ALAN JONES
PO BOX 25722
SCOTTSDALE, AZ 85255
480-664-7870

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF ARIZONA

Alan W. Jones and Kathryn Marie Jones,

Plaintiffs,

Vs.

Dallas Neurosurgical and Spine Associates, P.A.; Dr. Jeremy Denning; Dr. Richard Jackson;

Texas Health Presbyterian Hospital of Dallas;

Medtronic Corporation; James Sherman; Josh Tsokanas; Nora (Lora?) Jean Enty;

DOE DEFENDANTS 1-10,

Defendants.

CIVIL NO. CV-12-2286-PHX-BSB

COMPLAINT FOR DECLARATORY JUDGMENT;

JUDICIAL NOTICE OF PROPRIA PERSONA PLAINTIFFS;

DEMAND FOR JURY TRIAL;

NOTICE OF LAWSUIT AND REQUEST FOR WAIVER OF SERVICE OF SUMMONS

COMPLAINT

COME NOW Plaintiffs, Alan W. Jones and Kathryn Marie Jones, and for a Complaint to obtain a Declaratory Judgment against Dallas Neurosurgical and Spine Associates, P.A.; Dr. Jeremy Denning; Dr. Richard Jackson; Texas Health

Presbyterian Hospital of Dallas; Medtronic Corporation; James Sherman; Josh Tsokanas; Nora (Lora) Jean Enty; and DOE DEFENDANTS 1 – 10, allege as follows:

ALLEGATION OF JURISDICTION

a) **Jurisdiction Founded on Diversity of Citizenship and Amount.** Plaintiffs are citizens of the State of Arizona, while the defendants are both individuals and corporations with their respective citizenships, residences, state(s) of incorporation, principal places of business yet to be fully determined; but they are not all within the State of Texas. Medtronic has its World Headquarters in Minneapolis, MN and truly does operate all over the world (See Exhibit #1). The matter in controversy exceeds, exclusive of interest and costs, the sum specified by 28 U.S.C. section 1332 for plaintiff, Alan Jones. The same compliance with the sum specified by 28 U.S.C. section 1332, is true for plaintiff, Kathryn Jones.

b) **Jurisdiction Founded on the Existence of a Federal Question.** The action arises under the U.S.C. 28 section 1346; the U.S.C. Title 21, Chapter 1, Part 50; the U.S.C. 28 section 1350; the 45 CFR 46.102(d) ,etc.; and the 45 CFR 46.116, etc., as hereinafter more fully appears.

c) **Jurisdiction Founded on the Existence of a Question Arising Under Particular Statutes.** The action arises under the Act of Alien Tort Statute and the Act of Federal Tort Claims, as hereinafter more fully appears.

JUDICIAL NOTICE OF PROPRIA PERSONA

Plaintiffs respectfully request that the court take judicial notice that "Pleadings in this case are being filed by Plaintiff in Propria Persona, wherein pleadings are to be considered without regard to technicalities. Propria, pleadings are not to be held to the same high standards of perfection as practicing lawyers. **See Haines v. Kerner 92 Sct 594; also See Power 914 F2d 1459 (11th Cir 1990); also See Hulsey v. Ownes 63 F3d 354 (5th Cir 1995); also See InRe: HALL v. BELLMON 935 F2d 1106 (10th Cir. 1991)."**

In Puckett v. Cox, it was held that a pro-se pleading requires less stringent reading than one drafted by a lawyer (456 F2d 233 (1972 Sixth Circuit USCA).

Justice Black in Conley v. Gibson, 355 U.S. 41 at 48 (1957) held that "The Federal Rules rejects the approach that pleading is a game of skill in which one misstep by counsel may be decisive to the outcome and accept the principle that the purpose of pleading is to facilitate a proper decision on the merits." According to Rule 8(f) FRCP and the State Court rule which holds that all pleadings shall be construed to do substantial justice."

OPENING STATEMENT

On October 27th of 2010 – the second day of my wife's spinal fusion surgery – Dr. Jeremy Denning, a neurosurgeon, and his associate Dr. Richard Jackson of Dallas Neurosurgical and Spine Associates P.A. defrauded my wife, Kathryn Marie Jones. Together, Dr. Denning and Dr. Jackson experimented on Kathryn. The doctors implanted her with a bioengineered bone morphogenic protein named INFUSE, manufactured by Medtronic. They placed INFUSE at twelve locations adjacent to Kathryn's spine – in procedures that Medtronic very explicitly, in underlined bold

type, warns doctors **"must not"** be done. But Dr. Denning and Dr. Jackson did it anyway. Twelve times.

This was not done to save Kathryn's life. No, the doctors did not need to use INFUSE at all. They chose to use INFUSE. And they chose to use the INFUSE in a manner that the manufacturer warns doctors must not happen. They did not decide to do this spontaneously. The two doctors made the decision to experiment on Kathryn, to use the INFUSE in this manner, prior to the second day of her fusion surgery. We strongly believe that this was a premeditated decision.

Dr. Denning and Doctor Jackson could have performed Kathryn's surgery using only her own autogenous bone. In fact, Dr. Denning had assured Kathryn that he would do so. He had promised not to use cadaver bone. And he had never mentioned INFUSE at all. We did not know that such a product even existed. But Dr. Denning lied. He used both cadaver bone and INFUSE, in addition to Kathryn's own spinal fragments and ribs.

And then, after Kathryn's fusion surgery, Dr. Denning proceeded to tell more lies and to actively conceal his outrageous actions. For almost two years Dr. Denning has done nothing but lie to and deceive my wife and me. He has repeatedly denied that Kathryn's disabling and debilitating pain conditions, and other complications, are related to her spinal fusion surgery. He concealed the fact that her T12-L1 vertebrae had failed to fuse. Dr. Denning's deceit directly, purposefully dissuaded Kathryn from seeking appropriate medical care and diagnostic tests. Medical care that could possibly have mitigated further damage to her health and alleviated her pain. Tests that could have revealed Dr. Denning's fraudulent actions. And Dr. Denning continues that policy of fraudulent behavior even now.

On September 26th of 2012, just a few weeks ago, Dr. Denning sent Kathryn a reply to her email query to him regarding INFUSE. We had just learned about INFUSE, a product that has been linked to many severe conditions, even to cancer and death. In his email reply, Dr. Denning stated "We have use INFUSE in all our fusions for 6 years and continue to use this technology". And "We place it only in cages or spacers, where it is contained". That was very difficult for us to absorb. Dr. Denning stated that he uses INFUSE in "all" his fusions. But he had never told us about INFUSE. He had never mentioned it at all, not even once. Dr. Denning robbed Kathryn of her right to decide and to control what was implanted in her own body.

Then on October 1st of 2012, Kathryn's medical records arrived in the mail. She stayed up late to read them – and all alone in the middle of the night – Kathryn learned that Dr. Denning had abused and betrayed her. She had been brutalized.

As Kathryn read her surgical report from the second day of surgery, the truth was revealed. Kathryn was devastated by the discovery that Dr. Denning and Dr. Jackson had "removed a portion of the inferior facet bilaterally and placed some BMP over this" and "we did this at multiple levels from T12-L1 down to L5-S1". Twelve times Dr. Denning and Dr. Jackson placed INFUSE adjacent to Kathryn's spine. Twelve times that INFUSE was not in a cage, not in a spacer, not "contained". Dr. Denning had lied.

That night Kathryn was very dismayed and sorrowed to learn that Dr. Denning had used her as though she were totally worthless – as though she had no value as a human being. Dr. Denning had experimented on Kathryn and used her as a guinea pig; as nothing more than a laboratory rat. Kathryn had entrusted Dr. Denning with her life; and he had proceeded to purposely, permanently compromise her health and most likely shorten her life.

Dr. Denning is a fraud who stole my Kathryn from me. Kathryn's soul has been mortally wounded. Her spark and vitality have been destroyed. My Kathryn, my wife of 45 years, has disappeared. She is gone. A shadow has taken her place.

ALLEGATIONS COMMON TO ALL COUNTS

1. Plaintiffs are residents of the State of Arizona.

2. At all times relevant to this lawsuit, Defendant individuals were present during the acts of illegal human experimentation committed in this matter at the Texas Health Presbyterian Hospital of Dallas; while the corporate entities have a differing locations for their state(s) of incorporation, business locations, and

geographical business activity coverage, with Medtronic Corporation being global in nature.

3. DOE DEFENDANTS 1-10 are sued herein under fictitious names for the reason that their true names and identities are presently unknown to Plaintiff except that they are connected in some manner with the Defendants named herein and/or were the parents, agents, employees, employers, directors, officers, representatives, partners, licensees, licensors, or professional corporations of Defendants named herein and/or were in some manner presently unknown to Plaintiff engaged in the activities alleged herein and/or were in some manner and in some degree responsible for the injuries and/or damages to Plaintiff alleged herein, and Plaintiff hereby prays for leave to certify their true names, identities, capacities, activities, and/or responsibilities when the same are ascertained.

4. In all matters relevant to this lawsuit, the corporate entities acted either directly through its officers, directors, employees, contractors, agents, and vendors, distributors, etc. The conduct of Texas Health Presbyterian Hospital of Dallas related directly or indirectly to Plaintiffs and the claims set forth in this Complaint, including the conduct of officers, directors, employees, contractors, and agents, was authorized, accepted and/or ratified by Texas Health Presbyterian Hospital of Dallas.

5. On or about October 26, 2010, Plaintiffs Alan Jones and Kathryn Jones unknowingly became trapped in a disastrous course of events when they agreed to allow the defendants to provide medical services and products in order for Kathryn to obtain necessary medical treatment. Their decision to commit to this treatment was a direct result of fraudulent inducements by agents of the Texas Health Presbyterian Hospital of Dallas, agents of Dallas Neurosurgical and Spine Associates, P.A., and Dr. Jeremy Denning.

6. Undisclosed, unauthorized, off label, illegal, hidden, denied and unethical treatments were done upon Kathryn without our knowledge and it is our belief that such acts were for the direct financial benefit of multiple parties, individuals and corporate sponsors, and respondeat superior relationships.

7. We believe that extensive, dangerous, and life threatening experimentation was personally performed by Dr. Jeremy Denning and Dr. Richard Jackson, and others, unknown at this time, that will be discovered if this court grants our prayer for relief in this matter.

8. At all relevant times, Texas Health Presbyterian Hospital of Dallas had the duty and was the designated protector, the gate keeper, the security guard of privacy, health, liberty, safety, and shelter from the assault and battery that was inflicted upon her. The hospital however, even allowed into the operating room

(without disclosure and without authorization) various public "observers" that were paraded into the operating room to witness the devious actions which we have yet to fully discover.

9. Nearly two (2) years of fraud, deceit, cover-up have been accomplished by the defendants in an attempt to be able to get away with their lurid scheme(s), but now at least one facet of the plot has been discovered by us- "business growth" for global giant, Medtronic Corporation.

10. In early 2010, as we were moving into our new home, Kathryn began to experience severe pains in her right flank. As time passed, Kathryn also had difficulty using her right leg. Because she assumed that she was having problems with her hip, she went to her orthopedic doctor, who took x-rays in his office. When the doctor reentered the exam room, he told us that it was a good thing we had come to see him – because Kathryn would have ended up paralyzed if we had waited too long to seek treatment. The doctor explained that Kathryn had a severe back problem, and sent her for an MRI.

11. Back in 1995, Kathryn woke up one morning with severe pain in her lower back. X-rays showed scoliosis, with a pars defect, and spondylolisthesis at the L5-S1 level. Kathryn was provided a brace to wear, and underwent a course of physical therapy. Kathryn then diligently exercised every day, thus managing to

control her pain. Occasional flares would require Flexaril or Darvocet - but in general Kathryn's doctors thought her back condition was a mild, annoying problem

12. But now she might end up paralyzed! And the MRI showed even more horrendous problems - pinched nerve roots, Tarlov cysts, and arachnoiditis. That began a search for answers and solutions. We consulted multiple orthopedic spine surgeons, neurosurgeons, neurologists, and more. But they only wanted to give pain injections. They all said that Kathryn's spine was stable – even though she was barely able to walk, and had to use a cane inside our own home.

13. Then Kathryn remembered reading an advertisement in a Phoenix magazine for a doctor practice in Plano, Texas that specialized in correcting adult scoliosis. She scheduled an appointment for August of 2010. The scoliosis practice referred her to Dr. Jeremy Denning, a neurosurgeon, for a consultation regarding the arachnoiditis and Tarlov cysts. On August 11th of 2010, Kathryn had a consult with Dr. Denning at his Plano office. Dr. Denning reviewed her MRI and diagnosed a "grade II L5-S1 spondylolisthesis with right greater than left L5-S1 foraminal stenosis". Dr. Denning briefly discussed surgical options to correct those problems; and explained the minimally invasive techniques that he used. He also recommended that Kathryn undergo a myelogram procedure, in order to

accurately identify arachnoiditis. Kathryn objected, as she had read that myelograms can cause arachnoiditis. Dr. Denning reassured her, stating there was only one radiologist that he trusted to do the procedure, and that he would ensure that her test would be by that radiologist. The radiologist was called, and we went straight to his facility for the procedure.

14. Exhibit # 2 , 8-11-10 New Patient Consultation

15. The next day, Kathryn had a consult at the Plano scoliosis center. The scoliosis doctor would not discuss her particular health issues, but instead spoke in generalities. Because we were disappointed with the scoliosis doctor – and had been impressed with Dr. Denning – we went back up to Dr. Denning's office and spoke to his assistant. After we had returned home, we arranged to return to Plano on August 18th to discuss the myelogram, and possible corrective surgery, with Dr. Denning.

16. Kathryn and I returned to Plano on August 18th of 2010. Dr. Denning explained the results of the myelogram at length, and assured us that Kathryn did not have arachnoiditis. He related that he thought that the Tarlov cysts were meaningless and would not affect Kathryn's health. Dr. Denning then discussed spinal fusion surgeries. He said that he could do a mini-fusion of the L5-S1 vertebrae, or a major-fusion from T12-L1 to L5-S1. The major-fusion would

correct both Kathryn's scoliosis and the broken vertebrae with nerve damage at her L5-S1 level. Dr. Denning then described the removal of discs and the use of bone graft spacers. He described the spacers as small Lego blocks filled with ground-up bone. We asked where the bone would come from. Dr. Denning replied that he would use the broken pieces of Kathryn's vertebrae - or he could use cadaver bone. Kathryn immediately responded – Absolutely Not – NO cadaver bone.

17. Kathryn explained that auto-immune problems are common in her family. She told Dr. Denning about her Pernicious Anemia and Meniere's Disease. She said that our younger son has Erythema Multiforme, that her sister has Systemic Lupus, and that her mother also had several immune conditions. Kathryn explained in detail that she has always taken precautions not to receive donor blood, bone, or gum products. She has always made donations of her own blood prior to surgeries, and had refused donor gum for gum graft procedures.

18. Because of her Pernicious Anemia, Kathryn had severe recessed gums, and required grafts along the gum line of every tooth. Several months before seeing Dr. Denning, Kathryn had undergone her second gum graft procedure for eight teeth. The peridontist had removed almost the entire roof of Kathryn's mouth, in an extremely painful, four hour procedure. Months later, she was still not eating solid food. And she was facing at least three more gum graft

procedures. But, she was still adamant that she would not accept any donor gum grafts - even though that would again necessitate the removal of tissue from the roof of her mouth. Kathryn was very outspoken in her refusal to accept donor body parts. Besides, as she always said – It was just plain creepy, like having an alien inside of her body.

19. Kathryn then explained that I have acromegaly, and also have hypo-pituitary and hypo-thyroid conditions. I have COPD and asthma. I had Valley Fever twice. Because I have undergone surgeries to remove tumors in my brain and inside my heart, in addition to a double mastectomy, and many other surgeries – I have a compromised immune system. My body is unable to tolerate blood products from the general supply; so Kathryn has always been my designated donor. I am now facing the prospect of my second heart surgery, this time to repair a faulty heart valve, and intended to rely on Kathryn to again donate blood for me. Our two sons are not compatible matches. When we lived in Hawaii, we were advised to travel to California for my first heart surgery, because the state of Hawaii has laws against directed blood donations - so we went to Stanford, where Kathryn donated three units of blood for my open-heart surgery. And Kathryn intended to donate her own autologous blood, and have it shipped to Dallas, prior to her fusion surgery. Kathryn explained to Dr. Denning that she would not, under

any circumstances, accept cadaver bone. She could not have made her wishes any clearer; Dr. Denning understood her refusal to have donor blood or bone.

20. Dr. Denning then explained that he was positive that he could do the mini-fusion using only Kathryn's own bone and blood. He stated that he did not know if he could do so for the major-fusion; but he said that he would investigate the issue and let us know. We would then be able to make an informed decision as to which surgery would be the best for both Kathryn and me, and our future health. We explained to Dr. Denning that there was one more doctor in Phoenix for us to consult, and that we would call him in a week or so. He said OK, and promised to look into the cadaver bone issue.

21. Exhibit # 3 , Handwritten notes 8-18-10 office consult, two misdated office notes 9-23-10

22. At the beginning of September of 2010, we called Dr. Denning's assistant and told her that Kathryn wanted Dr. Denning to perform the major-fusion using the "pin-cushion" minimally invasive procedure. We asked if Dr. Denning had determined whether or not the major-fusion could be done using only Kathryn's own bone and blood. The assistant then arranged for Dr. Denning to call us on September 8th of 2010 to answer our questions. But Dr. Denning did not call. So we emailed a list of questions for Dr. Denning to answer. The assistant

later emailed back the answers. Dr. Denning verified that there would be enough of Kathryn's own bone recovered to use for the major-fusion. His answer to Kathryn's question – "Will I need donor bone?" - was "NO". So Kathryn then agreed to proceed with a two-day major-fusion in late October of 2010.

23. Exhibit # 4 , Email questions of 9-8-10.

24. Kathryn's fusion surgery was scheduled for October 26th and 27th of 2010. We arranged to drive to Dallas and remain there for at least a month. We planned to be away from home for approximately six weeks.

25. Prior to leaving for Dallas, Kathryn pre-registered online for the Texas Health Presbyterian Hospital Dallas, where her surgery would be performed. Included in the pre-registration was a Universal Consent Form that contained a clause stating that all medical devices were provided on an "as is" basis. It also contained a clause stating that warranty information would be provided on request. While sitting in a doctor's office, waiting for pre-surgery tests, Kathryn had read a Reader's Digest article detailing problems with pedicle screws, mesh, and other implants. The article recommended that patients obtain warranty information on all implants. So Kathryn called Dr. Denning's assistant and asked for warranties on the hardware that would be implanted in her back. The assistant told Kathryn that she would have a representative from Medtronic, the hardware manufacturer,

give Kathryn a call. There was no phone call. So Kathryn called Dr. Denning's office again, and was told that the hospital would supply all of the screws, rods, and spacers that would be used in Kathryn's surgery.

26. Kathryn then called the hospital and requested warranty information. Eventually she spoke on the phone and emailed Paula Hagan, the hospital attorney. Ms. Hagan told Kathryn that no warranties would be provided. Ms. Hagan then emailed the policy regarding the hospital's handling of implants. Paula Hagan told Kathryn that she would have to sign the Universal Consent Form, with the "as is" clause, or she could not have surgery at that hospital. On October 26th of 2010. Kathryn attempted to cross-out the "as is" clause on the Universal Consent Form. The hospital representative told her to sign the form without alterations, or to go home. Kathryn signed the form.

27. Exhibit # 5 , Hospital Consent Form and Paula Hagan emails.

28. On the first morning of surgery, October 26th of 2010, the approach was lateral, from the left side. Dr. Randall Kirby, a vascular surgeon, opened the large incision. According to an Aetna EOB dated January 25th of 2011, Diagnosis Code 49010, Dr. Kirby then did "Exploration Behind Abdomen". An Aetna appeal decision dated March 4th of 2011, Diagnosis code 868.04 for Dr. Kirby states "Injury other intra-abdominal organs, without open wound into cavity,

retroperitoneum". And in the surgical report for the second surgical procedure, Dr. Denning describes the first procedure as "She had undergone a prior retroperitoneal approach to her lumbar spine earlier in the day and was positioned lateral. Retoperioteneum means behind the membrane that lines the abdomen, and separates the abdominal contents from the spinal column. Even though the incision is in the side, the spinal column is approached from the front (anterior). In his first surgical report, Dr. Denning identifies the procedure as "Direct lateral anterior interbody fusion". And states "The first stage of the operation was going to be anterior releases and osteostomies with interbody fusion".

29. Exhibit # 6 , Dr. Denning first surgical report, Aetna EOB dated 1-25-11, and Aetna Appeal Decision dated 3-4-11.

30. The surgical report for the first procedure on October 26th of 2010, from Dr. Denning's records, indicates that Dr. Denning removed four discs – the L1-2, L2-3, L3-4, and L4-5. The report states that "we placed a trial spacer into the disc spacer and ultimately selected a 10x45mm PEEK intervertebral cage that was packed with locally harvested bone and bone morphogenic protein". Dr. Denning did this procedure four times. That report from Doctor Denning's records makes no mention of INFUSE Bone Graft (1 Medium and 2 Small packages), Muskuloskeletal Transplant Foundation DBX Mix 10cc (demineralized bone

matrix - cadaver bone), Clydesdale Spinal System Cage (4), or CAPSTONE Spinal System (1). But the hospital records indicate that every one of these products was implanted or transfused in Kathryn on the first day of her spinal fusion surgery.

