

Device lawsuits plague Cook Medical

At least 560 patients have sued the Bloomington firm

By **John Russell**
jrussell@ibj.com

The lawsuits against Cook Medical began four years ago with a trickle but have since turned into a gusher, now surpassing 500.

Patients around the country say the company's blood-clot filters—small, cage-like devices inserted into blood vessels to prevent blood clots from reaching the lungs—have broken apart, moved or poked through a vessel.

Some of the patients complain of pain, infections and the need for several surgeries to recapture the filter. At last count, 560 patients had sued—up sharply from about 100 last summer.

The lawsuits are casting a harsh glare on Cook Medical, a pioneer in medical devices and one of

Indiana's largest privately owned companies, with annual sales of \$2 billion and a global workforce of 12,000.

The Bloomington-based manufacturer already has had its hands full dealing with product-quality issues.

It has issued five recalls since 2014, the latest just last month, when it recalled more than 4 million catheters after receiving reports of tips splitting or breaking, requiring surgeons

See **COOK** page 24A



Cook's Marsha Lovejoy says the company's IVC filters "are not defective in design or manufacturing."

IBJ photos/Eric Learned



On the move

Volunteer 'ambassadors' spread word about \$27M transit center, route changes

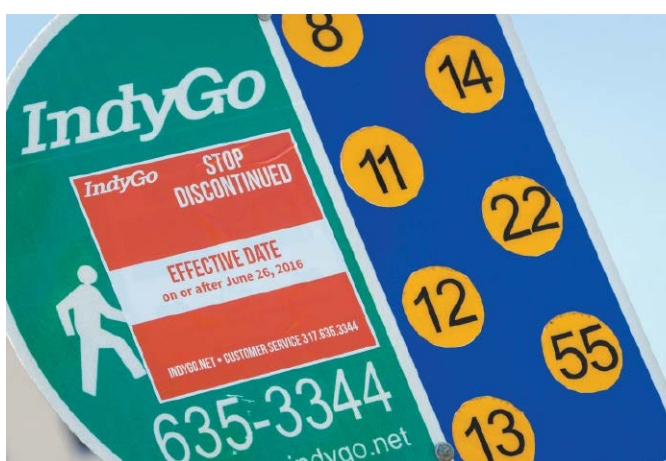
By **Susan Orr**
sorr@ibj.com

IndyGo is hitting the streets—but not by bus.

Teams of IndyGo volunteers, called "transit ambassadors," are on foot at bus stops around the city, spreading the word about big changes that will affect all 31 of the system's routes.

The changes coincide with—and many are actually caused by—the June 26 opening of the \$27.4 million Julia M. Carson Transit Center, which will serve as the transfer station for nearly every route.

For almost a month, teams of volunteers have been visiting bus stops three days a week. But with the changes imminent, the volunteers are on the move every day, boarding buses to



Stacey Carter, left, reviews route changes with IndyGo volunteer Liz Cleland. Some bus stops that will close altogether on June 26 are marked with stickers to alert riders.

connect with riders there. During peak crunch time, some 80 or so IndyGo employees will join them in the task.

"IndyGo has never done anything like this before," said Jerome Horne, IndyGo's community engagement coordinator.

One Monday afternoon, Horne met with a group of volunteers, each wearing a turquoise shirt with the phrase "Ask me about transit" printed on the back. Many are IndyGo riders.

As the volunteers prepared to fan out among bus stops along Ohio Street and Capitol Avenue, Horne gave brief instructions on interacting with riders.

See **TRANSIT CENTER** page 23A

Utility post sits open as cases stack up

Pence must first pick chair for nominating commission

By **John Russell**
jrussell@ibj.com

The ideal candidate is fascinated with electrical grids and has the patience to sit through long hearings on pipeline safety, underground transformers and solar power.

And for someone who likes utility rules and regulations, an appointment to the powerful Indiana Utility Regulatory Commission is a dream job, and the pay isn't shabby: about \$115,000 a year.

Yet for more than two months, one of the five seats on the agency has remained empty as the workload piles up. The state has not even put out a call for interested candidates.

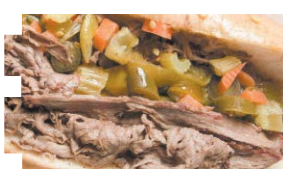
That's despite a law that requires a bipartisan committee to review applications and submit names of three candidates to the governor within 40 days of the vacancy. That deadline passed nearly three weeks ago.

Some longtime utility observers are wondering what's taking so long to bring the commission up to full strength, and whether that will delay important decisions.

