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Dollars for Doctors
How Industry Money Reaches Physicians

Heart Society's Tip Sheets Fail To Mention Risks

by *Charles Ornstein and Tracy Weber*
ProPublica, May 5, 2011, 9:48 p.m.

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For patients researching solutions for scary, often debilitating irregular heartbeats, the information sheets on the Heart Rhythm Society website offer reassuring remedies.

Implantable cardioverter defibrillators—devices that automatically deliver shocks to restore normal heart rhythms—are “99% effective,” [one sheet says](#). The sheet doesn't mention that the devices may also deliver [unnecessary and painful jolts](#), which can damage a patient's quality of life.

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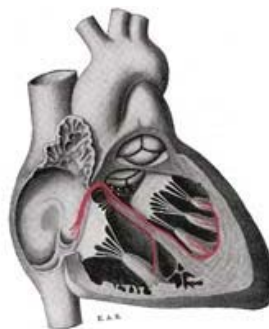


Diagram from Gray's Anatomy.

Nor does the sheet say that sicker and older patients were underrepresented in clinical trials of the devices, even though they are more likely to have heart rhythm problems, according to cardiologists who reviewed the information sheet for ProPublica.

“Even advertisements on TV run through the side effects real quick at the end of the ad,” said Dr. David Mann, an electrophysiologist in Louisville, Ky.

Another [society tip sheet says](#) that cardiac ablation, in which catheters are used to destroy abnormal heart tissue, is “an effective treatment for many types of [arrhythmias](#). It is successful in 90 to 98 percent of cases, eliminating the need for open-heart surgery or long-term drug therapy.”

But it too lists no limitations or [risks](#)—though they include blood clots, damage to the heart's electrical system and even puncture of the heart.

Among the society's biggest funders are makers of defibrillators and catheters used during cardiac ablation. Nearly half of the \$16 million in annual revenues last year came from the device and drug industries, according to [records on its website](#).

While there is no evidence of a quid pro quo, those who study

This article is part of an ongoing investigation:

Dollars for Doctors: How Industry Money Reaches Physicians

ProPublica is tracking the financial ties between doctors and medical companies.



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The Story So Far

ProPublica is investigating the financial ties between the medical community and the drug and device industry. In October 2010, ProPublica compiled the list of payments that drug companies make to physicians and built a publicly searchable database so that patients could look up their doctors.

Multimedia

Interactive Graphic:



The Heart Rhythm Society's annual conference is a marketing bonanza for drug companies and medical device makers. [Use this interactive graphic to find out how companies got their names seen.](#)

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Docs on Pharma Payroll Have Blemished Records, Limited Credentials

Handreds of doctors paid by pharmaceutical companies to promote their drugs have been accused of professional misconduct, were disciplined by state boards or lacked credentials as researchers or specialists, ProPublica has found. We compiled data from seven companies, covering \$27.8 million in payouts since 2009 for speaking, consulting and other duties. Read more.

This database only includes the seven companies that have disclosed payments. Their 2009 sales totaled \$159 billion—about a 38% market share. See the details of their disclosures.

Company	Total	Quarterly
El Lilly	\$102.2 M	\$30.4 M
GlaxoSmithKline	\$98.9 M	\$17.4 M
AstraZeneca	\$22.8 M	\$11.4 M
Pfizer	\$18.8 M	\$9.9 M
Merck	\$8.4 M	\$4.7 M
Johnson & Johnson	\$5.2 M	\$2.6 M
Cephalon	\$11.3 M	\$1.9 M

Source: [Lancet: Sex Pharma Offers To Paid Doctors to](#)

Look Up Your Doctor in Our "Dollars for Docs" Database

May 5, 2011: We are currently adding the latest records to our database; expect to see an update in the coming weeks.

Tracking the Money

[Our Dollars for Docs Database](#)

We compiled tens of thousands of records from all the companies that have disclosed their payments to doctors so far. [Search for your physician.](#)

May 5, 2011: We are currently adding the latest records to our database; expect to see an update in the coming weeks.

conflicts of interest in medicine say industry money may subtly affect what groups say—or don't—about the products made by their financial supporters.

In a statement to ProPublica, society President Douglas Packer and President-elect Bruce Wilkoff said industry support does not influence educational offerings or the group's positions on appropriate treatments.

"The risks and limitations of treatments are best conducted between a patient and his/her physician," they said. A disclaimer on the group's website also advises patients to consult a doctor.

In an interview Thursday at the society's annual meeting, Wilkoff defended the tip sheets. "Putting out a list (of side effects) doesn't really inform," he said. "It just produces anxiety."

