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End of the road for a critical medical device

Cerenovus, which makes Codman pumps, have decided to stop manufacturing it



HEALTH CRISIS: Dr Nancy E Kemeny in her office at Memorial Sloan Kettering Cancer Center in New York. A small, implantable pump made by a Johnson & Johnson subsidiary has been discontinued, with no replacement in sight. NYT

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Denise Grady and Sheila Kaplan

A medical device that can add years to the lives of cancer patients is about to become unavailable because its manufacturer has decided to stop producing it.

The device, the size of a hockey puck, is implanted in the abdomen to pump high doses of chemotherapy directly into the liver for cancer that has spread there, usually from colon or rectal tumors. The treatment can help prevent tumors from recurring after they are removed from the liver and can shrink inoperable growths in the liver so they can be cut out.

The pumps, which cost from \$7,000 to \$11,000 each, are used along with systemic chemotherapy that is dripped in through an intravenous line.

"I don't know what we're going to do," said Dr Nancy F. Kemeny, a medical oncologist at Memorial Sloan Kettering Cancer Center in New York and a pioneer in using the pump. "We have enough for another month or so."

She said her hospital implanted 146 of the pumps last year. Overall, more than 1,000 people have received the devices.

"They've increased survival more than anything else in this disease," Kemeny said.

At least 10 operations to implant the pump at Sloan Kettering have been postponed, according to Dr Michael D'Angelica, a liver surgeon at the hospital. Other medical centers have also advised patients with advanced cancer that the pump may no longer be an option.

At Northwestern University, Dr Ryan P. Merkow said he had only one pump but many patients who needed it. "Now I have to decide who gets this potentially lifesaving therapy," he said. One patient is about to become a father, and Merkow said, "I desperately want to help him."

The devices, called Codman pumps, are

could try to help but did not have the authority to compel manufacturers to sell a specific product.

Another company, Medtronic, makes a similar pump, but it is approved for use in the spine, not the liver. Kemeny said she hoped it could be used for her patients.

Medtronic issued a statement saying, "We acknowledge there is an important medical need for these patients, and physicians should use their best clinical judgment when evaluating the use of any commercially available pump outside of its labeling."

One obstacle is that the Codman pump requires a catheter that the Medtronic pump lacks. It is not clear whether replacement catheters could be obtained or whether the Food and Drug Administration would allow the adaptation.

Patients at Memorial Sloan Kettering who received the Codman pump lived about two years longer than those who did not, Kemeny and her colleagues reported last year, in the *Journal of Clinical Oncology*. They looked at 2,368 consecutive patients with colorectal cancer who had surgery to remove tumors that had spread to the liver. They were treated from 1992 to 2012.

Those who received pumps (785) survived a median of 67 months, compared with 44 months for patients who did not get them (1,583). The result was especially striking,

D'Angelica said, because patients who got pumps were sicker to begin with.

Weak evidence

The report was not based on the strongest type of evidence, which would come from a controlled study with patients picked at random to receive one treatment or another. But the researchers said the evidence was the strongest that could be obtained without a randomised study.

Kemeny began recommending the pump in the 1980s, and Memorial Sloan Kettering has been a leader in its use. Other centers also used it, but many stopped in the mid-to-late 1990s, thinking that improved chemotherapy would make it unnecessary. But there were still patients who needed the pump. Now, just as the device is being phased out, medical interest in it has started to rebound.

Kemeny never gave it up. She said patients came to Sloan Kettering from all over the United States and from overseas for the treatment, referred by doctors or based on their own online searches for help.

Peter Beckerman, 69, a carpenter from Holbrook, New York, said that after surgery for colon cancer, his doctor told him that his liver was covered with tumors and that he had about 20 months to live. But the surgeon also urged him to consult Kemeny.

That was 10 years ago. Beckerman received

The devices, called Codman pumps, are made by Cerenovus, a subsidiary of Johnson & Johnson, which told doctors in a letter dated April 4 that it had decided to stop production effective April 1 "because of significant and multiple raw material supply constraints within the manufacturing process."

Kemeny said that she and other physicians had appealed to the company to keep making the device but that it had declined.

"It has likely saved many lives and prolonged the lives of many more," D'Angelica wrote to the company. "I would implore you to reconsider this decision, if not just for economic or logistic reasons, for ethical reasons."

Mindy Tinsley, a spokeswoman for Cerenovus, said demand was "very low," with sales of about 300 pumps a year in the United States.

"Unfortunately, some of the suppliers that provide the materials, such as titanium rods required for production of these pumps, have elected to exit the business or have found that the required materials are no longer available," she said. The company was still pursuing alternatives, she added, but declined to explain what they were.

Angela Stark, a spokeswoman for the Food and Drug Administration, said the agency

the pump as part of a clinical trial. Gradually, over about a year, his tumors disappeared, and for the past eight years he has had no sign of cancer. "The pump saved my life," he said. "There's a whole lot of people out there in the same boat, doing good because of that pump," he said. "I'm really disheartened that they would stop making it, if it saves one life."

Another patient was 32 and learned just a few weeks after giving birth that she had colon cancer and that it had spread to her liver. She asked that her name be withheld because her child did not yet know she had cancer. Treatment with the pump shrank the liver tumors enough so that they could be surgically removed. Now, 10 years after the diagnosis, she has no evidence of cancer. She said she felt "extremely upset" to hear that the device that saved her life would no longer be manufactured. "I want other people to have the same opportunity I had," she said.

Recently, doctors from a dozen other hospitals in the United States and Europe, and the National Cancer Institute, have visited Memorial Sloan Kettering to learn how to use the pump, Kemeny said. But now, no one will be able to obtain it.

Dr Myron E. Schwartz, a liver surgeon at Mount Sinai in New York, said: "There's a group of patients where we can't figure out what to do. This thing really does work."

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