

February 3, 2021

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SC Court of Appeals

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

Reference: Appellate Case No. 2018-001842
ORDER dated Feb 01 2021

TO: The Honorable Judges of the South Carolina Court of Appeals,
and Ms. Jenny Abbott Kitchings, Clerk.

Dear Ms. Kitchings:

I received this day, February 3, 2021; the ORDER to deny my Motions dated October 28, 2020 that were as follows:

1. Request to correct the error the Court had made concerning why Appellant had filed her case; not according to the court records or as the attorneys indicated. Even though Appellant had pointed this out in many documents the Court never corrected.
2. Motion to add an addition to the Supplemental Records regarding the implementation of the Medtronic Infuse BMP device. (Even after the FDA in 2008 had notified the medical field not to use the Medtronic BMP Infuse Device in the cervical spine, seven years later (2015) this was ignored and the device was implanted into my cervical spine. Again, Proof Positive of the illegal actions of the doctor and hospital. (See attachment)

Appellant does not understand why this supplemental record was not added. Previously she had been advised by the Clerk of Courts office that she could send supplemental records until a decision had been made by the Judges.

These motions, if not accepted, give the attorneys for the Respondents a license to win the case. This cannot be legal. The most critical part of this case, and I had not heard that the Court had made any kind of decision. Here again following the rules, Appellant did not add anything new to the case except the FDA notification date the Respondents were informed not to implant the Infuse BMP device.

Also the Motion for the court to correct their mistake regarding why Appellant filed her case was illegal and should have been corrected in the lower Court or corrected when she filed with the Appellant Court. The Court made a mistake in filing my case under the lawyer's reason and not the Appellants. Please explain how a Court error so large can be denied?

Appellant Pro Se does not feel that she has been fairly advised of the Court's actions. (Appellant not hearing from the Court, partly due to the Corona Virus, had a friend check her computer to see if there was any information about the case. She learned that documents had been forwarded to a panel for consideration.) Appellant contacted the Clerk of Court's office in October and requested a copy of the documents because from the list it was almost impossible to know what had been submitted. One of the documents had been submitted for the attorneys without Appellant's rebuttal. Therefore, she needed to know exactly what had been given for consideration. (Even though she forwarded funds for the documents she still has not received them.)

Appellant would like the name of the individual who signed the order for the Court; denying my motions to be added as part of my Supplemental Records, the name was illegible, with no title. Also the Appellant would like to know if anyone from the Court has discussed this case with the attorneys without her being present? Therefore, Appellant wishes to Appeal the decision of the Court Order dated February 1, 2021. Is a Motion required?

Appellant is very sorry the Honorable Judges did not get to see these documents because they were a summation of all documents, making it easy to see all issues of the case.

Appellant would also state she feels she has not been fairly updated on the issues of the case. Therefore, Appellant requests a meeting concerning the Order to Deny her motions with the Honorable Judges and lawyers for the Respondents so that all parties may be updated on exactly what is going on with this case. I look forward to your response and thank you in advance for your consideration.

Yours truly,



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

/tg

Separate Copy is being mailed to the Honorable Judges.

Cc: Ms. V. Claire Allen, Chief Deputy Clerk
Attorneys for Young Clement Rivers LLP
Mr. Stephen L. Brown
Mr. Joseph J. Tierney, Jr.
Mr. Russell G. Hines,

The South Carolina Court of Appeals

Thelma R. Garrick, Appellant,

v.

Dr. George H. Khoury and Bon Secours St. Francis West
Ashley, Respondents.

Appellate Case No. 2018-001842

ORDER

Appellant's motion to supplement the record on appeal and motion to correct are denied.



FOR THE COURT

Columbia, South Carolina

cc:

Thelma R. Garrick
Joseph John Tierney, Jr., Esquire
Stephen Lynwood Brown, Esquire
Russell Grainger Hines, Esquire

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Feb 01 2021

STATE OF SOUTH CAROLINA
SOUTH CAROLINA SUPREME COURT
IN THE COURT OF COMMON PLEAS
COUNT OF CHARLSTON

Civil Action No. 2018 CP 10 1163

Thelma R. Garrick
195 Crescent Oaks Ct.
Orangeburg, South Carolina 29115
Telephone No. 803-534-9912

Plaintiff

VS

Dr. George H. Khoury MD
Bon Secours St. Francis, West Ashley
2145 Henry Tecklenburg Drive
Charleston, South Carolina 29414
Telephone No. 843-723-8823

