

SCRUTINY

Continued from Page 1A describing Arden's first pacemaker implant there, in February 2016.

She now works at Providence Medford, where, as of press time, she was accepting new patients.

Providence Health's communications director, Gary Walker, declined to comment on the allegations in the dismissed lawsuit, but said Arden has not done any pacemaker surgeries in Medford, and "a review of our data at Providence St. Vincent and at Providence Medford does not reflect any questions about services performed."

Asked about her hiring in Medford, he said, "We don't discuss an individual's hiring process, but I can tell you that we make every effort to review all available information before hiring any position."

Asked whether the hospital system would do further research now that it had seen the lawsuit, Walker declined to comment.

"We can't comment specifically on the case of one caregiver," he said. "We can tell you that, as a learning organization, Providence uses all the information and data available to make sure we are providing the right care in the right place at the right time for everyone we serve."

'A great success'

Grande Ronde Hospital is a small, 25-bed facility in La Grande that has several outlying clinics and employs more than 700 people, according to its website. A nonprofit, it reported nearly \$106 million in revenue in the fiscal year ending in April 2018.

In February 2016, Arden's implantation of the first pacemaker ever at Grande Ronde was dubbed by the hospital newsletter "a great success."

One year later, the long-time cardiology nurse practitioner, Onwezen, went to work at Grande Ronde and became Arden's assistant.

Onwezen had particular expertise in pacemakers. She also had knowledge of the law.

In 2007, Minnesota federal court records show, Onwezen and two other people sued their former employer, the medical device giant Medtronic, accusing it of offering "illegal kickbacks" as "fraudulent inducements" to doctors and hospitals to promote sales of the firm's cardiac rhythm devices, such as pacemakers and defibrillators.

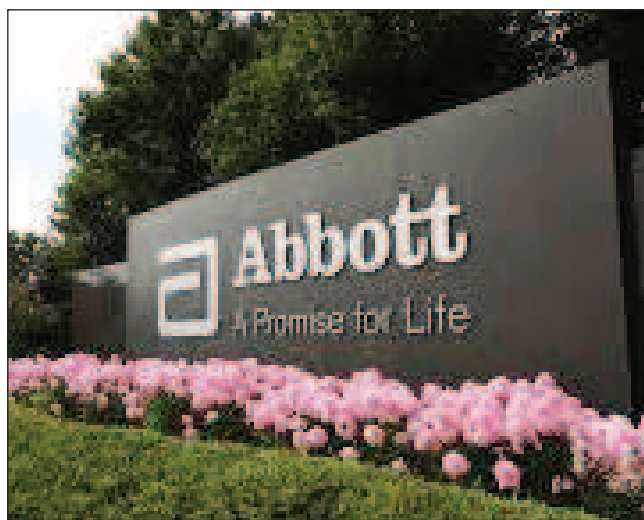
Under the federal False Claims Act, employees of businesses that defraud the government can blow the whistle and file a lawsuit on behalf of the federal government, collecting a percentage of any money recouped — such as from Medicare.

Such whistleblower lawsuits are filed under seal and kept secret while federal officials conduct an investigation, determine whether the allegations are true and decide whether they want to prosecute the case themselves to recoup funds that had been defrauded.

After investigating Medtronic in Minnesota, federal lawyers validated Onwezen's allegations and took over the case's prosecution, extracting a court settlement from the company of more than \$27 million in 2011 — though the firm continued to deny wrongdoing. Court records show that Onwezen and two co-plaintiffs split about \$3 million.

New misconduct claims

Six years later, having moved to Oregon, Onwezen found what she deemed wrongdoing at Grande Ronde.



Courtesy photo

In addition to naming Grande Ronde Hospital, a Aug. 15, 2018, suit also named Dr. Emilia Arden, two pacemaker manufacturers — Abbott Laboratories and Biotronik Inc. — as well as the companies' sales representatives, whom Kathy Onwezen, a cardiology nurse practitioner who worked at Grande Ronde Hospital, claimed had "induced" Arden's surgeries through gifts such as free travel.

According to her suit, she began complaining of misconduct to her superiors after just a month on the job, in March 2017. She tendered her resignation in June, only to withdraw it after hospital management promised to investigate, according to the suit.

She eventually left for good in April 2018, claiming the hospital had decided to "cover up Arden's misconduct and protect Grande Ronde's reputation."

In all, Onwezen claimed, "the lives of over 100 patients" were placed "in jeopardy" over the course of a year and a half as a result of "implanting unnecessary pacemakers and failing to monitor them" at Grande Ronde.

In addition to naming the hospital, the Aug. 15, 2018, suit also named Arden, two pacemaker manufacturers — Abbott Laboratories and Biotronik Inc. — as well as the companies' sales representatives, whom Onwezen claimed had "induced" Arden's surgeries through gifts such as free travel.

The sales representatives could not be reached for comment. Biotronik and Abbott did not respond to requests for comment.

In the suit, Onwezen claimed the cardiologist employed improper methods to justify pacemakers, including:

- Arden allegedly replaced a 90-year-old man's pacemaker with an MRI-safe model, even though the pacemaker leads that already were in the man meant he still couldn't undergo an MRI, meaning "implantation would be

pointless and not worth the extra cost."