31. Exhibit # 7 , Hospital records lists of product labels.

32. The medical records from Dr. Denning contain two surgical reports, one on October 26th and one on October 27th. The reports do not mention, do not describe, the procedure used to fuse the L5-S1 vertebrae. Nor do they describe the procedure used to fuse the T12-L1 vertebrae. But the hospital records contain three surgical reports. Those records indicate that the lateral approach DLIF L1-2, L2-3, L3-4, L4-5 was performed on the morning of October 26th of 2010, At the end of that procedure, Dr Kirby closed Kathryn and left.

33. The second surgical report from the hospital records, dated October 26th of 2010, states that "after she was cleared medically and informed consent was obtained, she was brought to the operating room". And, "she was already intubated and under general anesthesia". (That consent form was not in the hospital records.) Kathryn was then repositioned "prone on the Jackson table" and the second procedure of the day started at 12:50.

34. The second surgical procedure is described as a "minimally invasive L5-S1 right transforaminal lumbar interbody fusion". It involved a "Right L5-S1

far lateral diskectomy" and a "Right L5-S1 decompression hemilaminectomy". Dr. Lin, the physiatrist doctor in the rehab unit, described the procedure as a "Right L5-S1 far lateral discetomy and hemilaminectomy with posterior fusion and L5-S1 osteotomy and fusion". That second procedure appears to have been a posterolateral fusion – a posterior approach to repair the right side of the L5-S1 vertebrae. Dr. Denning states, in the hospital record, that "we turned her prone" as "we could not reach this area from the front through a direct lateral approach and, furthermore, we needed to decompress the L5 root on the right".

35. Exhibit # 8 , Hospital records second surgery report dated10-26-10, Dr. Lin report dated 11-10-10.

36. During the second surgery procedure, Dr. Denning drilled off the L5 inferior facet and also the superior portion of the right S1 facet. He then removed part of the medial pars and lamina on the right at L5. Dr. Denning then proceeded to scrape away the disk and scar tissue. Next he placed a PEEK intervertebral cage that was "packed with BMP, as well as locally harvested bone from her facetectomy". He "also placed some bone in the anterior disk space, along with a small sponge of BMP for Interbody fusion". Lastly, he "placed a small sponge of Gelfoam over the annulotomy defect and inspect the L5 root".

37. The hospital records indicate that the Muskuloskeletal Transplant Foundation DBX Mix, 10cc was "Transfused" on October 26th of 2010. There is no indication of how, when, or at what location that was done. Dr. Denning's surgical reports do not mention the cadaver bone at all. The hospital's surgical reports do not mention the cadaver bone at all. Not even once.

38. Exhibit # 9 , Hospital cadaver bone label and paper showing "transfused".

39. During that first day of surgery – both the first procedure in the morning and the second procedure in the afternoon – James Sherman, a Medtronic Vendor Representative was present in the OR from 8:05 until 15:18. Also present was Nora Jean Enty, "Business Growth Strategy" "Observer" from 8:05 until 12:10. Apparently Ms. Enty was interested only in the DLIF L1-2, L2-3, L3-4, and L4- 5 procedure. But why was she there at all? Who is she? We were never told that those people would be there, and did not provide consent for that.

40. Exhibit # 10 , Hospital records operating room procedure report, Dr. Denning records Privacy Policy.

41. At the end of the first day of surgery, Dr. Denning spoke with me. He told me that the surgery went well, and said that he needed to remove portions of two of Kathryn's ribs in order to have enough bone graft material for the spacers.

He also said that he had spent several hours repairing Kathryn's damaged nerve at the L5-S1 level. He did not mention any problems, simply said that all went well.

42. During the first day of surgery, Kathryn suffered a small pneumothorax (collapse) of her right lung. The pneumothorax apparently resolved prior to the second day of surgery. However, this pneumothorax was medically important, as Kathryn had had half of her lower left lobe surgically removed in 2007 due to Valley Fever. She has reduced lung capacity.

43. Exhibit # 11 , Hospital x-ray report dated 10-26-10.

44. The second day of surgery, the third surgical procedure, on October 27th of 2010, was a posterior approach - from the back. Dr. Denning's records state that the title of the operation is "Posterior T12 to L5 spinal osteotomies using the METRx tubes. The surgery was a minimally invasive procedure, the "pin cushion" method. It was a posterior lumbar interbody fusion. Dr. Denning used the "Medtronic Longitude percutaneous screw and rod system from T12 to S1". During the procedure, Dr. Denning was assisted by Dr. Richard Jackson, neurosurgeon, and Stephanie Cracknell, RNFA,NP – both associates in his practice. During this procedure, Dr. Denning "removed a portion of the inferior facet bilaterally and placed some BMP over this to aid in our posterior fusion, and

we did this at multiple levels from T12-L1 down to L5-S1". The screws and rods were then implanted.

45. Dr. Denning's report does not mention how the BMP was held in place, nor does it indicate if the BMP was enclosed in a cage or a spacer. Dr. Denning does not mention INFUSE. But the hospital's list of labels indicates that a XX Small package of INFUSE was used in a PLIF, and also provides a long list of cannulated screws, 2 rods, and a longitude set screw.

46. Exhibit # 12 , Dr. Denning surgical report of 10-27.

47. The hospital records indicate that a Medtronic Vendor Representative, Josh Tsokanas, was present from 8:15 to 9:00. And, once again, Medtronic Vendor Representative James Sherman was present from 8:15 to 13:15. So was Lora (or Nora?) Jean Enty, the "Business Growth" "Observer", from 10:56 to 12:57. Who were these people, and why were they there? Luckily for Kathryn, her "Patient's Right To Privacy" was "Maintained".

48. At Kathryn's first consult with Dr. Denning, on August 11th of 2010, he had diagnosed her with a Grade II spondylolisthesis. Her first surgical procedure was a lateral approach; both her second surgical procedure and her third surgical procedure were posterior approaches. Kathryn's spinal fusion was for levels T12-L1 to L5-S1.

49. The INFUSE Bone Graft/LT-CAGE Lumbar Tapered Fusion Device received FDA approval for use at levels from L4-S1, to treat patients with degenerative disc disease. It was approved to treats patients who may have up to Grade I spondylolisthesis. The product is to be implanted via an anterior open approach or an anterior laparascopic approach.

50. Exhibit # 13 , INFUSE FDA approvals-3 documents.

51. Kathryn's spinal fusion included the T12-L1, L1-L2, and L3-L4 levels – all higher than the approved use for levels from L4-S1. Kathryn's spondylolisthesis was worse than a Grade I, hers was Grade II. She did not have an anterior open approach or an anterior laparascopic approach in any of her surgical procedures. But Dr. Denning used the INFUSE anyway, at all levels of Kathryn's fusion from T12-L1 down to L5-S1. He used the INFUSE in all three of Kathryn's surgical procedures. He used it "off-label", without informing Kathryn of his intent, or obtaining her consent. As a matter of fact, Dr. Denning never mentioned INFUSE to Kathryn, or to me, at all. Nor does the product name INFUSE appear anywhere at all in Kathryn's surgical reports or medical records for almost two years. Not until Kathryn asked Dr. Denning if he had used it during her surgeries.

52. All spinal fusion surgeries have complications. Kathryn's fusion involved many levels, and multiple approaches; it was a major surgery that cost almost half a million dollars. Prior to Kathryn's surgeries, Dr. Denning briefly explained to us some of the possible restrictions that Kathryn might experience after her spinal fusion. He said that she would not be flexible, not able to bend from the waist. He told her that she would be unable to twist, and may not be able to lift her arms above her shoulders, nor would she be able to lift heavy objects. He told her that her recovery would be long, and slow – that she would see improvements quickly in the beginning, and then improvements would be slower to happen. Because Kathryn did not want to be paralyzed, she decided to undergo the fusion surgeries anyway.

53. But Dr. Denning failed to mention INFUSE, nor did he tell Kathryn that spinal fusion surgeries that include INFUSE have a higher rate of complications. "Safety issues associated with the use of rhBMP-2 (INFUSE) might include the possibility of bony overgrowth, interaction with exposed dura, cancer risk, systemic toxicity, reproductive toxicity, immunogenicity, local toxicity, osteoclastic activation, and effects on distal organs". Also "major complications, additional surgeries, neurologic/urologic injury, and major back/leg pain events". Anterior lumbar interbody fusions that include INFUSE have a

higher risk of implant displacement, subsidence, infection, urogenital events, and retrograde ejaculation. Posterolateral fusions that include INFUSE have a higher risk of early back pain and leg pain adverse events, and higher doses of INFUSE are associated with a greater apparent risk of cancer. (Because of the many levels of her spine that were fused, Kathryn received a fairly high dose of INFUSE.) Posterior lumbar interbody fusions that include INFUSE have a higher risk of radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes. None of this was ever explained to us. Not in relation to INFUSE, not at all. Dr. Denning did not tell us that any of these complications were a possibility. As I said, we did not know that INFUSE even existed, and had no idea that Dr. Denning would implant it in Kathryn.

54. Exhibit # 14 , "The Spine Journal" review article

55. The CLYDESDALE Spinal System received FDA approval for use with autogenous bone graft. It is approved for use in patients with DDD, who may have up to Grade I spondylolisthesis at one or two levels from L2 to S1. The cages may be implanted via a minimally invasive lateral approach.

56. Exhibit # 15 , FDA approval CLYDESDALE Spinal System.

57. The CLYDESDALE cages are not to be used for Grade II spondylolisthesis. But Dr. Denning used them anyway - four times. They are not

to be used at levels above L2, but Dr. Denning used it at L1-L2 anyway. The CLYDESDALE cages are not to be used with INFUSE, but Dr. Denning packed the cages with INFUSE anyway. Again, this was off-label use, and required disclosure and consent. But Kathryn did not even know anything about it.

58. The CAPSTONE Spinal System received FDA approval for DDD in patients with up to Grade I spondylolisthesis, at one or two levels from L2 to S1. The implants are to be packed with autogenous bone graft, and implanted via an open or a minimally invasive posterior approach.

59. Exhibit # 16 , FDA approval CAPSTONE Spinal System.

60. The CAPSTONE system is not to be used for Grade II spondylolisthesis, but Dr. Denning used it anyway. The CAPSTONE system is not to be used with INFUSE, but Dr. Denning packed it with INFUSE anyway. Once again, this is off-label use, but no disclosure was provided nor consent obtained.

61. The official Medtronic website warns doctors (in a report about the INFUSE BONE GRAFT/LT CAGE LUMBAR TAPERED FUSION DEVICE) – the same implant that had received FDA approval – "**the bone morphogenic protein solution component must not be used without the carrier/scaffold component nor with a carrier/scaffold component different from the one described in this document. The INFUSE Bone Graft component must not be**

used without the Medtronic Titanium Threaded Interbody Fusion Device component".

62. Exhibit # 17 , Medtronic INFUSE Bone Graft warning.

63. But Dr. Denning "removed a portion of the inferior facet bilaterally and placed some BMP over this to aid in our posterior fusion, and we did this at multiple levels from T12-L1 down to L5-S1". Twelve times Dr. Denning used INFUSE - without a carrier or scaffold component. Twelve times Dr. Denning placed INFUSE on the facet - where it was not contained. Twelve times Dr. Denning placed INFUSE on the facet - where it was not in a spacer or a cage. Twelve times Dr. Denning exposed the INFUSE to nerves. But in an email to Kathryn on September 26th of 2012, Dr. Denning stated that "We have use INFUSE in all of our fusions for 6 years" and "We place it only inside cages or spacers, where it is contained". And "it is not exposed to nerves in any of our surgeries". Twelve times Dr. Denning abused Kathryn's body – exposing her to serious, severe complications and conditions, possibly even cancer. To this date, Dr. Denning continues to lie and attempt to conceal his horrendous actions.

64. Exhibit # 18 , Dr. Denning 9-26-12 email.

65. Kathryn would never, ever, have consented to - or provided her permission for - any of the off-label procedures that Dr. Denning used in her spinal

fusion surgeries. She was completely unaware of Dr. Denning's intentions - completely unaware of his actions. Kathryn had thought that she was knowledgeable concerning the potential complications of her planned spinal fusion surgery.

66. Dr. Denning had been clearly, emphatically instructed not to use cadaver bone. Kathryn had no reason to think that Dr. Denning would do so anyway. There had been no discussion of INFUSE or BMP's. We were completely unaware of their existence, and had no reason to imagine that such a thing could be implanted in Kathryn's body without her knowledge. Kathryn and I thought that we had conveyed to Dr. Denning that Kathryn wanted to preserve the integrity of her own body. That it was extremely important to her. That it was also very important to her that she would continue to be able to donate blood for me. Kathryn was pleased and proud that she had been able to keep me alive when I had heart surgery. She anticipated doing so in the future, whenever I would require donor blood. And, of course, it was as important to me. I love her, and greatly appreciate her blood donations. If it were not for Kathryn, I would not be alive today. We both thought that we would be able to continue this expression of our love forever, but Dr. Denning destroyed that with his despicable actions.

67. Kathryn still trusted and believed in Dr. Denning, until the night that she read her surgical reports, on October 1st of 2012. Until that night, she did not fully understand how Dr. Denning had betrayed her. Dr. Denning had admitted that he had used INFUSE on September 26th of 2012, but Kathryn did not discover that he was lying to her about its manner of usage until she read her records. We learned just this week that the hospital records also contain information that had been concealed from us.

68. Including the two days of her surgical procedures, Kathryn was in the ICU for five days, in complete isolation. Alan was required to don a cap, gown, mask, and gloves to visit her - he was not allowed to touch Kathryn at all. The hospital records reveal that during her stay in the ICU, Kathryn had multiple bouts of atrial fibrillation and flutter; at one point she had an irregular heart rhythm with a rate of 80 to 110 beats per minute. Dr. Phillip Williams III managed Kathryn's cardiac care. (We had never met Dr. Williams before, and were not informed as to his practicing specialty). Kathryn also had a temperature over 101, and a blood pressure higher than 180 over 100. She suffered from hypokalemia (low levels of potassium chloride) and hypophosphatemia (low levels of sodium phosphate). We were not informed about any of these conditions. Obviously, Kathryn's body was under extreme duress and was not functioning normally. She was not doing well at

all. But apparently Kathryn's doctors could not decide if she was doing well or not. A hospital progress report of October 29th of 2010 shows that Kathryn had an episode of "Atrial fib/flutter reported. Per Dr. Williams." Yet, on that same day, Dr. Williams reported to Dr. Denning that Kathryn's cardiovascular system was "Regular rate and rhythm. S1. S2". And "the patient is currently stable", even though "She is currently on telemetry and we will watch her closely".

69. Exhibit # 19 , Hospital progress notes dated 10-29-10, Dr Williams report dated 10-29-10.

70. Next, Kathryn was moved to a regular nursing floor. She stood up on the first day, walked five steps on the next, and across the room the following day. When she was able to use the bathroom, she was moved to the acute rehab section of the hospital.

71. The rehab was incredibly hard on Kathryn. She had personal care lessons, strengthening exercises, and motion lessons with regard to spinal safety - and even lessons in how to safely enter/exit our truck. Every day for three or four hours she had therapy. Kathryn was exhausted the entire time. Her pain was managed with long-acting morphine pills, and augmented with quick-acting morphine pills - but there were several incidents where Kathryn lay on her bed and cried, because the pain was unendurable.

72. After more than a week in rehab, Kathryn was discharged from the hospital, and went to the hotel. Kathryn had to wear a back brace every minute that she was not in bed or in the shower. She used a rolling walker, and was not allowed to take more than three steps without the walker. Kathryn was allowed to sit in a chair for twenty minutes, and was then required to lie flat in bed. Basically, she was a partially-mobile invalid who could not dress herself, nor bathe herself, nor even comb her own hair. And that was almost three weeks after her spinal fusion surgery.

73. A visiting rehab nurse came to the hotel four or five times. He would check Kathryn's incisions, take her temperature and examine her, ask about her pain level, monitor her as she exercised, and walk with her in the hallway. The nurse was very concerned about the incision from the posterior surgery performed on the afternoon of October 26th of 2010. During his first visit with Kathryn, the nurse expressed his opinion that the incision was red, swollen, and appeared to be infected. He documented that "incision 11" was "erythemic" at the "distal end". So the nurse sent an email to Dr. Denning's office, asking for instructions and advice for treatment of the incision. But Dr. Denning, nor his staff, ever bothered to respond. So the nurse had no choice but to instruct me to in how to properly put Bactroban ointment on Kathryn's incision several times a day, and cover it

with gauze and tape. The nurse sent additional emails to Dr. Denning's office, but still received no reply. That incision did not fully heal until after we had been back home for several months.

74. Exhibit # 20 , Home Health Certification, Visiting nurse report.

75. On November 22nd of 2010, Kathryn had her first post-op office visit with Dr. Denning. He told us that Kathryn would be able to travel home to Phoenix at the end of the month. Dr. Denning gave me directions on how often to stop so that Kathryn get out and walk for a few minutes, how many hours to drive each day, etc. A trip that took us two days to go to Dallas, would take us five days to return home.

76. Near the end of that first post-op office visit, Kathryn asked Dr. Denning if she would set off the alarms at the airport, as we intended to fly to Dallas for her next office visit. Dr. Denning said that she might, so Kathryn asked for something to show the TSA , to prove that she had medical implants. Dr. Denning replied that he would write a note. So he went to his office, and returned in about five minutes with a note that he had handwritten on his prescription pad; and told Kathryn to carry it when she traveled.

77. That handwritten note is the clearest, most basic, proof of Dr. Denning's fraudulent attempt to conceal his actions from us. When Kathryn's

medical records came in the mail on October 1st of 2010, sitting on the top of the pile was Kathryn's official Medtronic ID card – the official card to use when traveling. Dr, Denning had kept that card from us because it contained the truth about Dr. Denning's actions. The truth that he did not want us to know. And because Kathryn did not have that card, she was searched in the Dallas airport as we returned home from her January post-op visit with Dr. Denning. I watched as Kathryn stood in a cubicle, clinging to her walker, silently crying - as a TSA worker poked her back, probing every screw and rod.

78. Exhibit # 21 , Medtronic ID card, Dr. Denning handwritten note.

79. During Kathryn's post-up visit on January 27th of 2011, she complained to Dr. Denning that her right leg pain had returned. The pain had begun to manifest itself when Kathryn had stopped regularly taking morphine pills. Apparently the morphine pills had been masking her leg pain. But Dr. Denning did not seem concerned about Kathryn's leg pain - instead he seemed to find her pain inconsequential and unimportant. Dr. Denning did not order any testing or imaging. He did not recommend any treatment.

80. Dr. Denning's office notes from that January post-op visit state – "Upon more careful questioning it was discovered that the Jones' have two vehicles that are quite high off the ground, a Jeep vehicle and a big truck that

require a very high step-up and use of a hand rail to get up into the vehicle and she has been unable to do that maneuver". And "they indicated they were not" planning to replace the vehicles. Also "I was a little concerned that she has not been driving yet". So Dr. Denning's PA wrote a prescription for Kathryn to undergo therapy because "she needs work to get in & out of her car".

81. Exhibit # 22 , Dr. Denning office notes dated 1-27-11.

82. Dr. Denning refused to investigate or treat Kathryn's right leg pain - but was concerned that she was not driving! She could barely walk, used a walker, and wore a heavy brace – yet she was supposed to hop in a car and drive to Starbucks. Neither of our vehicles is big or quite high off the ground; they are standard-issue from the factory. But even now, almost two years after her spinal fusion surgery, Kathryn is still unable to enter our car or truck by herself. She has driven less than ten times since her surgery. Kathryn also has difficulties on stairs and escalators, and severely restricts her activities. This is the only way that she is able to manage her leg pain. She later went through a course of physical therapy, but her right leg remains painful and does not function properly. It is a disabling condition that requires careful planning in order for Kathryn to live a semi-normal life.

83. Dr. Denning has repeatedly denied that Kathryn's right leg pain is related to her spinal fusion. Prior to her fusion surgery, Dr. Denning had assured Kathryn that she would still be able to drive our Jeep through the desert and explore. Unfortunately, she is barely able to drive down a city street. Kathryn drives only when it is absolutely necessary.

84. On April 28th of 2011, we returned to Dallas for Kathryn's six month post-op doctor visit. Once again, Kathryn complained of "back pain and right leg pain, which vary with her level of activity". Dr. Denning's PA explained "that after a surgery of this magnitude that it is a reasonable long term expectation that she might have a small degree of back pain with certain activities". Kathryn did not consider the level of her pain to be a "small degree". If that had been the case, she would not have mentioned it - Kathryn has a very high pain tolerance. But, as before, Dr. Denning did not order any investigational tests or recommend any treatment. During that office visit, Dr Denning reviewed Kathryn's x-ray and wrote in his report that "All pedicle screws are in place with no evidence of any lucency or loosening. The bilateral rods are intact with no evidence of any hardware failure". At that time, we were in the x-ray viewing area with Dr. Denning, and asked him to point out where the new bone fusions were - but he replied that they would not be visible on an x-ray. At the end of Dr. Denning's

report, it states that "we will get another AP and lateral x-ray of her lumbar spine so we can continue to assess the status of this fusion". That was it - come back in six months.