The influential IURC hears hundreds of utility cases a year and regulates \$14 billion worth of electric, natural gas, telecommunications, steam, water and sewer utilities. It determines rates and charges, environmental compliance plans, financing and bonding—issues that affect millions of ratepayers and scores of utilities.

The agency has a full agenda, with petitions worth hundreds of millions of dollars hanging in the balance for grid upgrades, efficiency programs, environmental improvements for power plants and other issues. Indianapolis Power &

See **IURC** page 24A



Ivy-leaguer
New Zionsville pub is steeped with Cub lore. **29A**

Stocks
Kim: Don't let fear drive investment choices. **17A**

Lists
Public companies **5B**
Private companies **9B**

Departments
People **12A** Not-for-Profit **18A**
Classifieds **19A** Records **18A**

COOK

Continued from page 3A

to retrieve them from inside the patient.

Cook makes more than 16,000 products—from stents to hernia-repair devices. The company declined to say how big a percentage of sales the filters represent.

For its part, Cook says its filters are safe and help save thousands of lives a year for patients who are at risk for pulmonary embolism, or blockage of an artery in the lungs.

Nationally, 100,000 people die each year from pulmonary embolism, according to the Centers for Disease Control and Prevention.

About 200,000 blood-clot filters—also known as inferior vena cava filters, or IVC filters, for short—are implanted nationwide each year. The market for IVC



“Five hundred lawsuits doesn’t strike me as a lot. You can get into the thousands.”

David Orentlicher, physician, IU law professor

filters is \$435 million, according to market research firm Axis Research Mind.

“IVC filters are an important option for physicians trying to prevent this life-threatening condition,” said Marsha Lovejoy, Cook Medical’s global manager of corporate content strategy. “We are dedicated to providing life-saving treatment options for patients.”

Cook is one of the nation’s largest makers of blood-clot filters, although it declined to say how many it sells a year.

It is one of three leading firms in the industry, along with New Jersey-based C.R. Bard Inc. and the Cordis subsidiary of New Jersey based Johnson & Johnson. A separate series of suits against C.R. Bard has been consolidated in U.S. District Court in Arizona.

The hundreds of lawsuits now sprouting up against Cook are sure to cost the company large sums to defend itself—and possibly millions of dollars more if a jury makes a big award, or the company decides to settle.

And some plaintiff’s lawyers say Cook is showing signs that it plans to settle at least some of the claims. In February, Cook hired attorneys from Faegre Baker Daniels in Indianapolis as “settlement counsel”—a term used for attorneys who

specialize in resolving disputes quickly and under favorable terms.

“To me, that sends a strong signal that Cook is looking carefully at these cases, seeing which ones have the most merit, and separating the wheat from the chaff for a settlement,” said Moze Cowper, an attorney in Austin, Texas, who is representing a Utah woman who claims she was injured from a manufacturing defect in a filter implanted in 2015.

But Cook said it has no plans to settle the cases. The company hired settlement counsel as a “routine response,” Lovejoy said.

“Courts routinely require parties to participate in settlement conferences like this one early in the proceedings,” she said.

She added: “Cook’s IVC filters are not defective in design or manufacturing. We will vigorously defend against those claims.”

See next page

IURC

Continued from page 3A

Light Co., for example, just filed a case asking permission to pass along \$100 million in costs for pollution controls on its Petersburg coal-fired power plant.

“I can’t imagine how four commissioners can manage the caseload,” said Jodi Perras, Indiana representative for the Sierra Club’s Beyond Coal Campaign.

The commissioners often split up the workload, with one commissioner and an administrative law judge overseeing small cases. Bigger, more complicated cases can get several commissioners assigned to them. Last year, the commission issued 335 orders, or nearly one a day.

The longer a vacancy remains open, the longer it could take for utilities to get a hearing, or for interested parties, such as consumer advocates, to get evidence considered.

“With fewer commissioners, that means each one has to attend more hearings, and that could arguably slow things down,” said Tim Stewart, a utility lawyer at Lewis & Kappes, which represents large industrial buyers of electricity, such as factories and shopping centers. “It would be a good thing to get this filled quickly.”

The current vacancy occurred in April when Carolene R. Mays resigned after Gov. Mike Pence appointed her executive director of the White River State Park Development Commission, an organization that operates 250 acres of state property on the east and west sides of the White River downtown.

Mays had served on the IURC since 2010. She was previously publisher of the Indianapolis Recorder newspaper and the Indiana Minority Business magazine.

