



SCREEN SAVER: Medicare will soon cover the cost of ultrasound screening for abdominal aortic aneurysms (AAAs) in high-risk individuals, thanks to a campaign led by Dr. Robert Zwolak, a DMS vascular surgeon. AAAs kill more than 15,000 Americans every year.

FLIGHT ATTENDANT AT DHMC

Hummingbirds may be among the world's smallest birds, but they pack a big punch at DHMC. Every spring and summer, inpatients get to watch the tiny iridescent creatures hover around feeders that have been set up by Joyce Langevin, R.N. Over a decade ago, DHMC's "hummingbird lady"—inspired by a patient's family who hung a hummingbird feeder outside of their loved one's hospital room—began placing and maintaining the feeders all around One West.

It's a task Langevin takes very seriously. Each year in late April, she starts to track hummingbirds' migration patterns on

www.hummingbirds.net. In early May, she sets up the feeders. And then every week until mid-September, she cleans and refills the feeders with a fresh, homemade sugar-water solution: four parts water to one part sugar—and hold the red food coloring, which, according to Langevin, can harm a hummingbird's delicate liver.

Langevin (pictured at left) retired in 2003 to battle breast cancer, but she has continued to care for DHMC's hummingbirds—and, indirectly, all

the patients on One West. "It's something I can still do for patients that I'm just not ready to give up," she says. A.P.



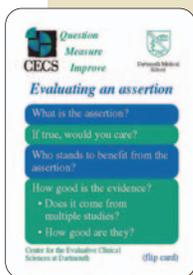
BE A CARD-CARRYING SKEPTIC

When researchers at Dartmouth's Center for the Evaluative Clinical Sciences created a handy wallet-sized card with tips to help doctors evaluate medical information, they didn't realize that it would become a hit with patients, too. Now it has even made the national press. "The card makes you think clearly about what someone is trying to tell you," Dr. Elliott Fisher told the *New York Times*. "If you are uncertain, don't leap to the conclusion that you should take this new drug."

The card contains the following questions:

- What is the assertion?
- If true, would you care?
- Who stands to benefit from the assertion?
- How good is the evidence? Does it come from multiple studies and if so, how good are they?

And as an added bonus, the flip side of the card contains tips for evaluating medical studies. To get a free "Evaluating Medical Assertions" card, e-mail CECSWeb@Dartmouth.edu, call 603-650-1684, or visit <http://www.dartmouth.edu/~cecs/>. L.S.C.



Heart-to-heart discussions about devices

The phrase "3D Symposium" may conjure up an image of a 3-D movie extravaganza. But the three D's stand for Dartmouth Device Development.

Key: It's an event dreamed up by Dr. Aaron Kaplan, a DMS cardiologist. He invites about 50 key stakeholders in the medical device industry to an annual retreat in Vermont. Attendees include leading clinical investigators; senior managers from medical device manufacturing firms; entrepreneurs; regulators, including the director of devices at the Food and Drug Administration (FDA) and his British counterpart; payors, including the chief medical officer at the federal Centers for Medicare and Medicaid Services; venture capitalists; investment bankers; and lawyers. The group spends a couple of days candidly discussing the development and commercialization of medical devices.

"The idea is you bring these folks together who are often transacting business—I don't like to say this—on opposite sides of the table," says Kaplan. "This is very unusual, providing a forum for people [who are] working on the same problems" but who don't normally work together because of perceived barriers. It's "a forum that removes a lot of those barriers and that can facilitate dialogue."

The first 3D Symposium, in 2003, "was phenomenal," says Kaplan. It was just after a new drug-eluting stent had been released, "and there was a concern about subacute thrombosis." A

stent is a metal mesh tube that's inserted in an artery to keep it open, and "drug-eluting" means it slowly releases drugs to reduce the risk of reblockage. This stent was the first of its kind recommended for FDA approval, but there were worries it might cause small blood clots. "The FDA had filed a letter and then came to the conference," says Kaplan. The discussion culminated in a published paper about developing better post-market surveillance strategies.

Process: That first year, participants also talked about differences between the European and U.S. regulatory environments. In Europe, the approval process for medical devices requires only that a device be proven safe. But in the U.S., both safety and efficacy have to be shown.

"There's a movement afoot called harmonization," to standardize the criteria in Europe and the U.S., says Kaplan. While the 3D discussions weren't responsible for the movement, they did help to demystify the process.

