David Kandzari, an Atlanta cardiologist, also has worked as a consultant to makers of medical devices. He received at least $100,000 from them in five years, according to corporate and government data.

Another organization he works with, the Food and Drug Administration, doesn’t appear to mind. In October, the FDA put Dr. Kandzari on a panel reviewing a medical device made by Boston Scientific Corp., one of the companies he has advised.

The FDA didn’t disclose the connection. It was among numerous financial ties the FDA hasn’t disclosed between medical-device makers and the doctors and other experts who review devices for it, a Wall Street Journal analysis of corporate, state and federal data shows.

In panels evaluating devices involved in cardiology, orthopedics and gynecology from 2012 through 2014, a third of 122 members had received compensation — such as money, research grants or travel and food — from medical-device companies, an examination of databases shows.

Nearly 10% of the FDA advisers received something of value from the specific company whose product they were evaluating.

The FDA disclosed roughly 1% of these corporate connections.

The situation concerns critics. “Undisclosed conflicts raise questions about the decision-making capacity of the committees and whether the public can have confidence in their recommendations,” said Joseph Ross, an associate professor at Yale School of Medicine.

The FDA follows the committees’ advice in a large majority of instances, on prescription drugs as well as on medical devices. On devices, it has convened more than 20 meetings this year for recommendations on whether to approve novel products or put new regulations on older ones.

The issue arose most recently in July regarding a panel
evaluating surgical tools called power morcellators that cut up uterine fibroid growths. A gynecologist stepped down from the panel not long after the Journal inquired about payments he had received from a maker of the devices, a connection the FDA hadn’t disclosed.

The FDA said under current law and policy, it discloses advisers’ financial interests only when it has determined the experts need a waiver in order to serve.

In making this determination, it has discretion. Having done paid work for a medical-device company doesn’t disqualify a doctor or scientist from sitting on an advisory panel, nor require public disclosure, as long as the work wasn’t related to the specific topic or product the panel focuses on, FDA officials said.

Current consulting work that is directly related to a panel topic is typically a disqualifying conflict, as is ownership of a large amount of the device maker’s stock, said FDA Associate Commissioner Jill Hartzler Warner. Still, if the FDA believes the individual’s expertise can’t be found elsewhere, it can issue a waiver.

It posts such waivers on its website. The agency said it can’t reveal any other financial ties or potential conflicts because what its scientific advisers tell it is confidential.

“Our challenge and our goal is to retain public confidence in the advisory-committee process and at the same time to obtain the very best advice,” Ms. Hartzler Warner said.

“If you have a financial interest with a sponsor or a related firm, but it’s not related to the product at the meeting, it’s not disqualifying,” she said. “The firms are often large and diverse, and whatever position the FDA takes, it won’t affect the relationship between the firm and the expert adviser.

Doctors said their consulting work doesn’t affect their panel decisions. “I’ve never sat there on a panel and thought, ‘I wonder what my friends at companies X, Y and Z would say.’ I just don’t view it that way,” Dr. Kandzari said.

In the panel in October, he voted to approve a heart device from Boston Scientific, a firm that has paid him between $5,700 and $8,190 in consulting fees and expenses for food, travel and lodging since 2011, according to company data. The consulting didn’t concern the kind of device the October panel evaluated, so it posed no conflict, he said.

Dr. Kandzari confirmed he has consulted for various device makers. He questioned the accuracy of payment data posted by companies, saying, among other things, that some payments were actually made to his employer.
The Food and Drug Administration, based in the Silver Spring, Md., offices above, uses some advisers on medical devices who have served as device-maker consultants, including Drs. David Kandzari, upper right below, and Andrew Brill; FDA executive Jill Hartzler Warner said the agency seeks to retain public confidence while obtaining the best advice.
As for Boston Scientific, it said that device makers “are not consulted, or engaged in any way in the selection of panel members.”

The FDA said broader disclosure could discourage people from sitting on advisory panels. The agency already has a challenge getting highly qualified experts to sign on, Ms. Hartzler Warner said. Edward Y. Cheng, an orthopedic surgeon at the University of Minnesota Medical School and Cancer Center, said doctors have a strong financial disincentive to serve because they must take time away from their practices.

Among ties not disclosed by the FDA were $6,666 in consulting fees Dr. Cheng received from a maker of all-metal hip implants a year before he sat on a panel evaluating the safety of that type of hip. Dr. Cheng said the work was unrelated to all-metal hips.

Dr. Cheng said it is the FDA’s job to gauge whether a conflict exists but added: “if I personally thought a conflict existed that would affect my ability to remain unbiased, I would decline to participate.” The FDA said it doesn’t comment on individual panel advisers or their finances.

There is no central way for the public to learn of ties between panel members and makers of medical devices or drugs, which pay hundreds of millions of dollars a year to physicians in consulting, speaking and other fees, according to data from the Centers for Medicare and Medicaid Services. Concerns that such ties could affect doctors’ medical decisions have led to calls for greater transparency.

Many large drug and device companies post their payments to doctors online, often as part of legal settlements over fraud allegations. Some states, including Massachusetts and Vermont, post payments to physicians in their areas.

Doctors often must disclose potential conflicts when writing for scientific journals or giving presentations at medical meetings. The federal government this year launched a database called Open Payments, which so far has five months of 2013 data on company payments to doctors and teaching hospitals. The Journal used all these sources as well as archives maintained by PharmaShine, a service of Obsidian Healthcare Disclosure Services LLC.

No database reveals doctors’ and medical scientists’ stockholdings, so any search can give only a partial picture of financial ties.

The Journal’s tally of payments to members of panels on cardiology, orthopedic and gynecology devices in 2014...
found that 64% received no value from device makers in the past five years. The rest did, varying from less than $15 for food and beverage to more than $500,000 in research funding.