85. Exhibit # 23 , Dr. Denning office notes dated 4-28-11.

86. In early July of 2011, Kathryn sqatted down to pick up a towel, and felt a rip inside her left flank area. Over the next two or three days, the area became very tender, and had a burning sensation. Then Kathryn noticed a large bulge on her left side, below the incision from the first surgical procedure, close to the incisions from her lung surgery. I was concerned, so I called Dr Denning's office and spoke to his PA. She told me to have the bulge diagnosed, so I took Kathryn to the ER. At the ER Kathryn had an ultrasound, and was diagnosed with edema. So we went to Kathryn's primary doctor, who diagnosed a fatty lipoma. Then we consulted a plastic surgeon, who diagnosed a muscle that was no longer anchored, due to surgical incisions. Kathryn then saw an ad in a magazine for a local orthopedic surgeon who does Medtronic minimally invasive spine surgery. That doctor's PA sent Kathryn for a CT scan. The local surgeon then also diagnosed an unanchored muscle and wrote Kathryn a prescription for physical therapy. This whole process took two months.

87. During that time, I called Dr. Denning's PA several times to say that we still did not have a definitive diagnosis. The PA just told me to keep trying. Many weeks later, she told me that she would speak to Dr. Kirby, the vascular surgeon - but she did not. Finally, I confronted the PA, and demanded to know why Kathryn could not see Dr. Denning, as it was almost time for her one-year post-op visit. At that point the PA said OK.

88. We went to Dallas on September 21st of 2011. First Kathryn saw Dr. Kirby, who was very rude. He said that Kathryn had lymph edema, and told her to get therapy. He wrote a prescription that turned to be useless, as it was not specific regarding the location of the lymph edema area to be treated. Then we saw Dr. Denning in Plano. He examined Kathryn's back and diagnosed a "lumbar sprain". He stated that she "had no bony abnormality". So he wrote a prescription for physical therapy and said to return in six months. That was Kathryn's last visit with Dr. Denning; she has not returned to Dallas or Plano since then.

89. Dr. Denning's notes indicate that he looked at Kathryn's CT scan (from her local surgeon), and wrote that it "showed no significant abnormalities with alignment anatomic and post op fusion changes from T12-S1". But then he also wrote that "The T12-L1 level is not fused, but the screws and rods are positioned well and have not pulled out". Dr, Denning did not tell us that the T12-

L1 level had not fused. Not on that day, not ever. He did not order any further testing, nor tell Kathryn to be careful, nor instruct her to inform him if she noticed symptoms or signs that her hardware might be loosening or moving. Nothing, nothing at all. When she returned home, Kathryn underwent a course of physical therapy. The therapy made her more flexible, but did not affect her pain or the bulge in her side. It is also worth noting that the local surgeon did not mention the failure to fuse either. We have no evidence that he was aware of it. As we only learned of the failure to fuse from Dr. Denning's records on October 1st of 2012, Kathryn has not yet had the opportunity to see the local surgeon.

90. Exhibit # 24 , Dr. Denning Quick Note dated 9-21-2011, Aetna EOB for therapy dated 10-11-11.

91. Late in 2011, around Thanksgiving, Kathryn's urethra/bladder pains increased in severity. Kathryn had been experiencing urethra pain continuously since mid-2009. Her OB-GYN told her to put estrogen cream on it, but that did not help. Prior to her fusion surgery, Kathryn had described her urethra pain as irritating, similar to a bad skinned knee. But after her spine surgery, the pain increased. It was at its worst at bedtime, and Kathryn would be unable to sleep. Then, in December of 2011, Kathryn began to experience flares of unendurable, debilitating pain, and went to the ER twice. At the first visit, she was given IV

morphine and diagnosed with a urinary tract infection. She was prescribed macrodantin. Ten days later, Kathryn was again at the ER for excrutiating pain in her urethra. Again, she had IV morphine, and that time was prescribed Cipro. Kathryn then consulted a urologist, who ordered every test imaginable – a urinary scope, a CT scan, a MRI, a cancer marker test, everything. Finally, the urologist diagnosed a pain condition, and sent Kathryn to a pain specialist for a pudendal nerve block.

92. As she was undergoing the testing, Kathryn was taking five pills of Uribel every day for her pain. But the Uribel adversely affected her balance. In January of 2012, as she reached up to take a framed photo off the wall, Kathryn lost her balance and had a bad fall. She landed hard on her knees, and then fell forward and smacked her face and head into the tile floor. She was really banged-up; with two black eyes, a sprained wrist, gouges in her legs that turned into cellulitis, bruised knees and more. The local surgeon told her that she was now "top heavy" due to her spinal fusion. He warned that the next fall could be fatal.

93. As Kathryn recovered from her fall, she continued to see the urologist. We contacted Dr. Denning's office via email several times to ask if her urethra/bladder problems could be related to her spinal fusion surgery. I sent the first email on April 3rd of 2012. There was no response, so Kathryn sent an email

on April 24th of 2012. That resulted in a confusing, rambling voice message from Dr. Denning's PA, so Kathryn sent another email. Dr. Denning still did not respond, so Kathryn sent a certified letter to Dr. Denning. She received an email from his assistant stating that the doctor would respond in two or three weeks. He did not respond, so Kathryn sent another certified letter on June 21st of 2012. Dr. Denning finally replied via certified letter dated June 27th of 2012, received July 5th of 2012.

94. Dr. Denning's letter states that "the lateral approach is the procedure that we elected to use and involved a less invasive procedure, and one in which we do not manipulate the autonomic nerves, specifically, the hypogastric plexi that reside in the anterior lumbar spine". He further stated that Kathryn did not have an anterior approach; so her procedure did "not involve manipulating those nerves at all". He then recommended that Kathryn consult the pain specialist

95. Exhibit # 25 , Email dated 4-3-12, note dated 4-24-12, letter dated 5-9-12, letter dated 6-21-12, letter dated 6-27-12.

96. As previously explained, Kathryn's first procedure was "retroperitoneal", behind the abdomen. An article in "The Spine Journal" explains that, during an anterior–lateral approach, in which "the spine was exposed using a retroperitoneal approach" the "delicate autonomic plexus was divided with a sharp

vertical incision in the midline from the bifurcation of the aorta caudally and retracted to either side". This procedure had to be done in order to expose the spine. (And remember, Dr. Kirby was exploring "behind the abdomen".) Dr. Denning stated in his letter that Kathryn did not have an anterior approach with manipulation of her nerves, but she did. The article in the "The Spine Journal" further states that "The autonomic plexus coordinating bladder sphincter control...is intimately associated with the aortic and vena cava and drapes down over the bifurcation and ventral surface of disc and sacral body. This area is necessarily manipulated during an approach to the lower lumbar segments". The article then states that "Anterior fusion with restoration of disc space height and lordosis may preserve better sagittal alignment and perhaps be associated with a more rapid recovery compared with posterolateral fusion techniques. However both anterior approaches and posterior lumbar interbody fusion approaches have risk of injury to intervening structures". And further "The mechanism of the injury as a complication of anterior spinal surgery is thought to be a disruption of the superior hypogastric plexus in the retroperitoneal space around the level of the bifurcation of the aorta and the lumbosacral junction". A complication known as retrograde ejaculation is most closely associated with anterior approach spinal

fusion; this condition is necessarily confined to men. Urogenital complications in women, resulting from spinal surgery, are rarely mentioned.

97. Exhibit # 26 , "The Spine Journal" clinical review.

98. Kathryn underwent a pain block injection of her hypogastric nerve plexus on June 29th of 2012. The injection did not affect her urethra/bladder pain at all. It did have a severe, adverse effect on her right leg. Immediately after the injection, Kathryn could not walk without assistance; she had no control of her leg. It would not function. And it was very painful. When lying in bed, Kathryn could not lift her foot more than two or three inches off the mattress. That sent Kathryn into a severe depression, as she had made the choice to undergo the nerve block without receiving any advice from Dr. Denning. But, when Dr. Denning's letter arrived a week later, Kathryn did not know what to think - Dr. Denning did not seem to be concerned about her at all, not since before she had her surgeries. The functioning of Kathryn's right leg gradually returned after several weeks. But the pain has never completely resolved, and remains at a higher level than prior to the injection.

99. Exhibit # 27 , Pain injection papers dated 6-29-12.

100. Kathryn now sees a uro-gynecologist for her urethra/bladder pain. The doctor has diagnosed her with a pain condition and interstitial cystitis, an

inflammation of the bladder lining. Kathryn takes three tablets of Hyoscyamine Sulfate daily for her urethra pain. She undergoes procedures in which a "cocktail" of compounded medications (including Heparin and DMSO) are infused directly into her bladder. She has had three of these procedures, and is scheduled for three more. The doctor has indicated that both of her conditions are chronic, and most likely permanent.

101. Kathryn is also experiencing extensive hair loss, which began early this year. In April, Kathryn started to find small clumps of her hair on her clothing and in the bathroom sink. She cut her hair short, in the hope that it would stop the hair loss. It did not. By early summer, Kathryn estimated that more than fifty percent of her hair was gone. We consulted with her primary doctor, an immunologist/allergist, a rheumatologist, a hematologist, and a dermatologist – to no avail. The only suggestion was to take supplements of ferrous sulfate, as the stores of iron in Kathryn's blood were low. Recently, the rate of hair loss has seemed to slow. But there has been no new growth since April. As usual, Kathryn sent an email to Dr. Denning about her hair loss, but did not receive a response until her records arrived, with a letter attached.

102. When the FDA approved INFUSE, it specified that Medtronic must "Perform post-approval studies to investigate the potential for an immune response

to rhBMP-2", and "Develop and validate a new antibody ELISA for antibodies to rhBMP-2". The FDA also required that Medtronic "Develop and validate a neutralization assay for antibodies to rhBMP-2". We do not know if Medtronic has done any of these studies, or developed any of the products. But we do know that Dr. Denning has been aware, since August 2010, that Kathryn has autoimmune conditions. He chose not to inform her that INFUSE could cause autoimmune responses. He chose not to order any of the above tests – even when informed that Kathryn was experiencing extensive hair loss.

103. Dr. Denning has consistently, repeatedly denied that the hair loss, the debilitating pain, and the disability that Kathryn has endured since her spinal fusion is in any way related to her surgery. It would be a miracle if that were true. But it is not true. And that is a tragedy.

104. At the end of this summer, in late August, Kathryn heard the end of a TV ad about out-of-control bone growth related to bone-graft spacers. She wondered what that meant, but did not think much about it. Then a few days later, as she was exercising, Kathryn noticed that her feet were lumpy and looked like Neanderthal feet. So she sent an email to Dr. Denning on August 18th of 2012, asking if the bone growth was related to her spine surgery. She also asked about

her hair loss. She received a reply email stating that Dr. Denning was out of town. That was all. Nothing else.

105. Exhibit # 28 , Email dated 8-18-12.

106. So then Kathryn decided to do an internet search. She learned that a product named INFUSE, manufactured by Medtronic, had been blamed for numerous complications of spinal fusion surgery. She also learned that INFUSE was widely used in spinal fusion surgeries. Because Kathryn knew that her fusion implants had been manufactured by Medtronic, she sent an email to Dr. Denning on September 22nd of 2012, asking "Do I have Medtronic inFUSE Bone Grafts?" She also requested copies of all of her records. She then sent a certified letter containing a copy of her email. Dr. Denning did not reply. So Kathryn sent another email, explaining that she was scheduled to undergo a bladder procedure, and needed the information so that she could make an informed decision about her urethra/bladder care. Still no response.

107. Exhibit # 29 , Email dated 9-22-12 (page 2).

108. On Saturday, September 22nd of 2012, Kathryn also sent an email to Paula Hagan, the hospital attorney. She asked Ms. Hagan the same questions regarding the Medtronic INFUSE product. Kathryn also sent the email via certified mail.

109. On Monday, September 24th of 2012, Kathryn again contacted Ms Hagan, as there had been no response. Over the next two days, many emails and phone calls were exchanged with Ms. Hagan and other hospital personnel. Finally, on September 25th of 2012, we received three copies of pages from Kathryn's hospital records. The pages contained labels from the products implanted in Kathryn during her fusion surgeries. Kathryn had been implanted with INFUSE. And she had also been implanted with donor bone. We were in shock

110. Exhibit # 30 , Email dated 9-22-12, email dated 9-25-12, email dated 10-11-12.

111. Finally, on October 26th of 2012, Dr. Denning's assistant sent an email response from Dr. Denning. In the email, Dr. Denning stated that he "use INFUSE in all our surgeries". "We place it only inside cages or spacers, where it is contained" and "it is not exposed to nerves in any of our surgeries". And most shockingly, "The other option is to use donor or cadaver bone which does not heal as well and can be rejected by the body". Then why did Dr. Denning use both INFUSE and cadaver bone? Why expose Kathryn to the risk of rejecting cadaver bone, especially when she had been very clear that she did not want any donor bone? Was Dr. Denning being malicious on purpose? Or did someone else write

this response – someone who did not know that Kathryn had been implanted with both INFUSE and cadaver bone?

112. So Kathryn sent a reply email to Dr. Denning's assistant, asking her if Dr. Denning himself had dictated the response. The assistant emailed back that Dr. Denning had dictated his response to her, and that he "did use INFUSE in your spine surgeries".

113. Exhibit # 31 , Email dated 9-26-12.

114. On October 1st of 2012, we received Kathryn's medical records in the mail. That night our lives were changed forever.

115. Exhibit # 32 , Letter dated 9-26-12.

116. During Kathryn's third surgery, when Dr. Denning and Dr. Jackson "removed a portion of the inferior facet joint bilaterally and placed some BMP over this", they were clearly using the BMP (INFUSE) in an "off-label" or "physician-directed" manner. And as an editorial from "The Spine Journal" states "physician-directed use has resulted in significant patient benefit for conditions outside of the original FDA approval". It also states "the knowledge gained has been invaluable and more is yet to be learned". But that is not all. The author then clearly states that "the best knowledge or evidence comes from thoughtful, careful,

hypothesis-driven investigations with meticulous assessment, and evaluation of outcome".

117. Dr. Denning and Dr. Jackson did not do this. Kathryn has received almost no post-surgery care from Dr. Denning. When Kathryn complained of leg pain, Dr. Denning did not order a CT scan, nor a MRI. He did no investigation to determine the cause of her pain. Instead Dr. Denning chose to blame Kathryn's leg pain on our "quite high off the ground" vehicles. And yet, leg pain is one of the most common complications of spinal fusion surgery with INFUSE. The pain can come from swelling, from ectopic bone growth, or from migration of the hardware. Still, Dr. Denning chose not to investigate

118. And when Kathryn asked Dr. Denning if her urethra/bladder pain might be related to her spinal fusion surgery – the answer was "no". Dr. Denning told Kathryn that she had undergone a lateral approach, not an anterior approach. Even though Dr. Denning's own notes state that Kathryn's first surgery was "retroperitoneal", behind the abdomen. And once again, Dr. Denning chose not to investigate. Following most fusion surgeries, the patient undergoes routine CT scans at three months post-op, six months post-op, one year post-op, and two years post-op. But Dr. Denning did not order any CT scans. He did not order any

MRI's. Even after Kathryn suffered a very bad fall, Dr. Denning did not order any investigational studies.

119. In its approval for INFUSE, the FDA instructed Medtronic to develop a test to determine if a patient was having an autoimmune response to INFUSE. But, once again, when Kathryn asked Dr. Denning if her extensive hair loss was related to her fusion surgeries – Dr. Denning said "no". And he chose not to investigate. Dr. Denning has ordered three x-rays of Kathryn's lumbar spine post-surgery. That is all. Nothing else. There was no "meticulous assessment".

120. Clearly, Dr. Denning and Dr. Jackson experimented on Kathryn. How else to explain their complete disregard of the Medtronic warning to doctors, regarding use of INFUSE. How else to explain the presence of Medtronic representatives in the operating room. And, how else to explain the lies and deception to Kathryn and me. But why? Dr. Denning and Dr. Jackson did no post-surgery "investigations". There was no "evaluation of outcome". Or was there? Did Dr. Denning and Dr. Jackson conduct an experiment - a trial - that was only concerned with the surgeries themselves, not with the patient outcome? Did the Medtronic representatives actively participate in the experiment, the trial? But a trial of what?

121. Ultimately, the answer to that question will never be revealed, unless the court grants our prayer for relief.. Kathryn has suffered irreparable harm from Dr. Denning and Dr. Jackson. She has been injured both physically and emotionally, for no reason. The doctors did not do a "well-designed and executed, and widely implemented" study "with imaging and technology intensive outcome assessment and interpretation". The damage to Kathryn served no purpose at all – it did not benefit anyone. But it greatly harmed Kathryn, me, and our entire family. Kathryn is a valuable human being. She is not a mere body for Dr. Denning and Dr. Jackson to use in an experiment. The doctors were totally reckless. Their actions were unconscionable, completely unacceptable, in civilized society.

122. Exhibit # 33 , "The Spine Journal" editorial.

DISCUSSION

This section is not completed as I certainly did not have sufficient time to do a thorough investigation and presentation of the issues. I pray that the court will allow me to supplement the complaint filing , asap.

PART 1 - TEXAS MEDICAL MALPRACTICE LAW

In the case of O'REILLY v. Wiseman, 107 SW 3d 699 - Tex: Court of Appeals, 3rd Dist. 2003, the Texas court issued its CONCLUSION as follows:

"This case illustrates the policy the legislature has adopted to limit medical malpractice claims. Section 10.01 of the Act sets up an absolute limitations period. In giving effect to the statute of limitations and the case law, we do not ignore the harsh effect it has upon Ms. O'Reilly's constitutionally protected right to redress. Nevertheless, the Supreme Court's holdings in this area of the law require us to find that Ms. O'Reilly's claim is barred by the statute of limitations. Because the facts of the alleged injury were discovered well within the two-year period, it was not impossible for her to bring suit before the limitations period ended four months later. We affirm the judgment of the district court."

I now continue with passages from O'Reilly v. Wiseman ruling- The court opened its discussion by stating:

"We are called upon to decide whether the open-courts provision of the Texas Constitution invalidates the two-year statute of limitations of the Medical Liability and Insurance Improvement Act (the Act) as applied to a particular patient. *See* Tex.Rev.Civ. Stat. Ann. art 4590i, § 10.01. For the open-courts doctrine to invalidate a statute of limitations, a showing must be made that due to the nature of the claim it was impossible or exceedingly difficult to discover the alleged wrong and bring suit within the two-year period. *See* Shah v. Moss, 67 S.W.3d 836, 846 (Tex. 2001); *Neagle v. Nelson*, 685 S.W.2d 11 (Tex.1985); *Nelson v. Krusen*, 678 S.W.2d 918 (Tex.1984); *Sax v. Votteler*, 648 S.W.2d 661 (Tex.1983)."

The court then proceeded to examine the Texas law:

"The Medical Liability and Insurance Improvement Act

The Act establishes the following statute of limitations in section 10.01, which provides, in relevant part, that:

"notwithstanding any other law, no health care liability claim may be commenced unless the action is filed within two years from the occurrence of the breach or tort or from the date the medical or health care treatment that is the subject of the claim or the hospitalization for which the claim is made is completed."

Tex.Rev.Civ. Stat. Ann. art. 4590i, § 10.01. Section 10.01 re-enacted the previous statute of limitations applicable to malpractice claims first established in 1975. Joseph P. Witherspoon, *Constitutionality of the Texas Statute Limiting Liability for Medical Malpractice,* 10 Tex. Tech L.Rev. 419, 421 (1979). The legislature rejected the Professional Liability Study Commission's[3] recommendation to restore the "discovery rule," applicable before 1975, which would begin the running of the limitations period from the time the patient knew or should have known of an alleged injury.[4] *Id.* Instead, the legislature enacted the two-year limitation, "without the allowance of any of the court-developed exceptions." *Id."*

The court then addressed the *Development of the Open-courts Provision by the Texas Supreme Court:*

"We are called upon to decide whether the open-courts provision of the Texas Constitution invalidates the two-year statute of limitations of the Medical Liability and Insurance Improvement Act (the Act) as applied to a particular patient. *See* Tex.Rev.Civ. Stat. Ann. art 4590i, § 10.01. For the open-courts doctrine to invalidate a statute of limitations, a showing must be made that due to the nature of the claim it was impossible or exceedingly difficult to discover the alleged wrong and bring suit within the two-year period. *See* Shah v. Moss, 67 S.W.3d 836, 846 (Tex. 2001); *Neagle v. Nelson*, 685 S.W.2d 11 (Tex.1985); *Nelson v. Krusen*, 678 S.W.2d 918 (Tex.1984); *Sax v. Votteler*, 648 S.W.2d 661 (Tex.1983).

The third case in the development of the open-courts doctrine was *Neagle,* a brief opinion applying the doctrine when a surgical sponge left in the abdomen of the plaintiff was discovered more than two years later. The court assumed that it was impossible for Neagle to discover the injury until more than two years after the surgery. *Neagle*, 685 S.W.2d at 12.

"The open-courts provision ... protects a citizen, such as Neagle, from legislative acts that abridge his right to sue before he has a reasonable opportunity to discover the wrong and bring suit." *Id.* The opinion failed to mention the balancing test formulated in *Sax;* however, the court cited *Sax* and *Nelson* with approval as declaring the limitations unconstitutional as applied based on the open-courts provision.

From these three cases, the court established the proper test to employ when analyzing the limitations period under the open-courts provision. As the court noted, the decisions in *Nelson* and *Neagle* were "premised on the fact that it 705*705 was *not possible* for the parties to discover the injury within the two-year period." *Morrison v. Chan*, 699 S.W.2d 205, 207 (Tex.1985) (emphasis added).[5] The open-courts doctrine is premised on the notion that "the legislature has no power to make a remedy by due course of law contingent on an *impossible condition." Id.* (citing *Nelson*, 678 S.W.2d at 921) (emphasis added).