In fact, demystifying the device development process has been an important result of the 3D sessions and the papers published afterward in leading journals like *Circulation* and *Health Affairs*. "Part of the dilemma is that often the clinical community sees device development as a black box," says Kaplan. The 3D papers have helped educate clinicians and the public by describing the device development process, the regulatory hurdles, and other challenges. It "also



JON GILBERT FOX

DMS's Kaplan has brought medical device movers and shakers to the table.

helps enrich dialogue to regulators and the business community as to how to meet patients' needs quicker," says Kaplan.

Other topics covered have included conflicts of interest and what's known as the Humanitarian Use Device/Humanitarian Device Exemption (HUD/HDE)—a process meant to facilitate the approval of devices intended for rare conditions. But a post-3D report, published in *Circulation*, raised awareness about misuse of the HUD/HDE process to circumvent the normal, long approval pathway. The report may have changed "the way start-up companies are looking at that pathway," says Kaplan. "I don't know how much of that is from the symposium, but it helped educate the community, . . . identified some of the pitfalls, and made sure [the process] is used more appropriately."

A topic being considered for next year's retreat is Institutional Review Boards—committees that review and monitor any biomedical research involving human subjects. The 2006 3D Extravaganza—er, Symposium—is already "sold out," or oversubscribed, as Kaplan puts it.

Laura Stephenson Carter

Editorials examine the bulk of the evidence

Bran and beans may help keep you regular, but don't count on them to protect you against colon cancer. Despite more than three decades of studies on dietary fiber and its relationship to colon cancer, the connection between the two remains ambiguous. Dr. John Baron, a DMS epidemiologist, explained why in a December editorial in the *Journal of the American Medical Association (JAMA)*.

"Part of the problem is dietary fiber itself," wrote Baron, who is just one of several DMS faculty members recently invited to write an editorial for a top journal. He studies the effects of nutritional interventions on cancer in the large bowel.

Intake: "Although the term fiber suggests a single entity," Baron explained in his *JAMA* editorial, "fiber actually represents a group of plant products that may have very different properties. Measuring dietary fiber intake is as uninformative as knowing that a patient with pneumonia took 'some antibiotic or other,'" he wrote.

In many studies, fibers are categorized by the foods that contain them, says Baron, such as cereal fiber, fruit fiber, or vegetable fiber. A more helpful strategy, he argues, would be to categorize fibers as either soluble (found often in fruits and vegetables) or insoluble (found in some grains). "Insoluble fibers have the stool-bulking effect that is often associated in the public mind with fiber," Baron wrote, "but soluble fibers typical-

ly do not have this effect because they are readily broken down in the large bowel."

Yet even in studies that do distinguish between insoluble and soluble fibers, the cumulative picture is still murky. For example, in some animal studies insoluble fiber has been shown to be protective, but in some human studies it seems to have no effect at all. Instead, soluble fiber has been associated with a lower risk of colon cancer. As Baron explained in his summary, "The relationship between intake of dietary fibers and colorectal cancer risk has depended on the type of fiber under discussion and the research design used."

Just over a page long, Baron's editorial provides a concise but comprehensive overview of what is known about fiber and its relationship to colon cancer. It also reviews a large study on fiber and colorectal cancer published in the same issue of *JAMA*. That study, from the Harvard School of Public Health, suggests that colon cancer may be a "fiber deficiency disease," such that modest fiber intake is sufficient to prevent increased risk. But the study found no protective effect in individuals

who ate the most fiber. Although Baron described the study as providing "valuable help," he also pointed out its many limitations—including the fact that it did not distinguish between soluble and insoluble fiber.

Touchstones: Summaries like Baron's can be important touchstones for researchers and the public, so to be invited by a journal to write an editorial is a significant honor.

At least five other members of the DMS faculty contributed editorials to prominent journals during 2005: Dr. Richard Comi on two new diabetes treatments to the *Annals of Internal Medicine*; Dr. Jack Cronenwett on endovascular aneurysm repair to the *Lancet*; Dr. Matthew Friedman on veterans' mental health to the *New England Journal of Medicine*; Dr. James AuBuchon on radiolabeled red blood cells to *Transfusion*; and Dr. Michael Simons on angiogenesis to the *Journal of the American College of Cardiology*.

JENNIFER DURGIN



JON GILBERT FOX

Fiber was the subject of a *JAMA* editorial by John Baron.