Of doctors who received something from companies, 32% got less than $500 in value and 26% received $10,000 of value or greater.

Before advisory-panel meetings, the FDA asks potential members to report all financial ties, including consulting fees, research grants and stock, in companies with business before the panel and their competitors. In general, if the value of current interests exceeds $50,000, a person will be excluded, said an FDA guidance document.

If the agency decides a payment isn’t truly a conflict, it can issue what is called a “502 authorization” letting the person serve, said Ms. Hartzler Warner.

The 502 authorizations, unlike waivers, aren’t publicly disclosed.

The FDA declined to say how many 502 authorizations it issues annually.

“The problem with the FDA’s policy is you don’t know how they use their discretion,” said Celia Wexler, a lobbyist for the Union of Concerned Scientists, a group that opposes political interference in scientific and regulatory matters.

“It’s very difficult for us to know to what extent the FDA probes, and the extent to which panel members take the disclosure requirements seriously.”

Shortly before the July panel on morcellator surgical devices — which reviewed concerns they could spread hidden uterine cancers — the Journal discovered that panel member Andrew Brill had received nearly $100,000 in consulting fees in 2013 from Johnson & Johnson, then the largest maker of morcellators. The information was on a J&J-run public database, which also shows that another J&J unit paid $6,000 to Dr. Brill in 2013.

Dr. Brill resigned from the panel just before it met. The FDA said he recused himself because of his financial interests with companies. It declined to discuss why it initially appointed him to the panel. Dr. Brill declined to comment.

Documents posted on the website of the American As-

---

**Paid Experts**

Of the 53 doctors and scientists who sat on FDA panels for orthopedics, cardiology or gynecology medical devices in 2014, more than a third received compensation of some kind from device companies from 2009 to 2013.

<table>
<thead>
<tr>
<th>REMITTED COMPENSATION</th>
<th>NO COMPENSATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>36%</td>
<td>64%</td>
</tr>
</tbody>
</table>

Value of compensation received 2009-2013

<table>
<thead>
<tr>
<th>$1-$499</th>
<th>$500-$9,999</th>
<th>$10,000-$516,000</th>
<th>UNKNOWN</th>
</tr>
</thead>
<tbody>
<tr>
<td>32%</td>
<td>26%</td>
<td>26%</td>
<td>16%</td>
</tr>
</tbody>
</table>

*Consulting fees, research grants, free food, travel and lodging.

Sources: Federal, state and corporate data; panel member disclosures. The Wall Street Journal.
sociation of Gynecologic Laparoscopists show Dr. Brill also had ties to another morcellator maker, Karl Storz GmbH of Germany, for which he was a consultant and speaker in 2012.

Another corporate connection the FDA didn’t disclose: Dr. Brill sat on a panel examining risks of surgical mesh products, which are used to support internal organs and treat urinary incontinence, in 2011 — a year when he received $82,600 from J&J subsidiaries, including one that makes surgical mesh. The information is on J&J’s website.

J&J declined to comment. It pulled its morcellators from the market earlier this year. Karl Storz didn’t respond to requests for comment.

Keith Isaacson, a doctor who served on the morcellator panel, had received nearly $12,000 in consulting fees from a J&J subsidiary in 2013, the Journal reported in July. Further review of databases shows that Dr. Isaacson also got $9,500 from J&J from 2010 through 2012 for consulting, food and education and training; and that he received $148,400 in consulting fees and other compensation from Karl Storz from 2009 through 2013. The information came from websites of J&J, a Massachusetts health agency and Open Payments.

At the panel’s meeting, Dr. Isaacson expressed doubt about data showing that women getting surgery for fibroids have a 1 in 350 chance of having malignant tumors that morcellators could spread, a panel transcript shows. He noted a recent study that found the risk was closer to 1 in 7,450.

Dr. Isaacson declined to comment. The FDA wouldn’t discuss the payments or why it placed Dr. Isaacson on the panel in view of these corporate ties.

Dr. Kandzari, the cardiologist who served on an October FDA panel evaluating a heart device, is the director of interventional cardiology and chief scientific officer at Piedmont Heart Institute in Atlanta. He has published many medical-journal articles. He said his consulting for device companies is aimed at helping firms design more-efficient clinical trials.

One FDA panel Dr. Kandzari sat on last year considered a pacemaker and a defibrillator made by Medtronic Inc. That is a company from which Dr. Kandzari received between $76,600 and $130,600 for consulting work, teaching, travel, lodging and meals from 2010 through 2013, according to company and federal databases. A panel transcript shows...
he abstained from voting on whether to approve expanded use of the devices because he wasn’t sure whether the benefits outweighed the risks.

Dr. Kandzari said his past consulting for Boston Scientific, the maker of the device that was being evaluated at the October panel, had concerned an arterial stent. The October panel focused on a different Boston Scientific product: a plug that seals a heart appendage to cut the risk of strokes caused by clots.

That plug, called the Watchman, had been backed by previous FDA panels but was being reviewed again because a study showed patients receiving it had more strokes caused by blood clots than patients getting the blood thinner warfarin.

While the panel in October deemed the device safe, a narrow majority that included Dr. Kandzari judged it not as effective as warfarin. Still, he voted yes in a 6-5 panel vote concluding its benefits outweighed its risks, tantamount to a recommendation of marketing approval.

Dr. Kandzari said despite his concerns that “stroke was not necessarily reduced with this technology,” he believed it should be available for patients who are at high risk of complications from warfarin.

Following the advisers’ vote, Boston Scientific told analysts it expected the Watchman to win FDA approval in the first half of 2015 and eventually reach $500 million in yearly sales.

Andrea Fuller contributed to this article.