After *Hellman,* the supreme court repeatedly held that to establish an open-courts violation, a plaintiff must show it was impossible or exceedingly difficult to discover the wrong[10] and bring suit, without mentioning the *Sax* balancing approach. *See Earle v. Ratliff*, 998 S.W.2d 882, 890 (Tex.1999) (patient who complained of constant pain to doctor and who had seen television report detailing risks associated with instrumentation implanted in him had "opportunity to learn of any negligence" prior to two-year period); *Husain v. Khatib*, 964 S.W.2d 918, 919 (Tex. 1998) (failing to mention open-courts provision in holding that if doctor's date of negligence can be ascertained "there are no doubts to resolve and limitations must be measured from" that date); *Jennings v. Burgess*, 917 S.W.2d 790, 794 (Tex.1995) (plaintiff knew defendant doctor had referred her to general practitioner and not specialist as requested, therefore she had reasonable opportunity to discover her alleged injury of negligent referral and bring suit within the two-year period). The court reemphasized that the open-courts doctrine "is premised upon the rationale that the legislature has no power to make a remedy by due course of law contingent upon an impossible condition." *Diaz v. Westphal*, 941 S.W.2d 96, 100 (Tex. 1997). The validity of the *Sax* balancing test between the restriction on the litigant's right to redress and the purpose

and basis of the statute remained in question, however, because the court was able to rely on the "impossible condition" to determine that no open-courts violation existed.[11]"

The court then applied such case history regarding the *Development of the Open-courts Provision by the Texas Supreme Court* to *Ms. O'Reilly's claim and determined that:*

"It was not impossible for Ms. O'Reilly to discover her injury within the two-year limitations period; when she learned she had breast cancer on December 27, she was aware of the possible negligence of those who had told her the earlier mammograms revealed no signs of cancer. Understandably, Ms. O'Reilly did not immediately hire a lawyer and head to the courthouse; she first hired a doctor and focused all her energy and attention on pursuing the medical treatment necessary to save her life. But as of December 2000, four months remained to sue Dr. Wiseman within two years of the date of his treatment in April 1999.

The legislature has adopted an absolute two-year statute of limitations to pursue medical malpractice claims. *See* Tex.Rev.Civ. Stat. Ann. art. 4590i. The supreme court has found that this restriction cannot survive an open-courts challenge if it would be "impossible" for the patient to sue within the two-year period. *See* Shah, 67 S.W.3d at 846-47; Weiner, 900 S.W.2d at 321; Moreno, 787 S.W.2d at 357. It is quite understandable that Ms. O'Reilly would concentrate on fighting her disease before pursuing her medical negligence claims, but because she had four months after discovering her injury in which to file such a claim against Dr. Wiseman, we cannot say that conditions made it impossible for her to do so.

The supreme court has held that the open-courts provision allows a patient to avoid the absolute two-year limitations only if it would be impossible or exceedingly difficult to discover the injury within that period. We agree that the application of this absolute limitations period to Ms. O'Reilly under these circumstances is exceedingly harsh. This is a choice the legislature has made to limit the time insureds are exposed to liability. As we read the teachings of the supreme court, the open-courts provision negates this absolute time period only if conditions make it virtually impossible to discover one's injury within two years. For four months after she learned of her injury, Ms. O'Reilly had a chance to pursue her negligence claims, even though we would all sympathize with her decision to get well 709*709 first. With the abolition of the discovery rule by *Morrison,* the absolute limitations period required Ms. O'Reilly to bring suit within the four months after she learned of her injury.[14]"

"[2] Ms. O'Reilly's attorney first attempted to obtain copies of her mammograms on May 17, 2001. They were received on August 31, 2001.

[3] The Professional Liability Study Commission was established by the legislature two years prior to the enactment of the Medical Liability and Insurance Improvement Act (the Act) to address the national problem of maintaining affordable and comprehensive health care in response to increasing insurance costs for health care providers in the 1970s. *See* Joseph P. Witherspoon, *Constitutionality of the Texas Statute Limiting Liability for Medical Malpractice,* 10 Tex. Tech L.Rev. 419, 421 (1979).
[4] The Study Commission recommended a provision permitting a malpractice claim to be filed within one year from the date the alleged injury was discovered or should have been discovered. Witherspoon, 10 Tex. Tech L.Rev. at 421.

[5] The court in *Morrison* held that the language of section 10.01, the legislative history, and the language in *Nelson* make it clear that section 10.01 was intended to abolish the discovery rule and require suit to be brought within a two-year period from the time of injury, not the time of discovery of injury. Morrison v. Chan, 699 S.W.2d 205, 208 (Tex. 1985).

[10] We will use the language "impossible or exceedingly difficult to discover the wrong" rather than "reasonable opportunity to discover the wrong" in describing what a plaintiff must show in an open-courts challenge. Much of the confusion surrounding these cases is the court's use of the language "reasonable opportunity to discover the wrong" to describe situations where it is "impossible or exceedingly difficult to discover the wrong" and bring suit within the two-year period. In all three cases which first developed the open-courts provision in terms of the limitations provision of the Act, the plaintiff was in a situation where it would have been impossible to discover the injury and file suit within the two-year period. Moreover, the court has repeatedly emphasized that the "reasonable opportunity" test is met through a showing that the nature of the claim made it "impossible or exceedingly difficult to discover the wrong" or that the plaintiff could not have discovered the wrong and brought suit within the two-year period. *See, e.g.*, Weiner v. Wasson, 900 S.W.2d 316, 321 (Tex.1995) (Stating that an open-courts violation is not found in "cases other than those involving claims that are by their nature exceedingly difficult or impossible to discover.").

[11] The balancing test was mentioned in only one case following *Nelson.* In *Weiner,* the court quoted *Sax* but relied on the "impossible condition" doctrine to invalidate the limitations provision. 900 S.W.2d at 318.

[12] The bases and purposes of the Act as found by the legislature are set forth in Tex.Rev.Civ. Stat. Ann. art. 4590i, § 1.02 (West Supp. 2003). The main purposes of the Act were to "improve and modify the system by which health care liability claims are determined" and "reduce excessive frequency and severity of health care liability claims" "in a manner that will not unduly restrict a claimant's right any more than necessary." *Id.* § 1.02(b). *See also* Sax v. Votteler, 648 S.W.2d 661, 667 (Tex.1983) (finding purpose of the limitations period was to limit length of time that insureds would be exposed to potential liability).

[14]*See also* Gutierrez v. Lee, 812 S.W.2d 388, 393 (Tex.App.-Austin 1991, writ denied) (noting "a provision is [not] unconstitutional [solely] because it limits the period in which the plaintiff may analyze his case" and holding that a three-month period is sufficient under the open courts doctrine).

[15] We need not reach the reasonable time analysis in this case because "the reasonable-time rule [is not applied] to cases other than those involving claims that are by their nature exceedingly difficult or impossible to discover," Weiner, 900 S.W.2d at 321, and Ms. O'Reilly has not established her prima facie case of an open-courts violation. Whether Ms. O'Reilly filed her claim within a reasonable time is irrelevant unless her claim is kept alive by the open-courts doctrine. We make no assertion as to whether the facts in this case would constitute a reasonable time other than to note that the reasonable time standard has been developed on a case-by-case basis and is generally a question of fact. *Compare* Shah, 67 S.W.3d at 847 (endorsing a one-year limit to what is considered unreasonable as a matter of law), *and* Gagnier v. Wichelhaus, 17 S.W.3d 739, 745 (Tex.App.-Houston [1st Dist.] 2000, pet. denied) (ten-month delay reasonable when taking into account "delay in providing medical records, the time for recovery, consultation with an attorney and investigation"), *and* DeRuy v. Garza, 995 S.W.2d 748, 753 (Tex.App.-San Antonio 1999, no pet.) (one-year delay reasonable), *and* Work v. Duval, 809 S.W.2d 351, 353-354 (Tex.App.-Houston [14th Dist.] 1991, no writ) (fact that injury was discovered four months prior to expiration of two-year limitations period irrelevant because plaintiff unreasonably delayed in filing suit for twenty-one months following discovery of injury), *with* LaGesse v. PrimaCare, Inc., 899 S.W.2d 43, 47 (Tex.App.-Eastland 1995, pet. denied) (one-year delay unreasonable); *see also* Neagle v. Nelson, 685 S.W.2d 11, 12 (Tex.1985) (Kilgarin, J., concurring) (reasonableness of delay before filing suit after discovery of injury should ordinarily be question of fact measured on "diligence" standard)."

I take great issue with this conclusion, as the matter of reality does not support its application. I believe that my opinion, which is based upon my personal experience regarding this issue, is supported by an overwhelmingly large amount of real data that conclusively destroys the Texas court's conclusion of

being equitable in any way what-so-ever in today's world, if not also in 2003. The court does not state any investigation or data of proof to support its conclusion. I speculate that the Texas court lacked any proof to support its decision regarding the four(4) months remaining before the two-year statute ran out, and that they made a conclusion based solely on unjustified conjecture. I feel that they made a grave error and executed great injustice upon the victim in this case, Ms. O'Reilly.

I have personally contacted more than 30 Texas attorneys; plus I made broadcast searches for Texas & Arizona attorneys on lawyer.com, LexisNexis, FindLaw, etc.; plus I contacted many local & out-of-state attorneys and I am still receiving "no" responses. My recent intensive effort resulted in finding no interest by any attorney in taking our medical malpractice case, merely on the basis that it is too close in time to the Texas state law statute of limitations of two-years. The attorneys have all required a minimum of six (6) months, before they would even take the time to consider investigating the merits of our case.

I feel that my personal experience is proof that a four (4) months' time period is not well within the two-year period, but instead meets the Texas Supreme Court's test that "a showing must be made that due to the nature of the claim it was impossible or exceedingly difficult to discover the alleged wrong and bring suit within the two-year period". **My experience and data also proves that a two-year statute of limitations regarding a medical malpractice claim, in a real world, actually turns out to give less than 18 months for the victim to be able to get a law suit filed.**

The Texas courts decision does not hold up when put to the test of reality in the world today, and thus should not be assumed to be equitable in any way what-so-ever in our case. In addition, the fact that the court considered this amount of time to be equitable, and that their determination of time is subjectively based on each case; what am I to believe to be their subjective analysis of our case? Would it be zero months, or maybe 2 months, or possibly 3 months? Would the court determine that I did not contact enough attorneys to prove that more than 6 months is needed in order to give a minimum amount of time? Would the court feel that 100 attorneys should have been contacted, or maybe 500 attorneys. It is subjective, and I have come to dislike the application of that word, as it can easily be manipulated, and the Texas court even decided that

savings one's life from dying of cancer is not relevant in its subjective determination of time in the O'Reilly case.

THEREFORE, I came to the conclusion that in order for Kathryn, us, me to have any possible chance of stopping these offensive actions from being allowed to go unpunished- I must attempt to file this complaint within the 12 days I had left, to request this court's relief before the most restrictive date possible of starting the clock is past (10-26-12). I am not suggesting that I believe that the date of October 26, of 2010 should be the date that the clock starts, as I definitely do not agree with that opinion; just that it might be the date that a court, or jury, would impose if it was to erroneously use the most extremely restrictive date possible under Texas law.

PART 1 – ARIZONA MEDICAL MALPRACTICE LAW AND FEDERAL TORT CLAIMS ACT AND CASE LAW

In the case of WALK v. D.J.RING, et al, Arizona No. CV-01-0090-PR, AZ SUPREME COURT, EN BANC, the court issued its OPINION (DISCUSSION) as follows:

DISCUSSION

¶11 Plaintiff claims she was entitled to have a jury decide the disputed facts or draw the disputed inferences "as to when she discovered (knew or should have known) sufficient facts which caused her [claim] to accrue." Petition for Review at 1. She also contends that Defendant concealed the real cause of her problems and the statute was thereby tolled because of constructive fraud or fraudulent concealment. Finally, she argues that Arizona should adopt the continuing treatment rule, which tolls the statute of limitations while the patient continues to receive care from the physician.

¶12 Defendant contends, on the other hand, that it is the knowledge of injury that triggers accrual of the cause of action and running of the statute of limitations and that Plaintiff's "actual failure to comprehend that a potential claim exists will not prevent the accrual of the cause of action and will not toll the limitation period." Response to Petition for Review (Response) at 6 (citing *Kowske v. Life Care Ctrs. of Am., Inc.*, 176 Ariz. 535, 537, 863 P.2d 254, 256 (App. 1993)). Pointing out that in 1992 or 1993 Plaintiff was aware that her exacerbated TMJ problems were the result of Defendant's work, Defendant argues that our "law is clear that a plaintiff, armed with the fact that he has been injured and the identity of the person whose care inflicted the injury, has an obligation to exercise reasonable diligence in pursuing a claim." Response at 7 (citation omitted). Thus, concludes Defendant, Plaintiff did not investigate with reasonable diligence and her claim is barred.

¶13 The relevant statute of limitations bars claims such as this two years "after the cause of action accrues." A.R.S. § 12-542. Application of the statute's simple words has been difficult and the moment at which accrual occurs has been the subject of controversy in cases dealing with claims of professional or fiduciary negligence. Use of the word "accrues" in the statute of limitations permits judicial construction of the events or knowledge that will trigger accrual. *See Kenyon v. Hammer*, 142 Ariz. 69, 76 n.6, 688 P.2d 961, 968 n.6 (1984).

A. The discovery rule

1. Decision of the court of appeals

¶14 The court of appeals agreed with Defendant that Plaintiff "had an opportunity to discover Dr. Ring's negligence when she was treated by another dentist." *Walk*, mem. dec. at ¶ 11. The court of appeals concludes that because Plaintiff had such an opportunity, the statute of limitations began to run. Because Plaintiff "recognized her [TMJ] pain and its connection to Dr. Ring's full-mouth reconstruction at least by June 28, 1994, [the] cause of action accrued no later than that date." *Id.* at ¶ 14 (arguing by analogy to *Kowske*, 176 Ariz. at 537, 863 P.2d at 256). Thus, the 1997 action was time-barred. *Id*

.

2. Arizona case law

¶15 In *Kowske*, the court of appeals held that the cause of action in a wrongful death case accrued when the surviving husband obtained medical records concerning his deceased wife. The statute was triggered at that time even though the doctor who forwarded the records stated that he "found no signs of misdiagnosis or mistreatment" and said that the autopsy also revealed nothing significant. *Id.* at 536, 863 P.2d at 255. The court held that the statute was not tolled even though plaintiff was not aware that his wife's death was attributable to negligence until he later consulted an attorney. *Id.* at 537, 863 P.2d at 256.

¶16 *Kowske* certainly is factually relevant to the present case. Both *Kowske* and the present case are situations in which the fact of injury is known but the possibility of negligence is difficult to discern. There are instances, of course, in which an unfortunate result would immediately put the plaintiff on notice that the result is not only unfavorable but might be attributable to some fault and should be investigated. *See, e.g., Trede v. Family Dental Ctr.*, 147 Ariz. 25, 27, 708 P.2d 116, 118 (App. 1985) (injury to plaintiff's hand during tooth extraction); *Speed v. DeLibero*, 580 A.2d 1242 (Conn.App. 1990) (patient underwent elective outpatient surgery and died from anesthesia-induced brain injury). In such cases, one may say as a matter of law that the patient is not only aware of the injury but also on notice to investigate whether the injury is likely attributable to the fault of someone responsible for her care. The bright-line rule drawn by *Kowske* and similar cases is properly applied to such cases and the action accrues even though the plaintiff has not sought an expert opinion on malpractice or a legal opinion that a cause of action exists. *See Kowske*, 176 Ariz. at 537-38, 863 P.2d at 256-57.

¶17 There are also cases, and this is one, in which factual context does not permit finding, as a matter of law, that a patient was promptly on sufficient notice of the confluence of "what" and "who" and that an unhappy result should be investigated to determine whether it is attributable to fault of those responsible for the patient's care. Contrary to Defendant's argument, we do not believe the statute is automatically triggered each time a professional's services have failed to produce the desired result or may even have brought about an adverse result. Indeed, it is often the rule that in such cases the question of accrual is for the jury. *Gust, Rosenfeld & Henderson v. Prudential Ins. Co.*, 182 Ariz. 586, 591, 898 P.2d 964, 969 (1995).

¶18 Over the years, our courts have discussed accrual in a series of cases. From early days, we have treated the question of accrual as one of equitable tolling. Thus, when the defendant secretly removed ore from a mine, we held it was equitable to commence the limitations period on the plaintiff's discovery of the trespass and conversion. *Tom Reed Gold Mines Co. v. United Eastern Mining Co.*, 39 Ariz. 533, 535, 8 P.2d 449, 450 (1932). In an early dental malpractice case that twice came to this court, we construed *Tom Reed* as having two distinct holdings: first, that "limitation does not begin to run against a trespass until the plaintiff knows, or reasonably should know, of the trespass, and [second,] that if the wrong constituting the cause of action is concealed, limitation will not begin to run until such concealment is discovered, or reasonably should have been discovered." *Acton v. Morrison*, 62 Ariz. 139, 144, 155 P.2d 782, 784 (1945).

¶19 The second time that case came to this court, we held that a patient was not barred from bringing an action against his dentist because the patient "should [not] be penalized for failing for even this long period of time to discover the true seat of his troubles." *Morrison v. Acton*, 68 Ariz. 827, 36, 198 P.2d 590, 596 (1948). The dentist in *Morrison* left a piece of metal in the patient's jaw after surgical removal of a wisdom tooth. As a result, the patient was left with serious pain in his mouth. The dentist was aware that his drill bit had broken and that this might be the cause of the plaintiff's post-surgical problems, but he failed to explain this to the plaintiff. We held the statute of limitations tolled until the plaintiff's discovery of the facts. In *Morrison*, as in the present case, the plaintiff knew his continuing pain and the failure of his jaw to heal were attributable to the dentist's procedure, but he was unaware of the dentist's negligence. A jury could find the same to be true in the present case.

¶20 The court of appeals adopted and applied the *Morrison* doctrine in *Mayer v. Good Samaritan Hospital*, 14 Ariz.App. 248, 482 P.2d 497 (1971). In *Mayer*, the plaintiff's injuries were caused by an episode of insulin shock sustained in 1964. Although the injuries became apparent that same year, the plaintiff did not file her action until four years later, approximately six months after discovering the physician's negligent conduct. Declining to interpret *Morrison* as resting only on the basis of fraudulent concealment, the court of appeals held that Mayer's action was not time barred. Our court of appeals concluded that the legislature intended to adopt a fair and just statute of limitations that would balance the ease or difficulty a plaintiff has in understanding the cause of an injury with a plaintiff's tardiness in allowing a claim to become stale after the first indications of injury are present.

The court said:

[W]e specifically reject the defendants' alternate argument that the statute begins to run from the time the injuries manifest themselves. However, this point in time may be important in considering the issue as to whether the plaintiff by the exercise of reasonable diligence should have known of defendants' negligence.

Id. at 252, 482 P.2d at 501. In *Kenyon*, this court adopted *Mayer*'s formulation of the discovery rule. 142 Ariz. at 73 n.1, 688 P.2d at 965 n.1.

¶21 We approved that formulation again in a case involving application of the discovery rule to a breach of contract claim, holding that "the important inquiry in applying the discovery rule is whether the plaintiff's injury or the conduct causing the injury is difficult for plaintiff to detect . . . ." *Gust, Rosenfeld*, 182 Ariz. at 590, 898 P.2d at 968 (discovery rule applied seventeen years after landlord's

[3] Our opinion in *Gust, Rosenfeld* relies on the discovery rule and not fraudulent concealment, while the concurring justice would have based the holding only on fraudulent concealment. *Id.* At 591-92, 898 P.2d at 969-70 (Martone, J., concurring).

breach of lease agreement containing "most favored nations" clause). The statute of limitations protects defendants from "stale claims where plaintiffs have slept on their rights." *Id.* A "blamelessly uninformed plaintiff cannot be said to have slept on his rights." *Id.* at 591, 898 P.2d at 969.[3]

¶22 We next addressed this problem in *Doe v. Roe*, 191 Ariz. 313, 955 P.2d 951 (1998). Reversing summary judgment, we held there was a genuine factual issue concerning application of the discovery rule, even though the plaintiff filed the action more than two years after she had her first memory that she had been sexually abused by her father. While an injured person "need not know *all* the facts underlying a cause of action to trigger accrual . . . [,] the plaintiff must at least possess a minimum requisite of *knowledge sufficient to identify that a wrong occurred and caused injury*." *Id.* at 323 ¶ 32, 955 P.2d at 961 ¶ 32 (second emphasis added) (citations omitted). *Doe* makes clear it is not enough that a plaintiff comprehends a "what"; there must also be reason to connect the "what" to a particular "who" in such a way that a reasonable person would be on notice to investigate whether the injury might result from fault.

¶23 While it is ordinarily sufficient when the plaintiff is aware of the injury and its causative agent (the "what and who" elements), summary judgment is warranted only if the failure to go forward and investigate is not reasonably justified. The plaintiff could not be charged with "a duty to file a complaint based on information she subjectively believed to be false or unbelievable at the time." *Id.* at 324 ¶ 35, 955 P.2d at 962 ¶ 35. Thus, the "jury must determine at

what point Plaintiff's knowledge, understanding, and acceptance in the aggregate provided sufficient facts to constitute a cause of action." *Id.* at ¶ 36. We pointed out that determinations of the time when discovery occurs and a cause of action accrues "are usually and necessarily questions of fact for the jury." *Id.* at 323 ¶ 32, 955 P.2d at 961 ¶ 32 (citing *Gust, Rosenfeld*, 182 Ariz. at 591, 898 P.2d at 969).

