

National group wants cancer warning labels on acid reflux drugs

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As a kid Charles Rutherford drank milk to soothe the burning sensation after eating peanut butter. As an adult he complained to doctors for years about chest pains only to be told it was due to stress.

Three years ago, the now 59-year-old Rutherford was diagnosed with Barrett's Esophagus, when [stomach acid](#) damages and changes the composition of the lining of the esophagus. Untreated it can lead to esophageal cancer, which is often deadly.

Like many people, Rutherford, had no idea his [acid reflux](#) put him at risk for cancer.

The Esophageal Cancer Action Network, a national organization based in Baltimore, wants that to change. In its latest effort, the nonprofit group known as ECAN filed a citizen's petition Monday with the U.S. Food and Drug Administration asking the agency to require warnings about the [cancer risk](#) of acid reflux on the labels of such over-the-counter medications as Prilosec and Nexium.

Current labels on those drugs warn people to get their doctors' recommendation before taking the medicine. The labels also tell people not to take the medication long term. There is no mention of cancer risk.

"We want something that is much bolder and stronger than is on packaging now," said David Rosen, a lawyer who worked for the FDA for 15 years and is filing the petition on behalf of ECAN.

The petition states that "the warnings should include a stronger, bold and prominent statement that persistent heartburn can be a sign of increased risk of esophageal cancer and explain that drug products do not eliminate that risk."

The drug company AstraZeneca developed both Prilosec, which now is available as a generic called omeprazole, and Nexium.

"AstraZeneca is confident in the safety and efficacy of Nexium when used in accordance with the FDA approved label, which has been established through numerous clinical trials," said spokeswoman Michelle Meixell in an emailed statement that did not specifically address ECAN's request of the FDA.

Neither the Pharmaceutical Research and Manufacturers of America Association nor Pfizer, which makes an over-the-counter version of Nexium, responded to requests for comment.

Auburn Bell, who teaches marketing at Loyola University Maryland, said that most companies wouldn't want a third party directing changes to their packaging.

"It opens it up for others to come in and say that you need this on a label or that on a label," Bell said. "If they say yes to one, will they have to say yes to everyone?"

ECAN's efforts are not intended to stop the use of over-the-counter drugs for treating reflux, Rosen said.

"I don't want to scare people from not buying the medications," Rosen said. "I want them to use it responsibly. If their symptoms persist they need to go see their doctor."

A spokeswoman for the FDA said the agency is reviewing the petition and will respond directly to ECAN.

ECAN members say that many people don't heed the current labels, taking too much of the medication or using it without consulting a doctor.

Sometimes the drugs work so well at relieving symptoms, such as bloating, coughing and irritated throat, that people believe they're fine and don't seek medical treatment. But that doesn't mean the cancer risk no longer exists. The cellular changes in many cases already have taken place and can lead to cancer.

"If you get rid of your symptoms you are not getting rid of your risk," said Mindy Mordecai, who started the esophageal cancer network after her husband died from the disease. "Many people who take over-the-counter medication have no idea that they're at risk."

Dr. Bruce D. Greenwald, a gastroenterologist and professor at the University of Maryland School of Medicine, said he supports the label change so that patients are better informed.

"People sometimes take something over the counter and it gets better and they think they have nothing to worry about," Greenwald said. "We want people aware that if the symptoms exists persistently you need to see your doctor."

Dr. Mark Noar, a Towson-based gastroenterologist also supports stronger labels. He said esophageal reflux is preventable if people are aware of the precautions they need to take.

The drugs "hide the continuing development of the disease," Noar said. "We have people walking around who think they are fine and they are at

risk for cancer."

When people know they are at risk, they can get monitored regularly by their doctor, Noar said.

Paul Campbell, 72, was getting regular endoscopies, or scans of his esophagus, by Noar after suffering with acid reflux for years. As a result, his Barrett's Esophagus was caught and treated early. The diagnosis scared Campbell and his family, who worried he would die. But his most recent scans have come back cancer free.

"I am just glad I could get treated," he said.

To treat patients with persistent reflux, Noar uses a treatment called Stretta, which involves placing a tube down the patient's throat and then applying radio-frequency energy to the weak area between the esophagus and the stomach to thicken and strengthen the barrier. This treatment process prevents food and stomach acid from backing up into the esophagus.

Other surgical treatments include a procedure where a ring known as a LINX device is placed around the outside of the lower end of the esophagus. The ring stops stomach acid from backing up into the esophagus. Another procedure called fundoplication wraps the upper part of the stomach around the lower esophageal sphincter, to make it harder for acid to splash up.

A recent poll ECAN commissioned by research firm Ipsos found that 86 percent of Americans don't know that acid reflux disease can cause [esophageal cancer](#). Only 14 percent of 1,000 people who took the survey were aware reflux could lead to cancer.

The group said that the cancer warnings are needed more than ever

because the number of people with Barrett's Esophagus continues to increase. About three million Americans currently have the condition and more than half don't know it because there aren't a lot of symptoms.

Esophageal [cancer](#) is often only discovered when it has reached advanced stages, when treatment isn't as effective. Most [people](#) find they can no longer swallow because a mass is blocking the [esophagus](#).

The FDA doesn't get many citizens petitions, maybe a couple a year, said Larry Stevens, a former FDA official who works for the FDA Group, a consulting firm of former agency employees.

Stevens said the agency would want documentation that the lack of warning is a public health problem. If it decided a warning label was worth pursuing, the agency would hold a hearing on the issue.

At the very least, ECAN gets their issue in front of the agency, he said.

"It will spark the FDA to look at the issue for sure and that may be what (ECAN) is really after, trying to bring the problem to the forefront," Stevens said.

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