Defendants

Complaint

2018 MAR -5 PM 12:29
JAMES L. ANDERSON
CLERK OF COURT
BY _____

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Doctor-Patient Relationship

Plaintiff's medical doctor made an appointment with Dr. George H. Khoury (here-in after known as Doctor) in 2011 from a spinal stenosis diagnoses. This resulted in surgery on April 12, 2011 (record not in medical file), and several weeks later a lumbar disk ruptured requiring another surgery on October 20, 2011 to replace disk with cadaver bones and grafting. After this surgery at Bon Secours St. Francis (here-in after known as Hospital) Plaintiff had slight problem with left sciatic nerve. Over time, pain escalated from the back down leg below the knee and at times into the groin. Plaintiff contacted Doctor in December 2014. X-rays and MRI of the entire spine was ordered by Doctor on 1-30-15. After being unsuccessful in trying to get out of having surgery again the surgery was scheduled on June 22, 2015 for August 20, 2015. Dates of all appointments outlined on personal calendar.

Surgery discussion between Defendant and Plaintiff

A fusion would be done to relieve pressure on left sciatic nerve. Date was set for August 20, 2015. There was no other pain. Only discussion with Doctor.

Reason for Case

Let me first say that I am not an attorney nor do I claim to be. I therefore ask the Court to be a little lenient. Thank you.

My reason for this case is to expose a Doctor and Hospital that there are consequences of their actions in experimentation and deceit no matter what their reasons for posterity or gain.

Complaint

Doctor performed major back surgery using medical devices for experimentation and benefit. Doctor premeditatedly, willingly, knowingly implemented experimental devices and medication known for it's permanent, debilitating injuries without Plaintiff's knowledge or permission.

Permanent physical and emotional damage done from the experimental devices inserted into the spine have caused pressure on all nerves resulting in spasms, and cramps above and below waist with any twisting of body thus causing constant pain. The pinched left sciatic nerve was never repaired causing even greater pain and often sharp knife-like pain when turning or twisting. Placing the large distribution port (still do not know name) into the lumbar spine when it did not have the depth required for this implant, and the Doctor knew of Plaintiff's medication allergy that was to be used to test this device; the Plaintiff was never a candidate.

Six months after the surgery during a visit in the Trident office on March 7, 2016, Plaintiff informed Doctor that she did not understand she was getting worse instead of better. The Doctor replied, "Your body is rejecting what I put in you." The next appointment was on April 18th and turned into a massive cover-up.

History Before Operation of August 20, 2015

Called Doctor in December about sciatica pain. Appointments:

January 16, 2015, left sciatic pain

January 30, 2015, MRI and x-rays (available)

February 2, 2015, follow-up on results

February 25, Pain clinic, shot of steroids (Had one but due to severe reaction cancelled others.)

March 16, 2015, follow-up, advised Doctor of reaction to shot

April 27, 2015, follow-up

May 20, 2015, follow-up. (Still trying to keep from having more surgery.)

June 22, 2015, finally agreed to have a fusion to relieve pressure on left sciatic nerve.

Operation date was set for August 20, 2015.

For Judges only,
Others have already
received

T. Garrick

Article 1

Case # 2018-00184



INFUSE LAWSUITS & MEDTRONIC DEFECT INJURY SETTLEMENTS

**Cincinnati, Ohio product liability lawyer and medical
device defect attorney reviewing Continuing Risks with
Medtronic's InFUSE Bone Graft System**

It is estimated that several thousand people have been
injured by Medtronic's InFUSE Bone Graft system since it
was approved by the US Food and Drug Administration
(FDA) in 2002.

The controversial product has been deemed ineffective
and dangerous, and officials

[http://www.mprnews.org/story/2013/06/17/business/medtronic-
infuse](http://www.mprnews.org/story/2013/06/17/business/medtronic-infuse)) at Yale University, after studying data and credible
research, have said the InFUSE device offers little to no
benefit.

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Pages 1 of 8

Early clinical studies, including those reviewed by the FDA, show the InFUSE procedure has the potential to inflame nearby tissues and bone. 15 to 20 percent of people who have had the InFUSE surgery report (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3717531/>) regular pain, primarily in the legs and back.

There is also mounting evidence that the graft procedure stimulates cancer growth, and that higher doses of InFUSE carry a greater risk for developing cancer.

Many thousands of InFUSE recipients, and also most surgeons, were unaware of these possible risks at the time of operation. As a result, ongoing legal action (<https://thelyonfirm.com/practice-areas/medical-device-litigation/>) holds Medtronic accountable for intentionally hiding adverse effects from doctors and their patients.

