

**Julie Horst**

**From:** AdvaMed SmartBrief [advamed@smartbrief.com]  
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**To:** Sherrie Conroy  
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July 22, 2009

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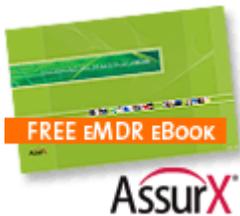
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■ **Boston Scientific: Study to boost implantable cardiac devices market**

Boston Scientific believes that its MADIT-CRT study, which is aimed at testing the efficacy of cardiac resynchronization therapy in slowing the progression of early-stage heart failure, could expand the market for implantable heart devices. The company plans to ask the FDA to get expanded label indication for CRT defibrillators by the end of the year and hopes to secure approval by mid-2010, CEO Ray Elliott said. [The Boston Globe/Reuters](#)

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Business & Market Trends

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■ **Mack Molding assigns name to medical device unit**

Mack Molding officially named its medical products division MackMedical, following nine years of "refining quality and supply management systems, hiring specialized staff and adding new technology," said Jeff Somple, president of Mack Molding's Northern Division. MackMedical manufactures Class III medical devices, surgical tools and high-end disposable products. [Bennington Banner \(Vt.\)](#) (7/21) Share: [in](#) [f](#) [t](#) E-MAIL

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■ **Pulmonx appoints former ArthroCare chief as CEO**

Pulmonx appointed Michael Baker, former president and CEO of ArthroCare, as its chief executive. Meanwhile, the company said it secured marketing approval from the FDA for Chartis System, a device that allows doctors to assess interlobar airflow in the lungs and other lung functions. [American City Business Journals/San Jose, Calif.](#) (7/21) Share: [in](#) [f](#)

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International Developments

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## ■ [Report: Lifestyle-related illnesses to affect India's health care sector](#)

The health care sector in India could be valued at as much as \$14.2 billion by 2012, driven by the increasing incidence of lifestyle-related diseases, rising income levels and shifting demographics, according to a report by consultancy firm KPMG. Medical-device manufacturing, diagnostic businesses and other emerging sectors are drawing investments as the country's health industry initiates reforms, the report noted. [Reuters](#)

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Clinica (U.K.) (subscription required) (7/21)

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Emerging Technologies

## ■ [FDA clears St. Jude Medical's wireless pacemakers](#)

The FDA granted approval to St. Jude Medical for Accent RF pacemaker and Anthem RF CRT-P, a cardiac resynchronization therapy pacemaker. The two devices are designed to wirelessly communicate with a home monitor or a programmer used by medical providers. [Minneapolis/St. Paul Business Journal](#) (7/21) [Share:](#) [in](#) [f](#) [t](#) [E-MAIL](#)

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## ■ [Needle-free sumatriptan-delivery system gains FDA approval](#)

The FDA approved Sumavel DosePro, a needle-free system that delivers the drug sumatriptan to treat patients with acute migraine and cluster headache. San Diego-based firm Zogenix said it intends to launch the Sumavel as soon as possible. [San Diego Union-Tribune](#) (7/21) [Share:](#) [in](#) [f](#) [t](#) [E-MAIL](#) [RELATED STORIES](#)

## ■ [Researchers equip mobile phone with diagnostic tool](#)

U.S. researchers have equipped a cell phone with a device, called CellScope, that can generate images and help diagnose tuberculosis, malaria, sickle cell anemia, among other diseases. They hope the device, which functions as a fluorescence microscope, can be used in developing countries that have limited access to medical diagnostics. [BBC](#) (7/22)

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## Government & Regulatory

### ■ Patient asks Congress to approve medical device bill

A 48-year-old former major league baseball umpire has joined those calling on Congress to pass a medical device safety bill that would reverse a Supreme Court ruling last year that limits lawsuits against medical device makers. Mark Hirschbeck has a pending lawsuit in a state court in connection with his hip replacement surgeries that he says caused him to suffer from chronic pain and forced his retirement. [The Times-Picayune \(New Orleans\)/The Associated Press](#) (7/21) [Share:](#) [in](#) [f](#) [t](#) [E-MAIL](#) [RELATED STORIES](#)

### ■ Group calls for inclusion of self-referral ban in health bill

A radiology group is urging the House to include in the health care reform bill introduced in Congress last week another bill that would prohibit the practice of self-referrals among physicians for MRI, CT and PET imaging services. Reps. Anthony D. Weiner, D-N.Y., and Bruce Braley, D-Iowa, of the Energy and Commerce Committee said HR 2962 could be included as an amendment to the Healthcare Reform Package being considered by the committee. [HealthImaging.com](#) (7/22) [Share:](#) [in](#) [f](#) [t](#) [E-MAIL](#) [RELATED STORIES](#)

### ■ White House backs Medicare cost-cutting mechanism, centrists say

Democratic centrists said they secured a verbal commitment from the White House to support a proposal that would give the executive branch power to implement Medicare spending cuts based on the recommendation of independent experts. They said the White House also verbally agreed to include the measure in the House health care bill. [The Wall Street Journal](#) (7/22) [Share:](#) [in](#) [f](#) [t](#) [E-MAIL](#) [RELATED STORIES](#)

## AdvaMed News

### ■ Social Media and Medical Devices: New Trends in Healthcare Definitions, Opportunities and Risks, July 23

The OTC and prescription-drug industries and other health care service and product providers were slower to start using social media but now are catching up. With opportunities inevitably come risks. Do social media pose new regulatory and legal vulnerability beyond those of traditional advertising and



promotion? What new liabilities might companies incur as a result of third-party blogging and tweeting, and what sorts of oversight and monitoring procedures might be implemented to minimize risks? [More information](#). **Medical Technology Learning Institute -- Education Beyond a Degree** [Share: !\[\]\(2bdfe261b986065ee0ac76460d6528c9\_img.jpg\)](#)



## ■ Reimbursement Professionals Workshop, Sept. 22 to 24, Washington, D.C.

"Reimbursement is a contact sport," said an expert speaker at MTLI's three-day medical technology reimbursement workshop. There are winners and losers and some players get hurt. Certainly it is not just a spectator event and merely knowing the rules is never enough. Creating, implementing and maintaining a successful reimbursement strategy takes skill, practice, team coordination, hard work and the ability to adapt to shifting circumstances. Doing it right can make the difference between a product's success or failure in the market. [More information](#). **Medical Technology Learning Institute -- Education Beyond a Degree** [Share: !\[\]\(23d9fc146e83b5c3013cfa32c784f8d5\_img.jpg\) !\[\]\(f5c463b8c1554ac5049d611bd8e33a51\_img.jpg\) !\[\]\(54f1390f33a36173a1b97c4b6eb40204\_img.jpg\) !\[\]\(1301e78e125668a3a0cedabdef0db7f3\_img.jpg\)](#)



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<a href="#">Vice President, Research and Development</a>	IRIS International, Inc.	Chatsworth, CA
<a href="#">Vice President, Regulatory Affairs and Quality Assurance</a>	IRIS International, Inc.	Chatsworth, CA
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Lead Editor: [Ashley McMaster](#)

### Mailing Address:

[SmartBrief, Inc.®](#), 1100 H ST NW, Suite 1000,  
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