Surgeon Offers Promising Pain Relief Theory

Kim Eaton, *The Tuscaloosa News*

(AP) — There may be treatment on the horizon for patients suffering from fibromyalgia, a chronic pain condition. Clinical trials that may begin as early as February could prove Tuscaloosa-based surgeon Dr. William "Skip" Pridgen's theory that fibromyalgia, other chronic pain conditions, and many gastrointestinal disorders are all caused by the same virus. The trials will also test a pain-treatment therapy for fibromyalgia, the most severe of those.

In addition, Dr. Carol Duffy, a University of Alabama assistant professor in the biological sciences department, will research lab results in the hopes that it will lead to a diagnostic tool for physicians. "Some of these patients' stories are just heartbreaking. They are in a lot of pain, they can't work anymore, are on disability," Duffy said. "There's a real need for this, and I really hope this is the answer. It will give a lot of people a much better quality of life."

Pridgen began developing his theory more than 10 years ago, when he noticed many of his patients with gastrointestinal issues had recurring symptoms that appeared to get worse during times of stress. After some research, he concluded those problems may be caused by the herpes simplex virus, the same virus that causes cold sores, and prescribed an anti-viral drug. At the same time, some of those patients also complained of other symptoms, for which he prescribed another anti-viral medication. When the patients returned, not only were their GI symptoms better, but other problems like depression, chronic fatigue and fibromyalgia were also improving with the drug combination.

Pridgen started working with Duffy, who studies how viruses replicate, in creating a randomized trial that will be funded by a start-up company the two started. Pridgen estimates the Phase II clinical trial, which will involve 140 fibromyalgia patients at 10 sites around the country, will take about a year.

Using blood samples from the clinical trial participants, Duffy will measure cytokine levels. Cytokines are signaling molecules that flow through the body's bloodstream and are produced at different levels and types based on what the body is experiencing. Studies show that patients with fibromyalgia have elevated levels of one type of cytokine and lower levels of another. Because a fibromyalgia diagnosis presently is based on a patient's subjective responses to a physician's questions about their pain, Duffy said by studying the cytokine levels, she can see if there is a correlation between those levels and the patient's reported pain levels.

"If the (clinical trial patients) are on the medication and they improve, then we can hypothesize that their self-reported pain levels will decrease and their cytokine levels will normalize," Duffy said. "Not only will they say they are feeling better, but

there will be some concrete data that shows their levels have stabilized."

If results from the Phase II trial are positive, the next step would be Phase III trials, which involve thousands of patients. Duffy said at that point they will approach pharmaceutical companies about purchasing the patent and those companies will complete the final trials, as well as try for approval to get the drug on the market. "Whoever ends up buying the patent will be able to pursue this treatment for other chronic pain conditions, irritable bowel syndrome, headaches and more," Pridgen said. "If this proves what we think it will, it is going to change the way people think about chronic pain and chronic conditions. It will have a huge impact on a lot of people."

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