What are InFUSE Bone Grafts?

Bones grafts are pieces of bone or bone substitute that can replace damaged or diseased bone in a number of joints and bones in the body. The vast majority of InFUSE bone graft operations involve the spine. In spinal fusion, doctors surgically fuse together individual vertebrae, which is meant to eliminate the irritation of nerves in the spine.

Medical implant companies like Medtronic have developed synthetic concentrated protein, called bone morphogenetic protein (BMP), which are injected into the spine to help the body form cartilage and bone, ostensibly to alleviate pain.

This pump is used to insert an InFuse BMP pump that pumps medication into the spine to grow bones. (yes abnormal bones covering spine)

2 of 5

ADDITIONAL MEDICAL DEVICE LITIGATION PRACTICE AREAS

Medical Device Litigation
(<https://thelyonfirm.com/practice-areas/medical-device-litigation/>)

Surgical Staple Injury & Surgical Stapler Lawsuits
(<https://thelyonfirm.com/practice-areas/medical-device-litigation/surgical-staple-injury/>)

Defective Catheters & Medical Device Lawsuits
(<https://thelyonfirm.com/practice-areas/medical-device-litigation/defective-catheters-lawsuits/>)

Da Vinci Surgery Lawsuits & DaVinci Injury
(<https://thelyonfirm.com/practice-areas/medical-device-litigation/da-vinci-surgery-lawsuits/>)

Dayton Medical Device Lawyer Reviews Defects & Recalls
(<https://thelyonfirm.com/practice-areas/medical-device-litigation/dayton-medical-device-lawyer/>)

Cleveland Medical Device Lawyer
(<https://thelyonfirm.com/practice-areas/medical-device-litigation/cleveland-medical-device-lawyer/>)

While advancements in synthetic bone graft technology play a welcome role in modern medicine, they can cause a myriad of problems, in some cases even, sterility (http://www.nytimes.com/2011/05/25/business/25spine.html?_r=1), cancer and death. Bone Graft surgeries are not to be taken lightly.

They should be reserved as a last-resort solution to a degenerative spinal condition. In recent years, there have been reports (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3717531/>) of patients being offered "unnecessary" spinal surgery for pain alone, without significantly abnormal radiographic findings.

InFUSE Bone Grafts Complications

Appellant's Complications

(Every day is different)

Bone Grafts are risky, and are associated with dangerous side effects. By spring 2011, the FDA had received hundreds of reports of adverse reactions associated with InFUSE Bone Grafts. Patients have reported the following:

- ✓ *Persistent neck and back pain*
- Back and Leg Pain ✓
- Infection
- Male sterility
- Sexual dysfunction
- Respiratory failure *(short of breath)*
- Excessive bleeding
- Fetal development problems
- Nerve damage ✓
- Urinary problems ✓
- Possible increased cancer risk ✓
- Inflammatory reactions
- Implant displacement and failure ✓
weakness at times ✓
Spasms ✓
Constant pain ✓

Mirena Lawyer Reviewing IUD & Birth Control Injury
[\(https://thelyonfirm.com/practice-areas/medical-device-litigation/mirena-iud-injury-lawyer/\)](https://thelyonfirm.com/practice-areas/medical-device-litigation/mirena-iud-injury-lawyer/)

Medical Device Recalls
[\(https://thelyonfirm.com/practice-areas/medical-device-litigation/medical-device-recalls/\)](https://thelyonfirm.com/practice-areas/medical-device-litigation/medical-device-recalls/)

Essure Birth Control Devices Posed Serious Complications
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Knee Implant Recall Lawyer & Injury Settlement
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Breast Implant Lymphoma Lawsuits
[\(https://thelyonfirm.com/practice-areas/medical-device-litigation/breast-implants-lymphoma-risk/\)](https://thelyonfirm.com/practice-areas/medical-device-litigation/breast-implants-lymphoma-risk/)

Zimmer Biomet Shoulder Implants & Device Injury Lawsuits
[\(https://thelyonfirm.com/practice-areas/medical-device-litigation/zimmer-biomet-shoulder-implants/\)](https://thelyonfirm.com/practice-areas/medical-device-litigation/zimmer-biomet-shoulder-implants/)

- Retrograde ejaculation
- Osteolysis (degeneration of bone tissue) ✓
- Abnormal bone formation ✓

These represent a large range of health issues. Many complications even require a second surgery to correct.

