impact of various therapies on the clinical course. The program also included three case presentations, which are included on the webcast.

An internationally recognized faculty led by Symposium Chair Barry H. Greenberg, MD and Co-Chair Mandeep R. Mehra, MD, presented the information through didactic lectures, case studies, and panel discussions.

The University of Minnesota has designated the webcast for a maximum of 5 category 1 credits toward the AMA Physician's Recognition Award. Each physician should claim only those hours actually spent on the educational activity. The webcast will remain active until March 31, 2004. The CME credit is valid through April 30, 2004.

The third annual primary care symposium will be held in Dallas, Texas on February 7, 2004, and planning is underway. The conference will be expanded to include CME credits for nurses and a special breakfast seminar for nurses and other allied health care professionals. Details will be available on the HFSA web site as they are finalized.

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September 12–15, 2004
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8TH ANNUAL SCIENTIFIC MEETING

Abstract Deadline: April 12, 2004