[4] There is some indication in Doctor Hodges' records that he, too, believed Defendant had fallen below the standard of care. *See post*, n.7.

[5] *Kowske*'s holding on this point cannot be reconciled with the language, and some holdings, in a number of other Arizona cases that state that the statute is triggered when the plaintiff knew or should have known that her doctor, lawyer, or other professional had been negligent. *See, e.g.*, *Yazzie v. Olney, Levy, Kaplan & Tenner*, 593 F.2d 100, 103 (9th Cir. 1979) (legal malpractice action accrues when client knows or should know of lawyer's negligence); *Kenyon*, 142 Ariz. at 73, 682 P.2d at 965 (medical malpractice); *Insurance Co. of N. Am. v. Superior Court*, 162 Ariz. 499, 502, 784 P.2d 702, 705 (App. 1990) (negligence of insurance agent); *Arizona Mgmt. Corp. v. Kallof*, 142 Ariz. 64, 66, 688 P.2d 710, 712 (App. 1984) (legal malpractice); *Long v. Buckley*, 129 Ariz. 141, 143, 629 P.2d 557, 559 (App. 1981) (same); *Russo v. Diethrich*, 126 Ariz. 522, 617 P.2d 30 (App. 1980) (medical malpractice); *Sato v. Van Denburgh*, 123 Ariz. 225, 227, 599 P.2d 181, 183 (App. 1979) (accounting malpractice action accrues when plaintiff knew or should have known of defendant's negligent conduct) (citing *Morrison*, 68 Ariz. 27, 198 P.2d 590; *Abernethy v. Smith*, 17 Ariz.App. 363, 498 P.2d 173 (1972) (medical malpractice)).

¶24 In the present case, the court of appeals believed that Plaintiff had a reasonable opportunity to discover Defendant's negligence because she was placed under the care of other doctors. Mem. dec. at ¶ 11. No doubt Plaintiff did have an opportunity to discover Defendant's negligence, but the core question is whether a reasonable person would have been on notice to investigate. Plaintiff's doctor assured her he had done nothing wrong, and we do not believe that as a matter of law she was on notice to commence investigating whether negligence was involved. This is especially true when the doctors to whom Defendant later referred Plaintiff for treatment failed to disclose *to her* their belief that Defendant had been negligent.[4] While her failure to question the consulting doctors for such information could be taken as a lack of diligence, we do not believe it can be said as a matter of law that a reasonable person in this circumstance can be required to undertake such questioning or be held accountable for not doing so. This is the very sort of factual determination that must be left for the jury under *Mayer, Kenyon,* and other cases discussed above.

¶25 Given that *Kowske* was decided before *Doe*, it is understandable that the *Kowske* opinion focuses more on traditional conceptions of the "what and who" elements than on the plaintiff's knowledge or constructive knowledge that a wrong might have occurred. Today, we disapprove *Kowske* to the extent that it suggests accrual occurs in cases of this type before a plaintiff is put on reasonable notice to investigate whether the injury is attributable to negligence.[5] The existence of injury or untoward 11 result is, of course, one of the factors to be considered on the question of reasonable notice, and our holding today is not meant to relieve a potential plaintiff of the reasonable duty to timely inquire whether any basis exists for legal action.

¶26 We believe that the analysis we have followed since *Tom Reed* in 1932 to date is applicable in the present case. The "what" is the fact of injury. With respect to those in a professional or fiduciary relationship with the tortfeasor, an adverse or untoward result, or a failure to achieve an expected result, is not, as a matter of law, always sufficient notice. To trigger the statute of limitations, something more is required than the mere knowledge that one has suffered an adverse result while under the care of a professional fiduciary. The history of the present statute supports that conclusion.

3. Legislative considerations

¶27 The legislature, we believe, is quite familiar with the distinction between the date of injury and the date of accrual of a cause of action. Former A.R.S. § 12-564(A) provided that the cause of action for malpractice must be brought within two years of the "date of injury." In *Kenyon*, we held this statute unconstitutional insofar as it discriminated "against those with claims against licensed health care providers as distinguished from all other malpractice claims, and which also discriminate internally between classes of medical malpractice claimants . . . ." 142 Ariz. at 83, 682 P.2d at 975. The special medical malpractice limitation statute therefore violated Arizona's equal protection clause — article II, § 13 — of the Arizona Constitution. *See id.* at 87, 682 P.2d at 979. Following the *Kenyon* decision, and evidently not wishing to give lawyers, accountants, stockbrokers, and other professionals the benefit of a date-of-injury trigger, the legislature returned to the accrual rule. Thus, the statute governing the present case provides that negligence actions must be filed within two years from the date of "accrual," specifically "including medical malpractice actions." A.R.S. § 12-542(A)(1). This, of course, takes us back to the accrual rule as formulated in *Mayer* and approved in *Kenyon*. *See ante* ¶ 17.

4. Other jurisdictions

¶28 Well-reasoned authority from other jurisdictions supports our conclusion. *See, e.g., Kitzig v. Nordquist*, 97 Cal.Rptr.2d 762 (App. 2000). The plaintiff in *Kitzig* underwent a series of unsuccessful oral surgeries over three years. Her injuries were apparent early in the treatment, and like the instant case, she received assurances from her dentist. Again like the current case, she went to another dentist and received further assurances. Toward the end of the third year, she sought the advice of a third dentist, who questioned the original dentist's work. After filing suit, she countered the defendant's statute of limitations defense with the statutory discovery rule, and the court held for her. "[T]he statute of limitations begins to run when the plaintiff suspects or should suspect that her injury was caused by wrongdoing . . . ." *Id.* at 767 (quoting *Jolly v. Eli Lilly & Co.*, 751 P.2d 923, 927 (Cal. 1988)). The court concluded that Kitzig could not be found, as a matter of law, to have subjectively suspected any wrongdoing with respect to her implant procedures at that time. *Id.* at 768-69.

¶29 A similar result was reached in *Hughes v. United States*, 263 F.3d 272 (3d Cir. 2001). The court held that the statute did not run against a patient who became a quadruple amputee because of gangrene resulting from an allergic drug reaction until the patient learned that had the

reaction been timely diagnosed, it could have been treated and arrested with medication. The action accrued only when the plaintiff discovered the known injury was due to "progression of the disease rather than the disease itself" and that "failure of his doctors to diagnose, treat or warn him led to his deteriorating condition." *Id.* at 276 (quoting *Augustine v. United States*, 704 F.2d 1074, 1078 (9th Cir. 1983)); *see also Waits v. United States*, 611 F.2d 550 (5th Cir. 1980) (holding that Federal Tort Claims Act claimant's awareness of injury was not enough to trigger statute, absent knowledge of act or omission responsible for causing it).

5. Application

¶30 In light of our cases and the statutory history and authority from other jurisdictions, we refuse to adopt the bright-line "what and who" rule advanced by Defendant. At the very least, 13 we interpret the "what" broadly enough to require the knowledge that would put a reasonable patient or client on notice to investigate whether the injury may be attributable to negligence of a professional or fiduciary. Given the facts of the present case, one cannot say as a matter of law that Plaintiff slept on her rights or was dilatory in failing to investigate or file. The issue of discovery and consequent accrual is for the jury.

¶31 In reaching this conclusion, we are well aware that there is another side of the coin and cases to support the opposing view. *See, e.g., United States v. Kubrick*, 444 U.S.111, 122-23, 100 S.Ct. 352, 359-60 (1979) (claim accrued under Federal Tort Claims Act when plaintiff had knowledge of injury and likely cause — loss of hearing due to administration of antibiotic — not when plaintiff learned that administration of drug might have been contrary to medical standards). The *Kubrick* majority held that the action accrued when the plaintiff was made aware of his injury and knew it resulted from the treatment given him, even if he was not aware there might have been negligence.

¶32 Perhaps the best argument for this view is that by rejecting *Kubrick*'s bright-line approach, we allow too many cases on discovery to go to the jury. It is true that in some cases the substantive merits of a claim may influence jurors to favor the plaintiff on the procedural question of discovery and potential barring of the action by the statute of limitations. This, no doubt, would be prevented by adopting a bright-line rule. But such a rule would also have some unjust effects. For example, it would bar meritorious actions by those who have been reassured by their doctors, those who have no reason to believe they were negligently injured, or those who had no way to ascertain they were injured through some wrongdoing. In addition, it would inject an element of mistrust into the relationship between patients and clients on the one hand and their professional care-givers and advisors on the other. In cases in which an adverse outcome is not in itself sufficient to put a reasonable person on notice to investigate whether a known injury is attributable to negligence, patients and clients should not be required to commence investigation of a malpractice action. We conclude that, on balance, the better rule is the one we have followed before and follow today.

¶33 The *Kubrick* majority justified the bright-line rule with the following reasoning:

A plaintiff such as Kubrick, armed with the facts about the harm done to him, can protect himself by seeking advice in the medical and legal community. To excuse him from promptly doing so by postponing the accrual of his claim would undermine the purpose of the limitations statute, which is to require the reasonably diligent presentation of tort claims against the Government. If there exists in the community a generally applicable standard of care with respect to the treatment of his ailment, we see no reason to suppose that competent advice would not be available to the plaintiff as to whether his treatment conformed to that standard. If advised that he has been wronged, he may promptly bring suit.

Id. The facts of the present case indicate that such advice is not always so readily forthcoming. Whatever Defendant believed about the propriety of his treatment, he did not tell Plaintiff about the opinion of his colleague or colleagues, and they did not volunteer such information. It is undeniably true that the "best medical treatment sometimes fails, . . . or produces bad side effects." *Kitzig*, 97 Cal.Rptr.2d at 768 (quoting *Gutierrez v. Mofid*, 705 P.2d 886, 899 (Cal. 1985)). We decline to adopt a rule that, in every case, would require a patient or client who suffered an adverse result to question her doctors or lawyers about the possible sins of their predecessors. We therefore conclude that for the present case, the questions of discovery, diligent investigation, and resulting accrual were for the jury.

B. Fraudulent concealment

¶34 It is, of course, quite possible that a jury would find that the facts known to Plaintiff in 1994 put her on notice that she may have been injured through Defendant's negligence and that she failed to take reasonable steps to determine that fact. If so, the statute would have begun to run in 1994 and the 1997 complaint would have been untimely. We must therefore turn to Plaintiff's alternative theory — fraudulent concealment. This theory is also well-rooted in Arizona law. We long ago held that a patient and a doctor were in a fiduciary relationship "calling for frank and truthful information from" doctor to patient. *Acton*, 62 Ariz. at 143, 155 P.2d at 784. "Fraud practiced to conceal a cause of action will prevent the running of the statute of limitations until its discovery." *Id.* at 144, 155 P.2d at 784. If the doctor "fraudulently concealed "from [his patient] the fact of his negligence," the statute of limitations would be tolled. *Id.* (citing *Peteler v. Robison*, 17 P.2d 244, 249 (Utah 1932), *disapproved on other grounds by Christiansen v. Rees*, 436 P.2d 435, 436 (Utah 1968)).

6 Presumably, actual knowledge of the doctor's negligence equates with discovery of the breach of trust.

¶35 Moreover, if fraudulent concealment is established, the patient is relieved of the duty

of diligent investigation required by the discovery rule and the statute of limitations is tolled "until such concealment is discovered, or reasonably should have been discovered." *Id.* (citing *Tom Reed*,
39 Ariz. 533, 8 P.2d 449). In fraudulent concealment cases, the duty to investigate arises only when the patient "discovers or is put upon reasonable notice of the breach of trust . . . ."[6] *Id.* (quoting *Griffith v. State*, 41 Ariz. 517, 528, 20 P.2d 289, 293 (1933)). Thus, our cases and those from other jurisdictions that recognize a fiduciary relationship agree that an actual knowledge standard applies to triggering the statute of limitations for a plaintiff who establishes a breach of the fiduciary duty of disclosure. *See, e.g., Demoulas v. Demoulas Super Mkts., Inc.*, 677 N.E.2d 159, 159 (Mass. 1997).

¶36 In the present case, the court of appeals gave the duty of disclosure a somewhat limited interpretation. "Fraudulent concealment occurs when a party wrongfully conceals *facts giving rise to the cause of action* so as to prevent a potential plaintiff from reasonably discovering the claim's existence during the limitation period." Mem. dec. at ¶ 18 (emphasis added). Further, the court of appeals said, "Dr. Ring never withheld or misrepresented the facts relating to Walk's injury." *Id.* At ¶ 19.

¶37 But what were the facts? Certainly Defendant disclosed what Plaintiff already knew — that she had TMJ problems and that they followed upon and presumably were the result of the reconstruction work. But we do not believe the duty to disclose is so limited. The statute is never triggered until the injury manifests itself; fraudulent concealment occurs with nondisclosure of the facts pertaining to negligence. *See Morrison*, 68 Ariz. at 34-35, 198 P.2d at 595; *Tom Reed*, 39 Ariz

[7] According to a January 16, 1992, entry in his chart for Plaintiff, Doctor Hodges evidently told Defendant that the occlusions placed by Defendant may have been improper and rotated Plaintiff's mandible.

at 535, 8 P.2d at 450. Defendant did not disclose all he knew. He knew that one and perhaps both [7]of the colleagues to whom he referred Plaintiff for help with her TMJ problems believed Defendant had been negligent in using improper techniques and in undertaking work that was contraindicated for her. He told Plaintiff, however, that he had done nothing wrong. Did he believe that, or was he simply allaying her suspicions and concealing the true cause of her injury? This, of course, is a jury question. Moreover, our cases do not limit the duty to disclose to actual knowledge. A doctor must disclose what he "knew or was chargeable with" knowing. *Morrison*, 68 Ariz. at 34-35, 198 P.2d at 595. At Doctor McDonald's deposition, it appeared that at least by the time the action was filed, Defendant did not argue with Doctor McDonald's view.

Q. Now, do you mean to imply here that Dr. Ring told you
that he thought he was negligent in treating Mrs. Walk?

A. He told me that he was — he felt that he was over his
head with this case, that this was — he had taken a class in California

on how to do this reconstruction technique, and that this was his first case and attempt to try that and that he explained to me how he did it. And we discussed what was wrong with that technique, and not just about anybody, but specifically in this person.

And this letter went to Dr. Ring for his approval before I sent it [to CNA]. I said, "this is serious language here, Dale." Deposition of Doctor McDonald, October 21, 1998, at 111.

¶38 This record does not permit us to make any definite conclusion with respect to the issue of Defendant's actual belief. We know only what Doctor McDonald told Defendant, what Defendant said to Plaintiff, what he may have later conceded to Doctor McDonald, but not what Defendant actually believed. We do know that when asked on deposition, Defendant said he never told Plaintiff that he had made a mistake or that the problem was due to any fault on his part. In fact, he said that he "was very careful to do just the opposite." Deposition of Doctor Ring, July 20, 1998, at 134. In fact, it is not clear that Defendant ever told Plaintiff that her TMJ problems were caused by his reconstruction work. His note, quoted *ante* ¶ 4, is somewhat ambiguous on the point, and he testified at deposition that in referring Plaintiff to yet another doctor, a chiropractic cranio-osteopath, for treatment of her TMJ problems, he did not "recall relating Mrs. Walk's problems to her dental work." *Id.* at 136.

¶39 Certainly if Defendant thought he may have been negligent in his treatment of Plaintiff, his fiduciary duty to disclose required him to explain that to her. *See Fowles v. Lingos*, 569 N.E.2d 416, 420 (Mass.App. 1991). What becomes difficult is the question of whether Defendant was under a duty to give Plaintiff Doctor McDonald's opinion of his negligence, even if Defendant honestly disagreed with it. *Id.* at 416 (there is no concealment if "there is [only] a difference of opinion concerning the standard of care" or failing to "divulge some adverse criticism.") (quoting *Geisz v. Greater Baltimore Med. Ctr.*, 545 A.2d 658, 672 (Md.App. 1988).

¶40 But the present case is not one in which there is a difference of opinion between unrelated specialists in the field or in the learned journals. The dentists to whom Defendant referred Plaintiff, specialists in whom Defendant had confidence and on whose opinions he relied, explained in detail what was wrong with Defendant's treatment. Unless Defendant had some principled basis for disagreement, the candor required by his fiduciary relationship required him to reveal the opinions of those specialists to Plaintiff. "[I]f the fiduciary nature of the relationship charges the fiduciary with a duty to disclose his wrong to the plaintiff and he fails to disclose, the statute of limitations will be tolled." *Bourassa v. LaFortune*, 711 F.Supp. 43, 46 (D.Mass. 1989). No doubt Defendant had no intent to deceive, but as we said in *Morrison*, to establish concealment a patient need only show a "breach of legal or equitable duty. . . . Neither actual dishonesty of purpose nor intent to deceive is an essential element of constructive fraud." 68 Ariz. at 35, 198 P.2d at 595.

¶41 Finally, we must bear in mind that Defendant did not just remain silent but made an affirmative statement that he had done nothing wrong. Having broached the subject of fault, one might conclude that candor would have required him to give Plaintiff all the information on the

question, including Doctor McDonald's opinion. If not, Plaintiff had the right "to rely [on her doctor's] advice
"without suspecting [she] was being deceived." *Lasley v. Helms*, 179 Ariz. 589, 592, 880 P.2d 1135, 1138 (App. 1994).

¶42 We therefore conclude that there are factual issues on the question of constructive fraud. If those issues are resolved in Plaintiff's favor, the statute of limitations would have been tolled until the time when Plaintiff had actual knowledge of the possibility of negligence or learned of Doctor McDonald's opinion about the treatment she received.

CONCLUSION

¶43 The trial judge erred in granting summary judgment on the facts of this case. Reasonable minds could differ with regard to whether, more than two years before filing her action, Plaintiff knew or should have known facts that would have put a reasonable person on notice to investigate whether her injury had been wrongfully inflicted. The same is true regarding her claim of fraudulent concealment. On this record, a jury could find that Defendant withheld from Plaintiff information that his fiduciary relationship required him to reveal. Both issues should be decided by a jury.

¶44 Accordingly, the court of appeals' memorandum decision is vacated, the trial judge's order granting summary judgment is vacated, the judgment is reversed, and the case is remanded to the trial court for further proceedings consistent with this opinion.

STANLEY G. FELDMAN, Justice
CONCURRING:

CHARLES E. JONES, Chief Justice

RUTH V. McGREGOR, Vice Chief Justice

THOMAS A. ZLAKET, Justice

In the above AZ SUPREME COURT opinion, the court went into great detail regarding the application of the "Discovery Rule", "FRAUD" – constructive or otherwise, and their relationship to the "Statute of Limitations" requirements on medical malpractice, other legal issues, and similar federal applications. I my opinion, this analysis points out an extremely glaring difference between the AZ & Federal (including the 5th district and the 9th district) holdings versus the constraints forced upon the Texas courts. As a matter of equity, federal rulings, Arizona state law, and Arizona state court rulings it appears to me that the fraud against Kathryn Jones and me and the conspiracy to defraud us by all parties, plus the assault issues that will be presented further- this court should maintain control over this matter and all related matters arising out of this/these acts and the use of inducement by the defendants to entice us to travel to Dallas for Kathryn to be the experimental subject of which I have provided the details and proof in great specifics in this filing. I pray for this court to ensure that we are not thrown to the curb and run over again.

AND THEN THERE ARE POSSIBLE CRIMINAL/CIVIL LAWS THAT MAY APPLY

ARS 13-1204 (A1,A3, & A4) may apply; ARS 12-562 may apply; ARS 44-455 may apply; ARS 13-1203 may apply; ARS 12-511 may apply; and possibly others such that the following discussion may be appropriate for further discovery and prosecution.

Strictly speaking, Kathryn Marie Jones was not a vulnerable adult when she sought care from Dr. Denning in August of 2010. But she was in constant pain due to nerve root compression; had functional disabilities that severely restricted her level of physical activity; and was under extreme emotional distress due to her concern that she would become paralyzed or have arachnoiditis (a condition with a high rate of suicide).

We contend that on "October 26' 2010, at 12:50", Kathryn became a "vulnerable adult whose life or health is being or has been endangered or injured by neglect, abuse, or exploitation". That was the time at which Dr. Denning began Kathryn's second surgery. A surgery that had never been mentioned, nor discussed with Kathryn or me. That was the time at which Dr. Denning and Texas Health Presbyterian Hospital of Dallas began experimenting on Kathryn.

Kathryn had not been told that a "transforaminal lumber Interbody fusion" would be performed on her. Prior to Kathryn's surgeries, in email questions submitted to Dr.Denning, we were told that the first day of surgery would be performed "completely from the side", because it gives "access to most of the discs". Kathryn did not consent to this second posterior procedure, performed on October 26th of 2010. Even though the progress report for the afternoon procedure indicates that "informed consent was obtained", it is difficult to imagine that Kathryn provided such consent, as she was "intubated" and "under general anesthesia" at the time. And neither Dr. Denning's nor the hospital's consent forms, signed prior to Kathryn's first surgery indicate in any way whatsoever that it is even remotely possible that Kathryn was consenting to her participation in an experiment or a clinical trial. In addition, it is worth noting that the hospital's pre-admission forms fail to reveal that Texas Health Presbyterian Hospital of Dallas is a "Research & Education Institute".