The delay in filling the vacancy is

caused, at least in part, by the fact that the nominating committee that screens candidates does not have a chair. The previous chairwoman, Gwen Horth, resigned last year after Pence named her chairwoman of the Indiana Parole Board.

“We are completing the background check on a new chair and anticipate having the new chair in place soon,” Kara Brooks, a Pence spokeswoman, told IBJ. “Once the new chair is appointed, the nominating committee will meet to determine the timeline for filling the current vacancy on the commission.”

But not just anyone can apply. Under state law, no more than three of the five commissioners can belong to one political party. Today, three of the four current commissioners are Republicans: Carol Stephan, Angela Weber and Jim Huston, all of whom were appointed by Pence in 2014.

The only Democrat is David Ziegner, a lawyer appointed in 1990 by Gov. Evan Bayh.

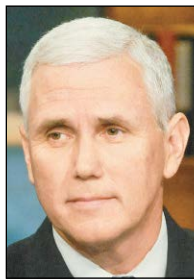
That means the current vacancy must be filled by a Democrat. It also means the longer the seat remains unfilled, the longer the Republicans have a 3-to-1 sway on the commission.

Some Democrats say that deprives the commission of robust discussions on such issues as alternative energy, energy efficiency and how to structure utility rates among various classes of customers.

“For example, certain commissioners will be more sympathetic to business, or to low-income customers, or municipalities, or to the utilities,” said Kerwin Olson, executive director of Citizens Action Coalition of Indiana.

Several large utilities, including IPL, Citizens Energy and Duke Energy, either declined to comment or did not return phone calls.

“The Democratic viewpoint is underrepresented on the commission, and I would say that hurts consumers and envi-



Pence

What the law says

Carolene Mays resigned from the IURC more than two months ago to become executive director of the White River State Park Development Commission. Indiana law says a bipartisan nominating committee recommends candidates to fill such a vacancy. But the committee has been without a chair since Gwendolyn Horth was appointed to the Indiana Parole Board in February 2015.

Steps for filling a vacancy:

- The governor “**shall promptly notify**” the chairman of the nominating committee.
- The chairman must call a meeting **within 10 days** and announce that candidates should notify the committee of their interest.
- The committee must submit three names to the governor “**no later than 40 days** from the time the vacancy occurs.”
- The governor **appoints a replacement** from one of those candidates, or can reject all three names and ask for three additional candidates within 40 more days.

Sources: Indiana Code, Indiana Utility Regulatory Commission

ronmentalists,” said Laura Arnold, president of the Indiana Distributed Energy Alliance, which advocates for renewable energy. She applied for a spot on the commission more than a decade ago, and finished among the top three candidates, but did not win the appointment.

And some environmentalists say the commission needs someone who will stand up to large utilities, some of which are operating decades-old coal plants.

Indiana Michigan Power Co., for example, is asking the IURC for permission to add \$230 million

in controls on its Rockport coal-fired plant, one of the biggest carbon polluters in the nation, as part of a plan to have the plant continue burning coal until at least 2035.

“There needs to be a balance of perspective and viewpoints on the commission,” said Perras of the Sierra Club. “This vacancy needs to be filled by a good candidate as soon as possible.”

About the agency

The Indiana Utility Regulatory Commission regulates \$14 billion worth of electric, natural gas, telecommunications, steam, water and sewer utilities. It approves rates paid by millions of households, businesses and schools. It has five commissioners (one seat is currently vacant) and a professional staff of about 75, including accountants, economists, engineers and attorneys.

Commissioners

Carol Stephan, chairwoman



Appointed: 2014, by Gov. Mike Pence
Term expires: 2020
Previous jobs: assistant general counsel, IURC; general counsel, Indiana Office of Utility Consumer Counselor; interim deputy director, Indiana Department of Workforce Development

Angela Weber



Appointed: 2014, by Pence
Term expires: 2018
Previous jobs: attorney, Ice Miller; administrative law judge, IURC; Marion County deputy prosecuting attorney; staff attorney, Indiana Department of Education

Jim Huston



Appointed: 2014, by Pence
Term expires: 2017
Previous jobs: chief of staff, Indiana State Department of Health; executive director, Indiana Office of Faith Based and Community Initiatives; Indiana assistant deputy treasurer

David E. Ziegner



Appointed: 1990, by Gov. Evan Bayh
Term expires: 2019
Previous jobs: general counsel, IURC; staff attorney, Indiana Legislative Services Agency

Sources: Indiana Code, Indiana Utility Regulatory Commission

Copyright of Indianapolis Business Journal is the property of IBJ Media and its content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder's express written permission. However, users may print, download, or email articles for individual use.