

September 27, 2020

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SC Court of Appeals

Ms. Jenny Abbott Kitchings, Clerk of Court
South Carolina Court of Appeals
1220 Senate Street
Columbia, South Carolina 29201

Reference: Appellate Case No. 2018-001842
Thelma R. Garrick v. Dr. George H.
Khoury and Bon Secours Roper St.
Francis W. Ashley, Charleston, S.C.

Dear Ms. Kitchings:-

Enclosed you will find additions to the Supplemental Records on Appeal. This information has recently come to light concerning my health; therefore, it is very important that this be entered into the record. It will not alter the dismissal of the case in lower court No. 2018-CP-10-01163 but will definitely have a strong bearing on the final decision making of the Appellant Court in this case.

My health continues to deteriorate. All continues to be a part of what has been previously filed. This means further damage to the spine and complications thereof from the implants in my spine. The complete changes will come after seeing a surgeon on October 1, 2020 regarding the swelling in my neck and throat. At this time I will only technically give you the information from the FDA stating they had sent out a Notification to health care providers and surgeons who once performed the operations. This notification was issued in 2008, long before my surgery. The Neurosurgeon knew of this in 2015 but still proceeded with the surgery anyway. Of course, this is only one of many complications I live with daily.

"Unapproved Use of the Medtronic Infuse System"

"The only INFUSE Bone Graft surgical technique that is FDA-approved is a procedure that operates through the abdomen. This procedure minimizes injury to the back muscles and nerves. Even so, Doctors have inadvisably used INFUSE in procedures not approved (off-label) by the FDA. Complications.

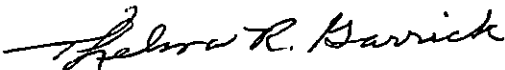
In 2008 the FDA issued a Public Health Notification to health care providers and surgeons regarding serious, even life-threatening complications arising from the unapproved (off-label) use of Infuse in cervical (upper back) spinal fusion. The FDA received dozens of reports of serious complications, including swelling of neck and throat tissue, which resulted in compression of the airway, and neurological structures in the neck.

This has led to serious emergency medical intervention. Patients who suffered these events needed respiratory support, or even a tracheotomy. The FDA reiterated that "safety and effectiveness" have not been demonstrated and "these products are not approved for this use."

There is MRI's showing loose screws and bone fragments from the operation. (There are thousands of people suing Medtronic with only one of these implants. I do not believe they thought I would survive because it is unthinkable that I came through with three defective implants in the spine when they have had deaths with only one implant.

I appreciate the filing of this evidence of complications happening from the Medtronic Infuse BMP Bone graft device, the LT-Cage and the ISOMED pain distribution port in the Lumbar.

Yours truly,



Thelma R. Garrick
195 Crescent Oaks Court
Orangeburg, South Carolina 29115
(803-534-9912)

/tg

The Honorable Judges of the Appellant Court
Mrs. V. Claire Allen, Deputy Clerk
Attorneys for the Respondents, Young Clement Rivers, LLP
Mr. Russell Hines, Mr. Joseph J. Tierney, Jr., and Mr.
Stephen Brown, Attorneys at Law
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PPS: I found out today, September 27, 2020 that Case No. 2018-001842 is ready for Consideration, therefore, wanted this to be made a part of the case.
Please advise if this is permissible.

Thelma Garrick
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Orangeburg, S.C. 29115

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