Included in Kathryn's hospital records is a "Presbyterian Hospital of Dallas" consent form. That form states that Kathryn "voluntarily requests" Dr. Denning to treat her condition "Scoliosis/Spondylolistheis". It was signed on 10-26-10 at 0630. Also included in the hospital records are two "September 23, 2010 Established/Follow Up Patient Visit" documents sent to the hospital from Dr. Denning's office. They were submitted for "pre-operative risk stratification by internal medicine".The consent form does not authorize experimentation. It does not authorize exploitation. But Dr. Denning and Texas Health Presbyterian Hospital of Dallas did both.

Both Dr. Denning and the hospital concealed their intended, their planned, experimentation from Kathryn and me. Dr. Denning's email of September 8th of 2010, in which he answers questions submitted to him regarding Kathryn's upcoming surgeries, is documented that Kathryn was actively prevented from discovering the intended experimentation. This concealment began less than one month after Kathryn's first consult with Dr. Denning on August 11th of 2010; and it has continued through Dr. Denning's recent email of September 26th of 2012 and Kathryn's email queries to Paula Hagan, which received no reply.

All of the plaintiffs were complicit in endangering Kathryn's life and health. She was neglected, abused, and exploited while under their care/their control. That neglect and exploitation began on October 26th of 2012, the point at which unauthorized activities, procedures, tests, treatments, experiments, and trials were first inflicted on Kathryn. Dr. Denning, Texas Health Presbyterian Hospital of Dallas, and others had been entrusted with Kathryn's life and health. Yet the plaintiffs pursued their nefarious actions, even though armed with the knowledge that they were endangering Kathryn's health. Prior to

Kathryn's surgeries, Dr. Denning's office submitted two "September 23, 2010 Established/Follow Up Patient Visit' documents to the hospital for "pre-operative risk stratification by internal medicine". Most of the information contained in those documents is fabricated. Dr. Denning even lied when he states "Mrs. Jones comes back to the office today". I did not see Dr. Denning at all between August 18th of 2010 and October 26th of 2010. Dr. Denning did not accidently exploit Kathryn, thus putting her in danger. No, every action of Dr. Denning was intentional and malicious.

The above parties were aware that Kathryn suffered a pneumothorax on October 26th of 2010. They were aware that Kathryn had decreased lung capacity due to a "lower left lobectomy secondary to Valley Fever". They were aware that a pre-op cardiac nuclear stress test had revealed that Kathryn has atrial arrhythmia, which could and did manifest as atrial fibrillation and flutter during her hospital stay. They were aware that Kathryn's blood tests showed irregularities and signs of infection.

See Exhibit # 34 , Consent form dated 10-26-10; two office visit documents dated 9-23-10; and Inpatient Rehabilitation - Admission History and Physical Note.

PLAINTIFFS' DEMAND CLAIM FOR RELIEF
Declaratory Judgment

1. The allegations set forth in paragraphs 1 thru 122 above are incorporated herein by reference, plus the plaintiff's Discussion sections and concurrent review, the judicial notice of propria persona, and plaintiff's opening statement are incorporated herein by reference.

2. Plaintiffs, Alan Jones an Kathryn Jones are entitled to declaratory judgment that the statute of limitations should stopped, the discovery rule should be applied, the fraudulent concealment should be ordered, the venue of this court and this location should be ordered, the jurisdiction of this court should be ordered, and the

plaintiffs should be given 2 years further to bring their final suit for all damages and given the true opportunity to obtain legal counsel to handle this extensively complicated case in an equitable manner.

3. Awarding of plaintiff the cost and equivalent charges equivalent to the cost of reasonable attorney's fees, and court filing fees incurred herein pursuant to the prosecution of this case, and awarding such other and further relief as the Court deems just and proper under the circumstances

Plaintiffs pray for this court to grant plaintiffs requests in whole or in part.

DATED this 25th day of 2012.

Alan Jones

Kathryn Marie Jones

Search

Medtronic Locations

As a global leader in medical technology, we serve patients and partner with medical professionals in 120 countries. Below are our main regional offices; key manufacturing, service, and research and development facilities; and Bakken Education Centers for physician training.

Medtronic Country Sites

United States - World Headquarters

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Phone: (763) 514-4000
Toll-free: (800) 633-8766
Mail Stop: L100

US Business Units – Main Locations **US Business Units – Main Locations**

Toll-free: (800) 633-8766

Medtronic Cardiac Rhythm Disease Management (CRDM)
8200 Coral Sea Street NE
Mounds View, MN 55112

Medtronic CardioVascular (Santa Rosa)
3576 Unocal Place, Fountaingrove A
Santa Rosa, CA 95403

Medtronic CardioVascular (Mounds View)
8200 Coral Sea Street NE
Mounds View, MN 55112

Medtronic Diabetes
18000 Devonshire Street
Northridge, CA 91325

Medtronic Neuromodulation
7000 Central Avenue NE
Fridley, MN 55432

Medtronic Spinal and Biologics
1800 Pyramid Place
Memphis, TN 38132

Medtronic Surgical Technologies
6743 Southpoint Drive North
Jacksonville, Florida 32216

Asia Regional Headquarters **Asia Regional Headquarters**

Medtronic International Ltd.
49 Changi South Avenue 2
Nasaco Tech Centre
Singapore 486056
Singapore
Phone: (65) 6436 5000

Canada **Canada**

Medtronic of Canada Ltd.
99 Hereford Street
Brampton, Ontario L6Y 0R3
Canada
Phone: (905) 460-3800
Toll-free: (800) 268-5346

Europe and Central Asia **Europe and Central Asia**

Medtronic International Trading Sàrl
Route du Molliau 31
Case Postale
CH-1131 Tolochenaz
Switzerland
Phone: (41 21) 802 7000

Greater China **Greater China**

Medtronic Medical Appliance Technology & Service
(Shanghai) Limited
Beijing Rep. Office Suite 1805-1812 E1 Tower Oriental Plaza
No.1 East Chang An Ave.
Dong Cheng District
Beijing, P.R., Beijing 100738
China
Phone: (86-10) 5869 8989

Japan **Japan**

Medtronic Japan Co., Ltd.
Comodio Shiodome
2-14-1 Higashi-Shimbashi,
Minato-ku
Tokyo, 105-0021
Japan
Phone: (81-3) 6430-2011

Korea **Korea**

Medtronic Korea Co., Ltd.
5F, Sajo Building
1001, Daechi-dong, Kangnam-ku
Seoul, 135-280
Korea
Phone: +82-2-3404-3600

Latin America **Latin America**

Medtronic USA, Inc.
Latin American Operations
Doral Corporate Centre II
3750 NW 87th Avenue
Suite 700
Miami, Florida 33178
Phone: (305) 500-9328

Middle East and Africa **Middle East and Africa**

Medtronic Mediterranean SAL
Regional Development Centre (RDC)
St. Charles City Centre - 6th Floor
Omar Daouk Street, PO Box 13-6572
Beirut, 2020-0908
Lebanon
Phone: (961-1) 370 670

Research and Development Facilities, Manufacturing Facilities, and Distribution Centers **Research and Development Facilities, Manufacturing Facilities, and Distribution Centers**

We expanded our facilities beyond the United States back in 1967 when we opened a service center in Amsterdam's Schipohl Airport, soon followed by a major manufacturing facility in Kerkrade, The Netherlands. Today, we have nearly 50 key facilities:

North America

Bartlett, TN
Brooklyn Center, MN
Brooklyn Park, MN
Chatsworth, CA
Columbia Heights, MN
Coon Rapids, MN
Corona, CA
Danvers, MA
Fort Worth, TX
Goleta, CA
Grand Rapids, MI
Jacksonville, FL
Littleton, MA
Louisville, CO
Memphis, TN
Montreal, Quebec, Canada
Mounds View, MN
Mystic, CT
Northridge, CA
Parker, CO
Redmond, WA
Santa Ana, CA
Santa Rosa, CA
Shoreview, MN
Spring Lake Park, MN
Sunnyvale, CA
Tempe, AZ
Warsaw, IN

Europe, Central Asia, Middle East, and Africa

Baroda, India
Deggendorf, Germany
Dusseldorf, Germany
Fourmies, France
Galway, Ireland
Heerlen, The Netherlands
Kerkrade, The Netherlands
Maastricht, The Netherlands
St. Aubin, France
Tolochenaz, Switzerland
Yokneam Elit, Israel

Asia-Pacific

Hong Kong, China
Osaka, Japan
Shanghai, China
Tokyo, Japan

Latin America

Humacao, Puerto Rico
Juncos, Puerto Rico
Tijuana, Mexico
Villalba, Puerto Rico

Bakken Education Centers **Bakken Education Centers**

Since opening our first education center in Minneapolis in 1990, we've expanded our commitment to customer education with centers all over the world. Thousands of medical professionals visit our state-of the-art facilities each year to gain hands-on experience with the latest

North America

Atlanta, GA
Brampton, Ontario, Canada
East Rutherford, NJ
Fort Worth, TX
Los Angeles, CA
Minneapolis, MN
Woodland Hills, CA

Europe, Central Asia, Middle East, and Africa

Beirut, Lebanon
Düsseldorf, Germany
Madrid, Spain
Maastricht, The Netherlands
Milan, Italy
Paris, France
Tolochenaz, Switzerland
Vienna, Austria
Watford, United Kingdom

Asia-Pacific

Hong Kong, China
Tokyo, Japan
Melbourne, Australia
Shanghai, China
Sydney, Australia

Latin America

Buenos Aires, Argentina

Last updated: 21 Sep 2012

Additional information

Education Namesake

Our Bakken Education Centers are named for Medtronic co-founder Earl Bakken. Learn more about his legacy.

Global Career Opportunities

To find open jobs around the world, go to Career Opportunities in our Careers section.

Dallas Neurosurgical & Spine

dallasneurosurgical.com

Jeremy W. Denning, MD
J. Michael Desaloms, MD
Richard H. Jackson, MD
Jon A. Krammerman, MD
Richard L. Weiner, MD, FACS
Gary C. Hutchison, MD, FACS

August 11, 2010

PATIENT: Jones, Katherine

NEW PATIENT CONSULTATION/EVALUATION

CHIEF COMPLAINT:
Low back pain radiating into the right buttock and leg with mid to low back pain for 40 years, history of scoliosis diagnosed in 1995.

HISTORY OF PRESENT ILLNESS:
The patient is a very pleasant, 60-year-old lady from Arizona who presents with a chief complaint of back pain, pain radiating into the right hip, right buttock, thigh, and leg. The patient has pain in both legs at night and pain in her back at the waist. The patient has terrible pain in her calves at times, in the back portion of her calves, and cramping in her feet. Occasionally, her whole right leg will feel "numb" and "weird." The patient has had pain in the right lower aspect of her back, in her mid lumbar area, as well as a right subcostal pain at times. These symptoms have gotten worse over the years and she is here for a neurosurgical opinion.

The patient was diagnosed with scoliosis in 1995 by an orthopedic surgeon in Arizona. The patient was referred here by Dr. O'Brien of the Baylor Scoliosis Center for evaluation of some perineural Tarlov cysts and possible arachnoiditis that was seen on imaging.

PAST MEDICAL HISTORY/PAST SURGICAL HISTORY:
1. Removal of left lower lobe of her lung from Valley Fever in 2007 at St. Joseph's Hospital.
2. Repair of broken left elbow in 2000.
3. Hysterectomy at St. Luke's Hospital in 1991.
4. Meniere's disease.
5. Pernicious anemia.

Dallas
8230 Walnut Hill Lane
Prof. Bldg. III, Suite 220
Dallas, Texas 75231
t 214.750.3646
f 214.739.6815

Allen/McKinney
1105 N. Central Expwy
Suite 2310
Allen, Texas 75013
t 972.747.6393
f 214.363.2351

Denton
3537 S. I-35E
Suite 220-B
Denton, Texas 76210
t 940.484.8800
f 940.384.4770

Plano
4708 Alliance Blvd
Suite 620
Plano, Texas 75093
t 972.665.4810
f 972.665.4815

Rockwall/Rowlett
7801 Lakeview Parkway
Suite 150
Rowlett, Texas 75088
t 972.475.2150
f 214.987.4865

10-1-12

MEDICATIONS:
1. Dyazide.
2. Oxybutynin.
3. B-12 shot once a month.
4. C-Estriol cream.
5. Duradrin capsule as needed.
6. Zovirax as needed.

ALLERGIES:
Fluconazole causes rash. Cephalosporins cause bleeding colitis. The patient also reports that the only pain medication she has ever been able to take is Darvocet. Morphine, she usually needs Compazine to prevent vomiting. The patient does not tolerate OxyContin, Percocet, Percodan, Vicodin, hydrocodone, ultram, Tylenol with Codeine. Again, Darvocet is the only thing that has been able to work for her.

SOCIAL HISTORY:
The patient is married and has two children. The patient does not smoke. The patient drinks wine twice a month. The patient does not work.

FAMILY HISTORY:
Noncontributory.

REVIEW OF SYSTEMS:
A full review of systems was reviewed with the patient and is available on the office chart.

PHYSICAL EXAMINATION:
The patient is 5 feet 4 inches and weighs 135 pounds. Blood pressure: 145/81mmHg. Pulse: 67/min. The patient is well developed, well nourished, and accurate to the stated age. Normocephalic, atraumatic. Neck is supple. There are no bruits. Lungs are clear to auscultation. Heart regular rate and rhythm. No murmurs, rubs, or gallops. Abdomen is soft and nontender. Extremity evaluation reveals no swelling with good distal pulses bilaterally. Inspection of her back reveals a lumbar hump, which is convexed to the right. Palpation of her mid back reveals some pain to deep palpation.

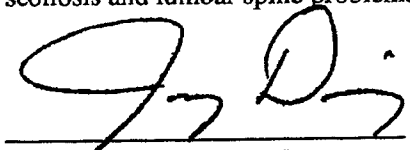
NEUROLOGICAL EXAMINATION:
Patient is awake, alert and oriented times three. Pupils are 3 mm and equally reactive bilaterally. The visual fields are intact to confrontational testing. Facial sensation is intact in all three distributions. The face is symmetrical. Hearing is intact. The palate elevates symmetrically and the tongue protrudes in the midline. The patient has grossly normal strength to manual testing. The patient can walk on her heels and toes. There is no pronator drift. There is no atrophy or fasciculations. Sensory examination is within normal limits to pinprick, fine touch, and proprioception with the exception of the right L5 dermatome where she has some patchy loss of light touch. Cerebellar examination is within normal limits to finger-to-nose and heel-to-shin testing. Gait examination is within normal limits including Romberg and tandem gait testing. Achilles reflexes are diminished. Otherwise, her reflexes are 2+ and symmetric. Toes are downgoing.

IMAGING STUDIES:
The patient has an MRI that she brought with her, which is dated June 18, 2010 and reveals severe degenerative spondylitic changes with scoliotic curve involving the entire lumbar spine convexed to the right with narrowing of the lateral recesses at L1-2 and L2-3 on the left. The patient has a grade II L5-S1 spondylolisthesis with right greater than left L5-S1 foraminal stenosis. There is no significant central canal stenosis. There is a mention of arachnoiditis involving the L2 nerve root, L4-5, and L5-S1 as well as Tarlov cysts at S1-S2.

IMPRESSION:
This is a 60-year-old lady with mid back and lower back pain as well as pain radiating into her right leg with a 40-year history of chronic back pain.

RECOMMENDATIONS:
We had a long discussion. First of all, I explained to the patient that I am not worried about the Tarlov cysts and that those are a non-entity as far as her pain. I do not know why she would have arachnoiditis. The patient has no history of meningitis or prior surgery, but this may be a simple misreading of the film. I think the symptoms in her lower back and right leg could certainly be from her spondylolisthesis at L5-S1. She does have a moderate lumbar scoliosis as well, degenerative in nature, which complicates things slightly.

My recommendation to the patient was first to see Dr. O'Brien for evaluation of her scoliosis, but as far as any imaging I did recommend to her a myelogram with weightbearing flexion/extension to evaluate her listhesis at L5-S1. With regard to the perineural cysts, this is a non-issue. I think the arachnoiditis is most likely a misreading of the film. The patient will see Dr. O'Brien for an evaluation regarding her scoliosis and lumbar spine problems. The patient will follow-up with me as needed.



Jeremy W Denning, MD

JWD/KR
D: 9/23/2010 @ 5:33 PM
T: 9/27/2010 @ 11:29 AM
J: 4149074

La Leesy 8-18-10

Anesthesia - No

Tarlov Cysts - Yes, but did not discuss cyst from myelogram

Nerve root damage - Yes, L5-S1

Tailbone (coccyx) - No they did not give me I-Stim and therapy with stim Wells, but no bowel or bladder control

Told in surgery Occ ed - Yes it

Autologous Blood Donation - Yes, 2 units between 3 and 6 weeks prior to surgery. Donate in PHX and ship to Dallas

Bone - will use piece of my own bone from L5 S1 vertebrae

Dallas Neurosurgical & Spine

dallasneurosurgical.com

Jeremy W. Denning, MD
J. Michael Desaloms, MD
Richard H. Jackson, MD
Jon A. Krumerman, MD
Richard L. Weiner, MD, FACS
Gary C. Hutchison, MD, FACS

Only email contact with Dr Denning after 8-18-10 office visit.

September 23, 2010
ESTABLISHED/ FOLLOW UP PATIENT VISIT

No

PATIENT: **Jones, Katherine**

Ms. Jones did contact our office several times wanting to proceed with surgery. This surgery would be to correct her lumbar spinal deformity and to prevent any further worsening of her spinal alignment as well as correcting her nerve compression at L5-S1. The patient understood that this would involve a direct lateral approach as well as a posterior approach and that if we were going to do this percutaneously I would recommend doing it in two days due to the increased time from the fluoroscopy. The patient understood there was a risk of the need for a blood transfusion, and she has ~~elected to auto donate~~ units of her own blood, which will be transported to Dallas prior to her surgery. The patient also understood that we will be using spinal instrumentation and that there are risks of nerve injury due to the direct lateral approach. The patient will likely have some hip flexor weakness that most of the time is temporary due to the muscle inflammation through the psoas muscle. There is ~~also the risk of dysesthetic~~ pain from a direct lateral approach, but this would be a less invasive approach for her. This will also involve a posterior approach where we will place percutaneous screws and instrumentation as well as an L5-S1 TLIF to address her nerve compression. This will mean for the patient probably at least a week stay in the hospital and likely a stay in the rehabilitation unit in the Jackson Building prior to going home.

The patient has had a bad reaction to multiple pain medications and it may be difficult for us to completely manage all of her pain postoperatively, but we will try to do our best to avoid medications that she has had bad reactions to and at the same time controlling her pain. The patient will need a preoperative medical clearance. Again, we will have this set up for sometime in October.

Jeremy W. Denning, M.D.

JWD/KR
D: 9/23/2010 @ 5:42 PM
T: 9/27/2010 @ 1:49 PM
J: 4149175

Dallas
8230 Walnut Hill Lane
Prof. Bldg. III, Suite 220
Dallas, Texas 75231
t 214.750.3646
f 214.739.6815

Allen/McKinney
1105 N. Central Expwy
Suite 2310
Allen, Texas 75013
t 972.747.6393
f 214.363.2351

Denton
3537 S. I-35E
Suite 220-B
Denton, Texas 76210
t 940.484.8800
f 940.384.4770

Plano
4708 Alliance Blvd
Suite 620
Plano, Texas 75093
t 972.665.4810
f 972.665.4815

Rockwall/Rowlett
7801 Lakeview Parkway
Suite 130
Rowlett, Texas 75088
t 972.475.2150
f 214.987.4865

Dallas Neurosurgical & Spine

dallasneurosurgical.com

Jeremy W. Denning, MD
J. Michael Desalonis, MD
Richard F. Jackson, MD
Jon A. Krauseman, MD
Richard L. Weiner, MD, FACS
Gary C. Hutchison, MD, FACS

Pre-Surgery Office Visits — 8-11-10 and 8-18-10 only

September 23, 2010
ESTABLISHED/ FOLLOW UP PATIENT VISIT No

PATIENT: Jones, Katherine

Mrs. Jones comes back to the office today. We had a long discussion. The patient did see Dr. O'Brien and did have her thoracolumbar myelogram with weightbearing images as well. This did reveal good information with regard to her back. This revealed a moderate dextroscoliosis of the lumbar spine with a mild compensatory upper thoracic scoliosis and a lower lumbar levoscoliosis. The patient has a grade I to II spondylolisthesis at L5-S1 that increases in severity with flexion and weightbearing and decreases with non-weightbearing and extension. This is from bilateral pars defects. There is a disk protrusion into and lateral to the right neural foramen causing severe, right foraminal stenosis and mild left foraminal stenosis. The patient has a retrolisthesis of L1-2 and L2-3 and some narrowing of the left L2-3 and L1 lateral recesses and foramen.

We had a long discussion with regard to her findings and options for treatment. I did explain to her that she originally came here to see Dr. O'Brien, and she stated understood this but wanted me to perform her surgery. As such, we had a long discussion regarding her options. One includes managing this with pain management versus a minimally invasive L5-S1 TLIF versus correcting her lumbar deformity. I explained to the patient that she would recover more quickly if we did her L5-S1 TLIF, but to correct her whole deformity would require a much longer recovery time. I told the patient that she and her husband needed to think about this before they made any decisions and they could certainly get another opinion back in Arizona. The patient will contact us if she decides to have any surgery, but she and her husband are going to think about her options. Again, I did recommend to her and she is going to see a surgeon closer to home for a second opinion. All of her questions were answered to her satisfaction. The patient will call us as needed.

Jeremy W. Denning, M.D.