Lobbying Medicare

The society's enthusiasm for certain treatments is not always shared by others. Take cardiac catheter ablation.

Representatives of the society [appeared before a federal Medicare committee](#) in October 2009 to urge that the program continue to pay for ablation for seniors with [atrial fibrillation](#), a rapid and irregular heartbeat.

"Patients benefit from it tremendously, the waiting lines are long, and I think the Heart Rhythm Society feels strongly" that procedure should be covered under Medicare, society board member Dr. Hugh Calkins said at the meeting.

Calkins, a professor of medicine and cardiology at Johns Hopkins University, was a paid consultant for at least two companies that make catheters used in the procedure, according to [his disclosure on the society's website](#).

[Committee members determined](#) there wasn't enough scientific evidence that the procedure worked in elderly patients. The panel, which advises Medicare on coverage issues, also recommended more research to see if ablation reduces the risk of stroke or death in patients.

In an interview, Calkins stood by his comments at the meeting and said there are a lot of patients who could be helped by ablation after other treatments have failed.

Heart Drug Controversy

Some members of the society and those who write about conflicts of interest also faulted [a website](#) that was jointly developed by the society and the American College of Cardiology.

The site, created last year to educate physicians about atrial fibrillation, features an audio and slide presentation by a prominent society member advocating for broad use of the anti-arrhythmic drug Multaq.

But initially, the site failed to mention that the physician was also a paid consultant for Sanofi-Aventis, the drug's maker and site sponsor. Only after the editor of another [cardiology website flagged the omission](#) did the site add the disclosure.

Cardiologist Steven Nissen, who writes about conflicts of interest in medicine, faulted the society at its conference last year during a debate about the influence of money on medicine.

"The Heart Rhythm Society Gets Caught in an Industry Scam," one of Nissen's slides



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bluntly said.

Officials of the Heart Rhythm Society attributed the lack of disclosure to a “production flaw” and said it was quickly fixed.

The drug Multaq—which costs \$9 per day—was predicted to be a blockbuster but has been dogged by concerns about safety and effectiveness since going on the market in 2009. In January, the Food and Drug Administration [issued a warning](#) after two patients on the drug suffered liver failure and required transplants.

John Mandrola, a Louisville, Ky., electrophysiologist who [blogs about heart rhythm issues](#), said he is disappointed that the society “so embraced a drug that really doesn’t work.”

“There’s no doubt the Multaq thing has given me a lot of reason to be more skeptical of these opinion leaders and thought leaders,” said Mandrola, who said he turned down an opportunity to consult for Sanofi on the drug.

Dr. Eric Prystowsky, the Indianapolis lecturer criticized by Nissen, said he disclosed his relationships in advance and that the societies chose not to publish them initially. His position that the drug is a viable treatment option was subsequently adopted by two medical expert committees that drafted guidelines for atrial fibrillation, he said.

A Sanofi official said the firm had no influence over the joint website but stood by the safety and effectiveness of Multaq. The company gave the society a total of \$935,000 in fiscal 2010 for ads, exhibits and courses at the group’s annual conference.

Some society members are urging more caution.

“We need to take a far more conservative approach of recommending procedures for patients when there is no data that those procedures are beneficial,” said Dr. Nicholas Stamato, an electrophysiologist in Johnson City, N.Y.

“I’m not so sure we’re keeping the patients’ interests at heart.”

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Merrill Goozner
Yesterday, 11:15 p.m.

I'm surprised you didn't ask the FDA for a response to the Heart Rhythm Society's failure to disclose risks on its website. The site seems to suggest it is sponsored by the Heart Rhythm Foundation. If makers of ICDs support the foundation, this is comparable to paid advertising.

The FDA's Division of Drug Marketing, Advertising and Communication regulates drug advertising to ensure that both benefits and risks are disclosed in any print, television or online advertising. Are there not similar rules for devices, whether the promotional material is directly paid for by a manufacturer or presented as “objective information” by a non-profit like the HRS? Either you've uncovered a loophole in the FDA regulations and/or law, or the agency has the responsibility to launch an investigation into the accuracy of the HRS website. I'd give them a call tomorrow if I were you.

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Dan Walter
Today, 7:34 a.m.

Calkins, Petrowsky and the rest of the HRS are beholden to device manufacturers. Catheter ablation for afib is a corporate-driven, risky and ineffective procedure.

Before anyone with afib falls for the hard sell, they should read this history of the evolution of the procedure: <http://collateral-damage.net>

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