- That pacemaker, and five more of the same model, were allegedly implanted by Arden over the course of two days after the pacemaker sales representative informed Arden of a promotion that would reward the sales rep — allegedly a personal friend of Arden's — for selling the most in a month.

- Arden allegedly told Onwezen "that Arden had to implant" some Biotronik pacemakers "to get a speaking engagement" and a free trip to a resort in Coeur d'Alene, Idaho.

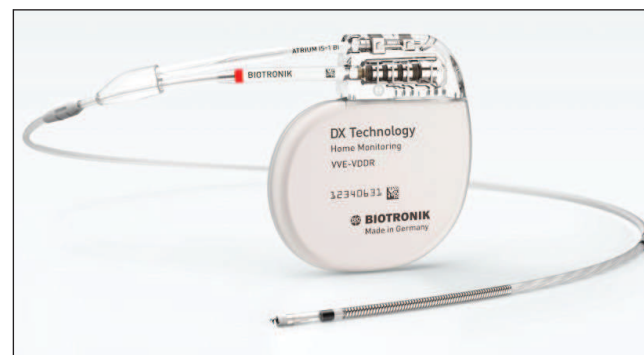
- Arden allegedly justified "pacemaker implantation whenever possible," including by citing a slow-heart-beat condition that sometimes occurs during sleep. Medicare prohibits implantation of pacemakers for that condition during sleep.

- Slow heartbeat, called bradycardia, is a common side effect of taking beta-blocker blood pressure medication, the suit claimed, and "Arden prescribed beta-blockers to her patients purposefully to induce bradycardia. Arden then used this bradycardia to justify the implantation of pacemakers."

- Arden "falsely documented that patients exhibited symptoms justifying pacemaker implantation. In reality, those patients did not exhibit the documented symptoms, and did not require pacemakers."

Cover-up alleged

Onwezen claimed in her suit that she first raised concerns with a cardiology



Biotronik Inc. photo

An example of a pacemaker from Biotronik Inc. According to a 2018 lawsuit, then-Grande Ronde Hospital cardiologist Dr. Emilia Arden allegedly told Kathy Onwezen, a cardiology nurse practitioner who worked at Grande Ronde Hospital, "that Arden had to implant" some Biotronik pacemakers "to get a speaking engagement" and a free trip to a resort in Coeur d'Alene, Idaho.

manager at Grande Ronde Hospital in March 2017. The manager allegedly responded that "she was concerned about Arden's high rate of pacemaker implantations, and ... had heard patients complaining that they did not understand why they had received pacemakers."

Onwezen and the manager allegedly reviewed the pacemaker surgeries, and the manager said "she did not find a single instance in which the pacemaker was necessary for the patient."

The suit claims that Grande Ronde management revoked Arden's authority to implant pacemakers in July 2017, then suspended her in August 2017 while her patient files were sent for further investigation.

The outside review allegedly concluded that Arden did not properly evaluate patients for conditions that would disqualify them for pacemakers; did not have adequate documentation to justify implantations; and that "patients experienced the same or worsened heart conditions after Arden's pacemaker implantation," according to the suit.

Onwezen claims she urged the hospital management to refer Arden's patients to outside cardiologists. But management decided that "such referrals could lead to the discovery that the pacemakers were unnecessary, and thereby damage Grande Ronde's reputation and reduce revenue," the suit alleged.

According to the suit, "Arden's former patients were informed that Arden's absence was due to a family emergency. In reality, Grande Ronde had suspended Arden for misconduct that harmed or could have harmed those

same patients."

In her statement, Mardi Ford, Grande Ronde Hospital's communications director, noted that it made "certain" reimbursements to Medicare over the questioned pacemaker surgeries, and that the case was voluntarily dismissed.

The federal government, which takes over some whistleblower cases in order to recoup defrauded funds, approved the dismissal of the case on Oct. 23, as well as the unsealing of the suit, "based on its determination that such a dismissal is commensurate with the public interest and that the matter does not warrant the continued expenditure of government resources."

Onwezen's former lawyer, Brown, says the investigation shouldn't end there.

"I would be pretty outraged if one of my loved ones was implanted with a pacemaker that they didn't need."

UNION

Continued from Page 1A two garages detached from the houses.

Wiggins said the city is now doing renovation work on one of the rentals and will start work on a second after the first is completed. The three home structures have been rented on a monthly and yearly basis for decades, but once they are restored, the city will begin renting them on a nightly basis. Wiggins said this will make it easier for people visiting Union to find a place to stay overnight.

A long-term goal of the city, Wiggins said after the meeting, is to turn the ranger station into an RV park with a community center building.

The City of Union's preparations for winter were not discussed at Tuesday's meeting but they were addressed in the written City Administrator/Public Works report presented to the councilors and available to everyone attending the meeting.

Wiggins, who has been city administrator since March 15, 2018, wrote that the city is in better shape for winter than at any time since he was hired. He noted that the city's snow-removal equipment for streets now consists of one large plow, a medium-sized plow, a small plow, a road grader, two sanders and a backhoe.

A written report submitted to the city council by Union Fire Chief Tod Hull indicated that the department in October responded to five calls for medical assistance, two motor vehicle accidents and one tree fire.

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Karen King Pendleton, Oregon

I got screened. Now, I'm talking about it.

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