JWD/KR
D: 9/23/2010 @ 5:39 PM
T: 9/27/2010 @ 1:56 PM
J: 4149173

A W Jones

From: Sandra Chavez [SChavez@dallasneuro.com]
Sent: Wednesday, September 08, 2010 2:24 PM
To: kmj
Subject: RE: SURGERY
Attachments: AVG certification.txt

Importance: High

Mrs. Jones;

Dr Denning had a minute to call our office in-between surgeries and had a chance to answer all your questions please see attached, I hope this is helpful, call/email me if you have additional questions.

Dr. Denning prefers to stage your surgery in 2 days, if he tries to do your surgery in one day it will take up to 8-10 hrs, that is a long time to keep you under anesthesia , he states most of the OR staff gets tired by the 6th hour, he prefers to do in two days, and be rested as well, but he also understands your concerns and is willing to accommodate you, and thinks if every thing runs smooth he will do your surgery all in one day.

Day One- surgery from the side with Dr Kirby
Day Two-surgery pincushion method from back side T12-S1 with Dr Jackson

I have not followed up with Dr Kirby and Dr Jackson until you have all the info you need, let me know what you think and I will make the arrangements.

Will the first surgery be focused on repairing the L5-S1 vertebrae? YES

Is it performed completely from the side? YES

Which side? LEFT SIDE

How long is the incision(s)? 4-5 INCHES

A W Jones

To: Sandra Chavez
Subject: RE: SURGERY

Hi Sandra –

Dr. Denning did not call this morning, so we were wondering if you could forward the following questions to him. He might find a few minutes to jot down the answers, and you could send them to us.

Will the first surgery be focused on repairing the L5-S1 vertebrae? Is it performed completely from the side? Which side? How long is the incision(s)? Is the repair more extensive than originally thought? What does Dr. Kirby do?

What will my condition be after the first surgery? Will the incisions be permanently closed? Will they have to re-opened during the second surgery?

Will the second surgery be to repair the discs and the scoliosis from T12 to S1? Is it performed completely from the back? Will the "pincushion method" be used?

Will there be enough of my own bone recovered to use for the fusions? Will I need donor bone?

How many units of blood will be needed? Will more be needed because there will be two surgeries, not one?

How long can I expect to be in the hospital? Will the recovery time increase due to two surgeries?

Thanks a bunch,

Kathryn Marie Jones

[illegible]

[illegible]

From: A W Jones [mailto:[redacted]]
Sent: Monday, October 11, 2010 4:37 PM
To: Hagan, Paula
Subject: Medical Devices

Dear Ms. Hagan –

I spoke with you several weeks ago about the medical devices that will be used in my surgeries with Dr. Denning scheduled for October 26 and 27. As you will recall, my concern was with the wording in the "Universal Consent For Treatment" form that Presbyterian Hospital will require me to sign upon admission. That form states that all medical devices are supplied on an "AS IS" basis. It also states that I may request manufacturer's warranty information.

As you know, I am not very comfortable with the clause about devices implanted in my back being provided in an "as is" condition. You told me that you would provide me with information about the hospital procedures concerning the handling of such devices; and I said that would give me a higher level of confidence. But I have not received that information.

Also, prior to speaking with you, I spoke with your assistant; and she said she would try to obtain warranty information for me. I have not received that either.

Could you please let me know the status of these endeavors. I will be leaving home in about a week to travel to Dallas. Thank you.

Kathryn Marie Jones

From: Hagan, Paula [mailto:PaulaHagan@texashealth.org]
Sent: Tuesday, October 12, 2010 4:57 PM
To: [redacted]@cox.net'
Subject: RE: Medical Devices

Dear Ms. Jones,

This is a follow up to my email from yesterday and our previous conversation. It is my understanding your surgeon, Dr. Denning, is planning to implant an interbody fusion device manufactured by Medtronic during your spinal fusion surgery scheduled for October 26.

I spoke again today with the manager of the hospital's Materiels Management Department responsible for ordering products and supplies for the Operating Room. He checked on your inquiry of whether Medtronic provides a manufacturer's warranty for spinal fusion devices and determined that Medtronic does not provide a warranty for any implantable medical devices. He was informed this is industry standard and not applicable solely to Medtronic.

Our manager described the following process to me regarding devices purchased by Texas Health Presbyterian Hospital Dallas and provided to patients:

All medical devices and supplies purchased by the hospital and furnished to our patients are newly manufactured. Medical devices to be used in surgery are typically delivered to the hospital several days before the patient's surgery unless it is a standard device that is already in the hospital's inventory. Devices are selected by the patient's physician. Then prior to surgery, the devices are wrapped and sterilized by the hospital's sterile supply department and then brought into the surgical suite at the time of surgery.

I hope this information is helpful and alleviates your concern about the "as is" wording in our universal consent form. If you have any further questions, please let me know. I also hope you have a safe trip from Phoenix to Dallas.

Sincerely,
Paula Hagan
Vice President & Assistant General Counsel,
Texas Health Resources
(214) 345-7788

From: Hagan, Paula [mailto:PaulaHagan@texashealth.org]
Sent: Monday, October 11, 2010 5:03 PM
To: 'A W Jones'
Subject: RE: Medical Devices

A W Jones

From: Sandra Chavez [SChavez@dallasneuro.com]
Sent: Monday, September 20, 2010 12:38 PM
To: [redacted]@cox.net
Subject: RE: Screws, Rods, Spacers, Hardware for my back

Mrs. Jones;

The hardware Dr Denning will be using for your surgery is manufactured by Medtronic, all the hardware needed for your procedure will be available at the hospital, Presbyterian Hospital of Dallas will be doing the billing as well. any questions regarding consents and warranties you may contact the hospital at 214-345-6789

Thanks
SC

From: A W Jones [mailto:]
Sent: Wednesday, September 15, 2010 5:18 PM
To: Sandra Chavez
Subject: Screws, Rods, Spacers, Hardware for my back

Hi Sandra –

Does the hospital or does Dr. Denning furnish the hardware that will be put in my back? Who will bill me for this hardware?

At the admissions office, the hospital will expect me to sign a form called a "Universal Consent For Treatment". This form states that all medical devices sold or furnished to me by the hospital are sold or furnished on an "AS IS" basis. This does not make me feel very comfortable.

However, the form does then go on to say that manufacturer's warranties may apply, and that I may request warranty information concerning such devices. If the hospital furnishes the devices, I will contact them to obtain warranty info. Do you know of a contact that I could email or call?

If Dr. Denning furnishes the devices, do you provide me with warranty info?

This is not a rush - we are just trying to take care of as many issues as we can, as early as we can.

Thanks,

Kathryn Marie Jones

UNIVERSAL CONSENT FOR TREATMENT

General consent. I understand that my health condition requires inpatient or outpatient admission. I consent to and authorize testing, treatment and hospital care by Hospital nurses, employees and others as ordered by my doctor and his/her consultants, associates and assistants, or as directed pursuant to standing medical orders or protocols. I understand that it may be necessary for representatives of outside health care companies to assist in my care. I also understand that persons in professional training programs may be among the individuals who provide care to me. I understand that in connection with my treatment, photos or videos may be taken. Any tissue or body parts removed from my body may be retained or disposed of by the Hospital at its sole discretion.

Communicable disease testing. I acknowledge that Texas law provides if any health care worker is exposed to my blood or other bodily fluid, the Hospital may perform tests, without my consent, on my blood or other bodily fluid to determine the presence of hepatitis B and C and HIV. I understand that such testing is necessary to protect those who will be caring for me while I am a patient at the Hospital. I understand that the results of tests taken under these circumstances are confidential and do not become a part of my hospital patient record.

Independent physicians. I acknowledge that the doctors taking part in my care do not work for the Hospital. They are engaged in the private practice of medicine, and are not employees, servants or agents of the Hospital. In addition to my attending doctor, other doctors who may take part in my care may include radiologists, pathologists, anesthesiologists, neonatologists, cardiologists, emergency physicians and other specialists. I acknowledge that the Hospital is not responsible for the judgment or conduct of doctors who treat or provide a professional service to me. The exception to this is that some medical residents – doctors taking part in a program of post-graduate medical education under the supervision of more experienced physicians – are employees of the Hospital.

No guarantee. I acknowledge that no guarantees or warranties have been made to me with respect to treatment to be provided at this Hospital. I understand that all supplies, medical devices and other goods sold or furnished to me by the Hospital are sold or furnished by the Hospital on an "AS IS" basis, and Texas Health Resources disclaims any expressed or implied warranties with respect to them. With respect to specific supplies and devices, manufacturers' warranties may apply, and I may request manufacturer's warranty information concerning such supplies and/or devices.

Newborn child(ren). If any children are born to me during this admission, my signature below is on behalf of myself and such child(ren) as the legally authorized representative of such child(ren), and the paragraphs regarding "General consent", "Communicable disease testing", "Independent physicians" and "No guarantee" shall apply regarding any treatment provided to such child(ren).

If the person signing this form is not the patient, please give full name, phone number and address:

Please provide manufacturer warranty info concerning hardware used in my spinal procedures.

I have read and understand this information.

Signature of patient or legally authorized representative*	Relationship to patient	Reason patient unable to sign
Witness	Title	Date of signature

*For purposes of this form only, a "legally authorized representative" is: 1) a legal guardian, 2) an agent authorized in a medical power of attorney or directive to physicians, 3) an attorney appointed by a court, 4) an attorney retained by the patient or the patient's legally authorized representative, 5) a parent or legal guardian of a minor, or 6) a person authorized under the Texas Consent to Medical Treatment Act: the patient's spouse, adult child, a parent of the adult patient, a person clearly identified in advance of incapacity to act for the patient, the nearest living relative or a member of the clergy.

HOSPITAL BOX MUST BE CHECKED

Texas Health Resources

UNIVERSAL CONSENT FOR TREATMENT
Form 998541055 (Rev. 12/08)

☐THA ☐THFW ☐THSW
☐THAMH ☐THHEB ☐THW
☐THAZ ☐THK ☐OTHER
☐THC ☐THP _____
☐THD ☐THS

PATIENT IDENTIFICATION

9080

BA10434 12/08 $22,000

AUTHORIZATION FOR VERBAL RELEASE OF PROTECTED HEALTH CARE INFORMATION

1. **"DIRECTORY INFORMATION"** – I understand that "Directory Information," such as my presence in the hospital and room number, as described in the Texas Health Resources Notice of Privacy Practices, may be released to all who ask for me by name, unless I object by specifically requesting to be a "No Information" patient as described below.

   ☐ **No Information** – I do not authorize release of any information, including Directory Information, concerning my admission or treatment. I choose to be a "No Information" patient and I realize that mail, flowers, telephone calls and visitors will be refused on my behalf. (The hospital staff will not be able to acknowledge my presence.) I also understand that if I make phone calls from the hospital, caller identification systems may result in my location being disclosed to persons who receive the calls.

2. **MEDICAL INFORMATION AND DISCLOSURE** – I understand that medical information about my condition and treatment may not be released, except in situations as described in the Texas Health Resources Notice of Privacy Practices, **unless I give my permission** as provided below:

   ☒ **I authorize** this hospital and medical staff members to discuss my medical history, diagnosis, treatment and prognosis with those listed below. I understand this may include information regarding testing, examination and treatment for HIV, AIDS-related illness, mental health and drug, alcohol or chemical abuse.

   ☒ Spouse Alan Jones

   ☐ Children

   ☐ Parent(s) KHJ

   ☐ Other

   Note: I understand my medical information will not be discussed via telephone with the person(s) named above if I choose to be "No Information" since telephone calls will be refused on my behalf.

This authorization will expire at the end of my hospitalization or outpatient service, unless I revoke the consent prior to that time.

Signature of patient or legally authorized representative*	Relationship to patient	Date of signature
Kathryn Marie Jones	Self	10/26/10
Witness	Title	Date of signature
[signature]	Admit Rep	10/26/10

*A "legally authorized representative" is: 1) a legal guardian, 2) an agent authorized in a medical power of attorney or directive to physicians, 3) an attorney appointed by a court, 4) an attorney retained by the patient or the patient's legally authorized representative, 5) a parent or legal guardian of a minor, or 6) a person authorized under the Texas Consent to Medical Treatment Act: the patient's spouse, adult child, a parent of the adult patient, a person clearly identified in advance of incapacity to act for the patient, the nearest living relative or a member of the clergy.

HOSPITAL BOX MUST BE CHECKED

Texas Health Resources

AUTHORIZATION FOR VERBAL RELEASE OF PROTECTED HEALTH CARE INFORMATION

Form 998540228 (Rev. 12/08)

PATIENT IDENTIFICATION

- ☐ Texas Health Arlington Memorial Hospital
- ☐ Texas Health Harris Methodist Hospital Azle
- ☐ Texas Health Harris Methodist Hospital Cleburne
- ☐ Texas Health Harris Methodist Hospital Fort Worth
- ☐ Texas Health Harris Methodist Hospital Hurst-Euless-Bedford
- ☐ Texas Health Harris Methodist Hospital Southwest Fort Worth
- ☐ Texas Health Harris Methodist Hospital Stephenville
- ☐ Texas Health Presbyterian Hospital Allen
- ☒ Texas Health Presbyterian Hospital Dallas
- ☐ Texas Health Presbyterian Hospital Kaufman
- ☐ Texas Health Presbyterian Hospital Plano
- ☐ Texas Health Presbyterian Hospital Winnsboro
- ☐ Other

FG 21892 (12/08)

9100

(4603201796)(1467727)
JONES ,KATHRYN MARIE
[redacted]1950 60 / F IP
10/26/10 SUR
96210 DENNING JEREMY W

Texas Health Resources

❑ THA ❑ THFW ❑ THS
❑ THAMH ❑ THHEB ❑ THSW
❑ THAZ ❑ THK ❑ THW
❑ THC ❑ THP
❑ THD ❑ OTHER_____

NOTICE TO PATIENTS – THIRD-PARTY PAYOR INFORMATION

Based on the information you have provided us about your insurance or other third-party coverage:

You have coverage with _____.

1. **This hospital ❑ IS / ❑ IS NOT a participating provider under your third-party payor coverage on the date services are to be rendered.**

This information is provided in good faith based on our understanding the information you have provided us. Even though you may have insurance, having coverage does not mean that every procedure is covered by your specific plan. You are financially responsible for whatever your third-party payor does not pay for, subject to any limitations in your plan and its contract with this hospital.

2. **You are advised that a physician or other health care provider who may provide services to the consumer while in the hospital may not be a participating provider with the same third-party payors as the hospital.** For example, your admitting physician, emergency room physicians, pathologists, radiologists, anesthesiologists, neonatologists, hospitalists and others bill separately from the hospital and may not participate in the same health plans as this hospital. You will be responsible for paying those providers subject to the terms of your health plan or insurance, if any.

_____

Signature of patient or legally authorized representative

Name of patient:_____

Record number:_____

Date: _____

_____

Signature of hospital representative

This notice is required by Sec 324.101, Health & Safety Code, as amended by S.B. 1731, effective Sept. 1, 2007, to be provided to the patient upon admission, or when the patient first receives services. In the Emergency Department, to be provided before discharge.

Hospital Copy 10-26-10

LIVING WILL

A. Statement of Declarant

This Declaration is made on 4/29/97, in Honolulu, Hawaii. I, KATHRYN MARIE JONES, being of sound mind, and understanding that I have the right to request that my life be prolonged to the greatest extent possible, willfully and voluntarily make known my desire that my dying shall not be artificially prolonged under the circumstances set forth below, and do hereby declare:

My instructions shall prevail even if they create a conflict with the desires of my relatives, hospital policies, or the principles of those providing my care.

If I should develop a terminal condition or a permanent loss of the ability to communicate concerning medical treatment decisions, with no reasonable chance of regaining this ability, I do not want to have my life prolonged. I would not want to be subjected to surgery or resuscitation. Nor would I want to have life sustaining medicine or procedures. Instead, I request care, including medicine and procedures, for the purpose of providing comfort and pain relief.

CHECKLIST

I have also considered whether I want tube feeding to be provided and have selected one of the following provisions by putting a mark in the space provided:

KMJ I **DO NOT** want my life prolonged by tube or other provision of fluids by a tube or other artificial feeding or other provision of fluids by a tube if my condition is as stated above.

_____ I **DO** want my life prolonged by tube or other artificial feeding and provision of fluids by a tube if my condition is as stated above.

If neither provision is selected or if both are selected, it shall be presumed that tube or other artificial feeding or provision of fluids by a tube are requested to prolong the declarant's life.

This declaration shall control in all circumstances.

I understand the full import of this declaration and I am emotionally and mentally competent to make this declaration.

Kathryn Marie Jones
KATHRYN MARIE JONES

4603201796)(1467727)
JONES ,KATHRYN MARIE
[redacted]950 60 / F IP
10/26/10 SUR
96210 DENNING JEREMY W

CareGate.Link

Jones, Kathryn Marie (MR # 1467727) H3NO-1011091

Author	Service	Author Type	Type	Filed	Note Time
Denning, Jeremy Wayne, MD	(none)	Physician	Op Report	11/05/10 1418	11/04/10 1754

Transcription ID
D013089100

Transcription Status
Available

Authorization Info
Authorized by Denning, Jeremy Wayne, MD at 11/10/10 1529

OPERATIVE REPORT

PATIENT: JONES, KATHRYN
DATE OF BIRTH: 03/01/1950
ACCOUNT: 4603201796
MRN: 1467727
ADMISSION: 10/26/2010
DISCHARGE: 11/03/2010
AUTHOR: JEREMY W. DENNING, MD

CC:
JEREMY W. DENNING, MD, <Admitting>

DATE OF PROCEDURE:
October 26, 2010.

PREOPERATIVE DIAGNOSES:
1. Thoracolumbar degenerative scoliosis.

2. L5-S1 isthmic spondylolisthesis, degenerative disk disease, lumbar spondylosis.

POSTOPERATIVE DIAGNOSES:
1. Thoracolumbar degenerative scoliosis.

2. L5-S1 isthmic spondylolisthesis, degenerative disk disease, lumbar spondylosis.

PROCEDURES PERFORMED:
1. Anterior L1-2, L2-3, L3-4, L4-5, spinal osteotomies.

2. Direct lateral anterior interbody fusion using Medtronic PEEK intervertebral prostheses 10 x 45 mm 0- degree at L1-2, 10 x 45 mm 6-degree lordotic at L2-3,12 x 45 mm 0-degree at L3-4,12 x 45 mm 6- degree lordotic at L4-5.

3. Interbody fusion using locally harvested bone and bone morphogenic protein.

4. Intraoperative microdissection.

5. AP and lateral fluoroscopy.

6. Somatosensory evoked potential and lumbosacral EMG continuous monitoring.

SURGEON:
Jeremy W. Denning, M.D.

ASSISTANT:
Randall Kirby, M.D.

ANESTHESIA:
General.

ESTIMATED BLOOD LOSS:

Printed by WASHINGTON, SONJA [WASHIS]

Aetna

Aetna Life Insurance Company
P.O. BOX 981106
EL PASO, TX 79998-1106

011620 J280EVBB 024761 (1)

EXPLANATION OF BENEFITS

THIS IS NOT A BILL

Please Retain for Future Reference

Date Printed: 01/25/11

KATHRYN JONES [redacted]

QUESTIONS? *Contact us at* **aetnanavigator.com**
1-866-565-1236
Or write to the address shown above.