Some studies

(<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3717531/>)

suggest a 40 percent reoperation rate for patients over the age of 65, with a 20 percent non-age specific reoperation rate.

The evidence is now clear how risky these procedures can be. However, since Medtronic and its well-compensated research team misled the public, most of these adverse events were unpublished. The full story

(http://www.nytimes.com/2011/06/29/business/29spine.html?_r=0) was not clear until 2011, when independent doctors came forward with their own observations and studies.

(<https://i1.wp.com/thevonfirm.com/wp-content/uploads/2019/05/accident-adult-african-1539678.jpg?ssl=1>)

Hernia Mesh Injury & Product Recalls

(<https://thevonfirm.com/practice-areas/medical-device-litigation/hernia-mesh-injury/>)

Stryker Recalls Defective Shoulder Implant

(<https://thevonfirm.com/practice-areas/medical-device-litigation/stryker-recalls-shoulder-implant/>)

LivaNova Heater-Cooler Devices Injury Lawsuits

(<https://thevonfirm.com/practice-areas/medical-device-litigation/livanova/>)

Hip Implant Defect Lawsuits & Hip Replacement Injury

(<https://thevonfirm.com/practice-areas/medical-device-litigation/hip-implant-defect/>)

CareFusion AVEA Ventilators

(<https://thevonfirm.com/practice-areas/medical-device-litigation/carefusion-avea-ventilators/>)

INFUSE Lawsuits & Medtronic Defect Injury Settlements

(<https://thevonfirm.com/practice-areas/medical-device-litigation/medtronic-infuse-defects/>)

Transvaginal Mesh Implants

(<https://thevonfirm.com/practice-areas/medical-device-litigation/transvaginal-mesh-implants/>)

Medical Device Corruption

In recent years, Medtronic has faced increased scrutiny for the InFUSE Bone Graft system. In addition to harming thousands of patients with their product, Medtronic is accused of intentionally hiding dangerous side effects. Also, since its FDA approval, there are multiple reports of clinical investigators receiving generous "consulting" payments from the medical product industry, including Medtronic.

In June 2011, the U.S. Senate launched an investigation into these allegations, and revealed that a number of the researchers received royalties and consulting fees from Medtronic.

With the help of an incriminating article published in The Spine Journal ([http://www.thespinejournalonline.com/article/S1529-9430\(13\)00542-1/abstract](http://www.thespinejournalonline.com/article/S1529-9430(13)00542-1/abstract)), the official journal of the North American Spine Society, investigators found that researchers were paid millions to exaggerate the products' benefits and grossly understate the risks.

The Spine Journal report observed that in multiple industry-sponsored trials, patients reported ZERO complications or adverse effects attributed to their own products. However, documents from FDA documents and other published data reveals a large gap in adverse reactions, and exposes the industry's "internal inconsistencies," which ultimately disregarded patient safety for profit.

IVC Filter Lawsuit
(<https://theyonfirm.com/practice-areas/medical-device-litigation/ivc-filter-lawsuit/>)

It is estimated that Medtronic's InFUSE system is used in about 25 percent of the 432,000 spinal fusion procedures a year in the United States. In 2010, they generated almost \$900 million in sales.

Medtronic has a horrific ethical track record. In fact, the US Department of Justice (DOJ) has investigated (<https://www.justice.gov/opa/pr/minnesota-based-medtronic-inc-pay-99-million-resolve-claims-company-paid-kickbacks-physicians>) Medtronic several times. In another incident, Medtronic paid \$40 million to settle a case where the DOJ accused the company of paying kickbacks to doctors as an incentive to use InFUSE and other similar products.

Unapproved Use of the 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 (<http://www.ncbi.nlm.nih.gov/pubmed/21297932>) are so prevalent in some procedures, that many surgeons who once performed these operations no longer recommend it.

✓ 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.

Appellant's neck and
throat is swelling, and
tests are continuing.

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."

Case # 2018-001842

Medtronic Lawusits

(https://i1.wp.com/thelyonfirm.com/wp-content/uploads/2015/08/shutterstock_282701687-e1447423230546.jpg)

If you or a loved one have suffered the side effects of a faulty InFuse system, and have questions about the legal remedies available to improve quality of life and medical care in Ohio, contact The Lyon Firm at (800) 513-2403. You will speak directly with Mr. Lyon, and he will help you answer these critical questions.

Article 2

Case #2018-001842

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SEARCH

Dangers of the Medtronic Infuse Bone Graft

The Medtronic Infuse Bone Graft has been used off label in a number of procedures and has caused serious complications including cancer, neck swelling, airway compression, difficulty breathing, nerve damage, and other life threatening complications.



Infuse Side Effects: Difficulty Breathing, airway compression, neck swelling, respiratory depression, nerve damage, cancer, male sterility, death

Numerous publications have recently reported that the use of the Medtronic Infuse Bone Graft has been associated with major injuries and damages. Bone growth can become rapid and uncontrolled. This bone graft has also been associated with many types of cancer. Off-label use can also result in severe neck swelling, difficulty breath, swallowing and speaking because of airway compression. The bone growth may cause nerve injuries or severe pain in the extremities. Some patients have reported infertility as a result of the implant. 1,2

Recent investigations have discovered that these bone grafts have been used for off-label use and serious complications have resulted. The off-label use involves implantation in the lumbar or cervical spine. Further, surgeons with significant financial ties to Medtronic allegedly failed to disclose these complications in clinical trials and studies. 1,2

FIND MORE LEGAL ARTICLES

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SEARCH

Both congressional subcommittees of Congress and the US Department of Justice have issued subpoenas to Medtronic relating to off-label use of the Medtronic Infuse Bone Graft. Chairman of The Senate Finance Committee, Senator Baucus and Senator Grassley wrote a letter to Medtronic in June 2011 stating:

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"Last year, the Milwaukee Journal Sentinel reported that a Medtronic-funded study published in 2004

found that 75% of bone morphogenetic protein 2 (BMP-2) patients experienced ectopic bone growth, where potentially harmful bone growth occurs outside of the fusion area. The authors, who had financial ties to Medtronic, 'concluded that although not desirable,' the ectopic bone growth 'did not appear to have an ill effect on the patients.' However, in a separate 2008 study conducted by physicians without financial ties to Medtronic, "neurological impairment occurred" in five patients who had the same ectopic bone formation.

According to the New York Times, a recent study 'found that men treated with Infuse developed a condition that causes temporary or permanent sterility at a far higher rate than men who received a bone graft.' This link to sterility was not reported in the original Medtronic-funded study. In addition, the Milwaukee Sentinel Journal reports that one author of the original study, Thomas A Zdeblick, an orthopedic surgeon at the University of Wisconsin School of Medicine and Public Health, received 'more than \$23 million in various royalty payments from Medtronic since 2002.' In addition, 'Zdeblick also is the editor of the journal where two of the Infuse papers that failed to mention the link [to sterility] were published.'

We are also concerned that other severe side-effects of Infuse and similar bone-growth products developed by Medtronic may have been unreported or under-reported in clinical literature. Reports have linked Infuse to potentially fatal swelling in the neck and throat, and radiating leg pain. ✓ Concerns have also been expressed about a potential link to cancer." 2,3

The Committee went on to request a score of documents and payment records. Rudolph F.X. Migliore, P.C. is investigating cases of patients who received a Medtronic Infuse Bone Graft off-label and have suffered serious side-effects including neck swelling, airway compression, many types of cancer, uncontrolled bone growth, arm and leg pain and male infertility. If you or a loved one have had a bone graft and suffered complications contact our office today for a free case evaluation at 631-543-3663 and visit migliorelaw.com/dangerous-medical/medtronic-infuse-bone-graph.

With over three decades of experience, the law firm of Rudolph F.X. Migliore, P.C. is well positioned to help victims of Medtronic Infuse Bone Graft. The firm has handled over 1,200 product liability cases and works with co-counsel to obtain major verdicts.

Rudolph F.X. Migliore, P.C.
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MiglioreLaw.com

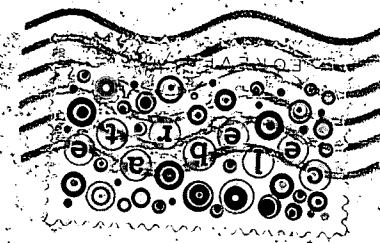
1. online.wsj.com/article/SB10001424052702303627104576413663395567784.html
2. pharmalot.com/2011/06/spinal-tap-congress-investigates-medtronic/
3. finance.senate.gov/newsroom/chairman/release/?id=a7e974b6-b4b6-4e2c-a738-edefac30fcb6

Hebra R. Parick
195 Crescent Oaks Ct.
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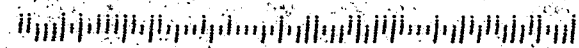


FEB 08 2021

SC Court of Appeals

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

29201-376999



Shelton R. Garrick
195 Crescent Oaks Ct
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Case #001842

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SC Court of Appeals



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