Notes:

Member: KATHRYN JONES
Group Name: AETNA ADVANTAGE PPO -ARIZONA

Member ID: [redacted]
Group Number: 0888105-10-001 BV DB*61

All Remarks Appear After Final Clair

Claim Activity for KATHRYN JONES (Self)

			Patient Responsibility (shaded columns)							Total Patien
DATE AND TYPE OF SERVICE	SUBMITTED CHARGES	NEGOTIATED OR ALLOWED	PENDING OR NOT PAYABLE	SEE REMARKS	YOUR COPAY	YOUR DEDUCTIBLE	AMOUNT REMAINING	PAID AT	PLAN PAYS	YOUR SHARE OF AMOUNT REMAINING	Responsibili
	A	B	C		D	E	F		G	H	I
This is the claim detail for the bills **received on 01/13/11**					Claim ID: EQ34PLPX901						
RANDALL P KIRBY											
10/26/10											
99222											
INPATIENT PHYSICIAN SERVICE	373.00		**255.31**	1			117.69	50%	58.84	**58.85**	**314.16**
49010											
EXPLORATION BEHIND ABDOMEN	2,844.00		**1,701.26**	1			989.18	50%	494.59	**494.59**	
							153.56	100%	153.56		**2,195.85**
35761											
EXPLORATION OF ARTERY/VEIN	2,610.00		**-,504.05**	2			105.95	100%	105.95		**2,504.05**
21600											
PARTIAL REMOVAL OF RIB	3,375.00		**3,095.31**	3			279.69	100%	279.69		**3,095.31**
Column Totals	9,202.00		**7,555.93**				1,646.07		1,092.63	**553.44**	**8,109.37**

Less Amount Already Paid $888.9

You May Owe RANDALL P KIRBY: **$8,109.37**

General Remarks:

1 - *You are covered for expenses at a level set by your plan sponsor. The charge for services exceeds that amount. You are responsible for the amount indicated. If you have additional information we should consider, please let us know. 551*
2 - *Your plan provides coverage for charges that are reasonable and appropriate as determined by Aetna. This procedure has been paid at the reasonable and customary rate which is 25% of the single procedure rate because it involves an additional surgical procedure performed on the same date as the primary procedure. You may be responsible for this amount. U67*
3 - *Your plan provides coverage for charges that are reasonable and appropriate as determined by Aetna. This procedure has been paid at 50% of the reasonable and customary rate due to multiple procedures performed on the same date of service. You may be responsible for this amount. U65*

Continued on Next Page

Aetna

Customer Resolution Team
P.O. Box 14462
Lexington, KY 40512

March 4, 2011

Kathryn Jones
[redacted]

Subscriber Name:	Kathryn Jones
Member Name:	Kathryn Jones
Member ID Number:	[redacted]
Provider Name:	Multiple
Date(s) of Service:	October 26, 2010
Patient Account Number:	NA
Payer:	Aetna Life Insurance Company
Case Number(s):	20110[redacted]

Subject: Final Appeal Decision

Dear Ms. Jones:

This letter is in response to the appeal request we received on January 5, 2011. This appeal is about the following issue(s):

- The reimbursement at the nonpreferred benefit level subject to the plan's recognized rates Randall P Kirby, MD.
  - Billed charge
    $9596.00
  - Diagnosis code
    756.12: Spondylolisthesis, congenital.
    737.43: Scoliosis associated with other conditions.
  - Procedure code
    22558 80: (Assistant surgeon). Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar.
  - Denial code
    U14: Your plan provides coverage for charges that are reasonable and appropriate as determined by Aetna. This has been paid following Aetna's guidelines for multiple procedures or services performed on the same date of service.
    U65: Your plan provides coverage for charges that are reasonable and appropriate as determined by Aetna. This procedure has been paid at 50% of the reasonable and customary rate due to multiple procedures performed on the same date of service. You may be responsible for this amount.
    U67: Your plan provides coverage for charges that are reasonable and appropriate as determined by Aetna. This procedure has been paid at 25% of the reasonable and

- Procedure code
  95920 26 59: (Professional component). Intraoperative neurophysiology testing, per hour (list separately in addition to code for primary procedure).
  95900 26: (Professional component). Nerve conduction, amplitude and latency/velocity study, each nerve; motor, without f-wave study.
  95861 26: (Professional component). Needle electromyography; 2 extremities with or without related paraspinal areas.
  95926 26: (Professional component). short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in lower limbs.
  95925 26: (Professional component). Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper limbs.
- Denial code
  777: Charges for or in connection with services or supplies that are, as determined by Aetna, considered to be experimental or investigational are excluded from coverage under your plan. You are not responsible for this charge unless you agreed in writing to be responsible for the charge before the service was given. The amount shown as the amount this provider "may bill you" will be higher if you agreed to be responsible.

- The reimbursement at the nonpreferred benefit level subject to the plan's recognized rates by Richard H Jackson, MD.
  - Billed charge
    $12,983.75
  - Diagnosis code
    756.12: Spondylolisthesis, congenital.
    737.43: Scoliosis associated with other conditions.
  - Procedure code
    22612 80: (Assistant surgeon). Arthrodesis, posterior or posterolateral technique, single level; lumbar (with or without lateral transverse technique).
    22214 80: (Assistant surgeon). Osteotomy of spine, posterior or posterolateral approach, one vertebral segment; lumbar.
    22216 80: (Assistant surgeon). Osteotomy of spine, posterior or posterolateral approach, one vertebral segment; each additional vertebral segment (list separately in addition to primary procedure).
  - Denial code
    U14: Your plan provides coverage for charges that are reasonable and appropriate as determined by Aetna. This has been paid following Aetna's guidelines for multiple procedures or services performed on the same date of service.
    V40: This procedure was originally billed with multiple units. Each separate unit has been considered for claim processing.

- The reimbursement at the nonpreferred benefit level subject to the plan's recognized rates by Jeremy Denning, MD.
  - Billed charge
    $13,946.00

- Denial code
  557: You are covered for expenses at a level set by your plan sponsor. The charge for services exceeds that amount. You are responsible for the amount indicated. If you have additional information we should consider, please let us know.

- The reimbursement at the nonpreferred benefit level subject to the plan's recognized rates by Jeremy Denning, MD.
  - Billed charge
    $65,639.00
  - Diagnosis code
    756.12: Spondylolisthesis, congenital.
    737.43: Scoliosis associated with other conditions.
  - Procedure code
    22851: Application of intervertebral biomechanical device(s) (eg, synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (list separately in addition to code for primary procedure).
    22226: Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure).
    22224: Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar.
    22558 59: (Distinct procedural service.) Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar.
  - Denial code
    U65: Your plan provides coverage for charges that are reasonable and appropriate as determined by Aetna. This procedure has been paid at 50% of the reasonable and customary rate due to multiple procedures performed on the same date of service. You may be responsible for this amount.
    U67: Your plan provides coverage for charges that are reasonable and appropriate as determined by Aetna. This procedure has been paid at 25% of the reasonable and customary rate due to multiple surgical procedures performed on the same date of service. You may be responsible for this amount.
    W67: Charges for or in connection with services or supplies that are, as determined by Aetna, considered to be experimental or investigational are excluded from coverage under your plan. While this service or supply itself is not experimental, it is performed in connection with another service or supply that is considered to be experimental. You do not have to pay this charge unless you agreed to do so in writing before the service or supply was given.

- The reimbursement at the nonpreferred benefit level subject to the plan's recognized rates by Dallas Neurology Associates.
  - Billed charge
    $5,647.36
  - Diagnosis code
    756.12: Spondylolisthesis, congenital.
    721.3: Lumbosacral spondylosis without myelopathy.
    724.02: Spinal stenosis, lumbar region, without neurogenic claudication.

22558: Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar.
22558 59: (Distinct procedural service.) Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar.
22851: Application of intervertebral biomechanical device(s) (eg, synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (list separately in addition to code for primary procedure).
22226: Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure).

- Denial code
  U65: Your plan provides coverage for charges that are reasonable and appropriate as determined by Aetna. This procedure has been paid at 50% of the reasonable and customary rate due to multiple procedures performed on the same date of service. You may be responsible for this amount.
  U67: Your plan provides coverage for charges that are reasonable and appropriate as determined by Aetna. This procedure has been paid at 25% of the reasonable and customary rate due to multiple surgical procedures performed on the same date of service. You may be responsible for this amount.
  V40: This procedure was originally billed with multiple units. Each separate unit has been considered for claim processing.
  U14: Your plan provides coverage for charges that are reasonable and appropriate as determined by Aetna. This has been paid following Aetna's guidelines for multiple procedures or services performed on the same date of service.

We reviewed all available information, including:

- Your appeal request
- Operative reports
- Your plan benefits
- The provider's claim

Our decision

Based on our review of the above information, we are upholding the previous decision to deny additional reimbursement for the services performed on October 26, 2010 by Dallas Neurology Associates, Jeremy Denning, MD, Richard H Jackson, MD, Nolan B Jenevein, MD and Randall P Kirby, MD.

However, we will allow laminectomy (Code 63047 and Code 63048) by Dallas Neurology Associates on October 26, 2010.

How we made our decision

You are requesting additional reimbursement for the services performed pertaining to your spinal surgery. You do not believe Aetna followed the procedures in determining the recognized charge.

Based upon a review of the operative report, coverage is approved subject to all terms of the plan decompression services billed by Current Procedural Terminology codes 63047 (Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root(s), (eg, spinal or lateral recess stenosis)), single vertebral segment; lumbar) and 63048 [Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with

We are here to answer your questions
If you have further questions about this appeal decision or the appeal process, please call Member Services at the number on the member ID card. Please include the case number listed at the top of this letter when responding or inquiring about this issue.

We want to know!
Please visit our website for a short survey about Aetna's appeal process.
https://www.aetna.com/form_assets/members/survey.html

Thank you for giving us the opportunity to address your concerns.

Sincerely,

Tangula Unruh

Tangula Unruh
Sr. Complaint and Appeal Analyst
Customer Resolution Team

Enclosure

Tissue Utilization Tag

PATIENT: JONES, KATHRYN MARIE

MED REC NUMBER: 1467727

DOB: [redacted]/50

FINANCIAL NUMBER: 4603201796

ADMITTING PHYSICIAN: DENNING, JEREMY

PRODUCT: Synth Mix 10CC

PRODUCT NUMBER: 17223

ALT UNIT NO: 01791352

Signed Out by [redacted] Date and Time 10-26-10 0915 Volume _____ gm

Date Used _____ Time Used _____

Physician _____ Procedure _____ Issued / Checked _____

****

INSTRUCTIONS / CAUTIONS

1. PROPERLY IDENTIFY INTENDED RECIPIENT.
2. CULTURE FROZEN BONES ONLY BEFORE IMPLANTING.
3. FILL OUT COMPLETELY THE INFORMATION ABOVE.
4. PLACE UTILIZATION TAG IN RECIPIENT'S CHART WHEN COMPLETED.
5. DISCARD UNUSED PORTION OF THAWED BONE.
6. RETURN JARS TO BLOOD BANK.
7. SEE CIRCULAR OF INFORMATION FOR FURTHER GUIDELINES.
8. DO NOT STORE BONE PRODUCTS IN REFRIGERATOR OR UNMONITORED FREEZER.
9. IF FROZEN BONE IS NOT TO BE IMPLANTED, RETURN TO THE BLOOD BANK FOR PROPER FROZEN STORAGE WITHIN 30 MINUTES.

[redacted]

Musculoskeletal Transplant Foundation
Exp Date: 12Apr2012
ITEM: 088100 SERIAL No: 01791382105000018
DESC: DBX Mix, 10cc

CHART COPY

Texas Health Presbyterian Hospital of Dallas

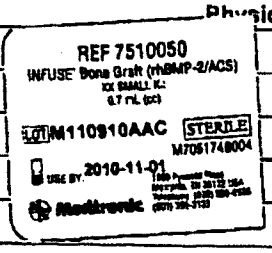
8200 Walnut Hill

Dallas, TX 75231

Physician's Progress Record

Date	Time	Physician's Progress Record

PLIF T12-S1



Implants.

Qty	Part #	Description
2	7575540	5.5x40 Cannulated Screw
3	7575545	5.5x45 Cannulated Screw
4	7576545	6.5x45 Cannulated Screw
2	7576540	6.5x40 Cannulated Screw
1	7571220	220mm Rod
1	7571190	190mm Rod
11	7570955	Longitude Set Screw

(4603201796)(1467727)
JONES ,KATHRYN MARIE
[redacted]/1950 60 / F IA
10/26/10 SUR
96210 DENNING JEREMY W

Op Report (continued)

PREOPERATIVE DIAGNOSES:
1. Degenerative thoracolumbar scoliosis.

2. Isthmic L5-S1 spondylolisthesis with severe right L5-S1 neuroforaminal stenosis and mild left L5-S1 foraminal stenosis.

3. Multilevel degenerative lumbar spondylosis.

POSTOPERATIVE DIAGNOSES:
1. Degenerative thoracolumbar scoliosis.

2. Isthmic L5-S1 spondylolisthesis with severe right L5-S1 neuroforaminal stenosis and mild left L5-S1 foraminal stenosis.

3. Multilevel degenerative lumbar spondylosis.

TITLE OF OPERATION:
1. Minimally invasive L5-S1 right transforaminal lumbar interbody fusion.

2. Right L5-S1 far lateral diskectomy for decompression of the right L5 nerve root.

3. Right L5-S1 decompressive hemilaminectomy.

4. Posterior L5-S1 transforaminal lumbar interbody fusion using an 8 x 26 PEEK intervertebral prosthesis.

5. Locally harvested autograft.

6. Bone morphogenic protein posterior.

SURGEON:
Jeremy W. Denning, M.D.

ASSISTANT:
Tina Coleman, NP

ANESTHESIA:
General.

ESTIMATED BLOOD LOSS:
40 mL.

COMPLICATIONS:
None.

INDICATIONS FOR SURGERY/PROCEDURE IN DETAIL:
The patient is a very pleasant lady who presented with degenerative lumbar scoliosis and an isthmic mobile L5-S1 spondylolisthesis with severe right neural foraminal stenosis, underfilling of the right L5 nerve root and left neural foraminal stenosis as well. She had multilevel foraminal stenosis on the concavity of her curve as well. She opted for surgical treatment as she had failed multiple modalities of conservative treatments in the past. She had chronic mechanical and axial back pain in her thoracolumbar spine, as well as right leg pain in an L5 distribution correlating to her root cut off on the myelogram. There was also

TEXAS HEALTH DALLAS

JONES,KATHRYN MARIE
MRN: 1467727
Acct #: 4603233510
Adm: 11/03/2010, D/C: 11/10/2010

Routed Notes

D/C Summaries signed by Lin, Alberto I., MD at 11/15/10 1033

Author: Lin, Alberto I, MD Service: Rehab Author Type: Physician
Filed: 11/15/10 1033 Note Time: 11/10/10 1315

Acute Inpatient Rehabilitation Discharge Note

[redacted]

Discharge Date: 11/10/2010

Discharge Diagnoses:
1. Right L5-S1 far lateral discectomy and hemilaminectomy with posterior fusion and L1-L5 osteotomy and fusion
2. Gait dysfunction
3. Balance dysfunction
4. ADL dysfunction
5. Hypertension
6. GERD

Reason For Admission:
This is detailed in the history and physical. Please refer to that summary.

Most Recent Laboratory and Radiology Data:

Component	Value	Date/Time
WBC	8.16	11/3/10 1952
HGB	11.3	11/3/10 1952
HCT	33.2	11/3/10 1952
PLT	347	11/3/10 1952

No results found for this basename:
uwbc,urbc,keto,uprotqn,bact,nit,leuko

Component	Value	Date/Time
NA	138	11/4/10 0801
K	3.5	11/4/10 0801
CO2	32*	11/4/10 0801
CL	93*	11/4/10 0801
BUN	9	11/4/10 0801
CREAT	0.56*	11/4/10 0801
GLU	96	11/4/10 0801
CA	8.9	11/4/10 0801

Hospital Course:

Kathryn Marie Jones is a very pleasant 60 y.o. female who benefited greatly from the acute inpatient rehabilitation stay status post right L5-S1 far lateral discectomy and hemilaminectomy with posterior fusion and L1-L5 osteotomy and fusion with resulting functional deficits in gait, transfers, activities of daily living requiring 24 hour nursing supervision, physiatric management and close interdisciplinary rehabilitation.

- Functional gait, transfers and balance dysfunction. Physical therapy for gait, posture and transfer retraining with appropriate durable medical equipments with focus on safety precautions and patient education.

- Activities of daily living and self-care dysfunction. Occupational therapy for transfer retraining with focus on static and dynamic balance with activities of daily living. Patient education regarding safety precautions, compensatory techniques

10-1-12 19

Texas Health Dallas
8200 Walnut Hill Lane
Dallas,TX 75231

MRN: 1467727
Account #: 4603201796
Chart MR#:
Location: H3NO-H314-01
DOB [redacted]/50 Sex: Female
Admit Date: 10/26/10
Physician: DENNING, JEREMY
Patient: JONES, KATHRYN MARIE [redacted]

Blood Bank

--Transfusion Medicine--

Date collected: 10/26/10
Time collected: 06:58

Test
ABO Rh Blood Type O POS
Antibody Screen Negative

Products issued

Dt/Tm Issued	Unit Number	Product	ABO/Rh	Status
10/26/10 09:45	17223	Synthes Mix 10CC		Transfused

Crossmatch Summary

Dt/Tm Verified	Dt/Tm Collected	Unit Number	Product	ABO/Rh	Crossmatch Result
10/26/10 08:47	10/26/10 06:58	W041010166885	Auto RBC	O Pos	Elect XM OK
10/26/10 08:47	10/26/10 06:58	W041010169194	Auto RBC	O Pos	Elect XM OK

Cancelled Tests

Date collected	Time collected	Order Name	Cancel Reason
10/26/10	06:58	Electronic Crossmatch	

Legend:
H= High, L= Low, C= Critical, a= Amended, f= Footnote, @= See interpretive text

Lab Use Only: 59046952
Report type:Final-Medical Records-Do Not Discard
Page: 4 of 5
Chart MRN:
Acct: 4603201796
MRN: 1467727
JONES, KATHRYN MARIE

Tissue Utilization Tag

PATIENT: JONES, KATHRYN MARIE

MED REC NUMBER: 1467727

DOB: [redacted]60

FINANCIAL NUMBER: 4603201796

ADMITTING PHYSICIAN: DENNING, JEREMY

PRODUCT: Synth Mix 10CC

PRODUCT NUMBER: 17223

ALT UNIT NO: 01791352

Signed Out by [signature] Date and Time 10-26-10 0915 Volume _____ gm

Date Used _____ Time Used _____

Physician _____ Procedure _____ Issued / Checked _____

****

INSTRUCTIONS / CAUTIONS

1. PROPERLY IDENTIFY INTENDED RECIPIENT.
2. CULTURE FROZEN BONES ONLY BEFORE IMPLANTING.
3. FILL OUT COMPLETELY THE INFORMATION ABOVE.
4. PLACE UTILIZATION TAG IN RECIPIENT'S CHART WHEN COMPLETED.
5. DISCARD UNUSED PORTION OF THAWED BONE.
6. RETURN JARS TO BLOOD BANK.
7. SEE CIRCULAR OF INFORMATION FOR FURTHER GUIDELINES.
8. DO NOT STORE BONE PRODUCTS IN REFRIGERATOR OR UNMONITORED FREEZER.
9. IF FROZEN BONE IS NOT TO BE IMPLANTED, RETURN TO THE BLOOD BANK FOR PROPER FROZEN STORAGE WITHIN 30 MINUTES.

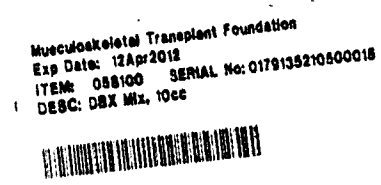


CHART COPY

Texas Health Presbyterian Hospital of Dallas

8200 Walnut Hill

Dallas, TX 75231

Texas Health Dallas	MRN:	1467727
8200 Walnut Hill Lane	Account #:	4603201796
Dallas,TX 75231	Chart MR#:	
	Location:	H3NO-H314-01
	DO[redacted]50	Sex: Female
	Admit Date:	10/26/10
	Physician:	DENNING, JEREMY
	Patient:	JONES, KATHRYN MARIE

Cancelled Tests

Date collected	Time collected	Order Name	Cancel Reason
10/26/10	06:59	ABORh Type/G	Duplicate Order
10/26/10	06:59	Electronic Crossmatch	
10/26/10	06:59	Gel Antibody Screen 2Cell	Duplicate Order
10/26/10	07:05	Electronic Crossmatch	Wrong Accession
10/28/10	05:24	Magnesium	Lab reordered with new accession
10/29/10	03:45	Magnesium	Lab reordered with new accession

Legend:
H= High, L= Low, C= Critical, a= Amended, f= Footnote, @= See interpretive text

Lab Use Only:	Report type:Final-Medical	Chart MRN:
59046952	Records-Do Not Discard	Acct: 4603201796
		MRN: 1467727
	Page: 5 of 5	JONES, KATHRYN MARIE

REASON FOR UNPLANNED RETURN TO SURGERY:

SITE MARKED / PROCEDURE AGREES WITH:
SURGERY SCHEDULE: Yes
HISTORY PHYSICAL: Yes

PER DOCTOR'S ORDER: Yes

CASE SERVICE: NEURO

PROCEDURE DUE TO BLUNT OR PENETRATING TRAUMATIC INJURY: No
ENTIRE PROCEDURE PERFORMED USING AN ENDOSCOPE/LAPAROSCOPE: No
MULTIPLE PROCEDURES PERFORMED THROUGH THE SAME INCISION: No

PREOP DIAGNOSIS: SCOLIOSIS

10/27/10 10:41:48AM

NAME: JONES, KATHRYN MARIE
GENDER: F BIRTHDATE: 3/1/50 AGE: 60 Y
MEDICAL RECORD NUMBER: 1467727 ACCOUNT NUMBER: 4603201796
SURGERY DATE: 10/26/10 8:05

ANTIBIOTIC

[ ] DECLINED
ANTIBIOTIC GIVEN: LEVOFLOXACIN (LEVAQUIN)
DOSE: 500 mg
ROUTE: IV - IV (PUSH)
GIVEN BY: BOEHLER, LILLIAN M
DATE/TIME: 10/26/10 8:30
PHASE: INTRAOP
ANTIBIOTIC GIVEN: LEVOFLOXACIN (LEVAQUIN)
DOSE: 500 mg
ROUTE: IV - IV (PUSH)
GIVEN BY: BOEHLER, LILLIAN M
DATE/TIME: 10/26/10 12:30
PHASE: INTRAOP
NURSING NOTES:

10/27/10 10:41:48AM

1st day

NAME: JONES, KATHRYN MARIE
GENDER: F BIRTHDATE: 3/1/50 AGE: 60 Y
MEDICAL RECORD NUMBER: 1467727 ACCOUNT NUMBER: 4603201796
SURGERY DATE: 10/26/10 8:05

CASE STAFF

NAME: JAMES SHERMAN- MEDTRONIC
ROLE: VENDOR REPRESENTATIVE
TIME IN: 10/26/10 8:05 TIME OUT:10/26/10 15:18

TIME OUT

TIME OUT PER PROTOCOL: 10/26/10 9:00:00AM
BY SURGICAL TEAM AND REVERIFIED PRIOR TO INCISION

TIMEOUT CRITERIA	RESPONSE
PATIENT	Yes
ACCURATE AND COMPLETE CONSENT	Yes
PROCEDURE	Yes
SITE	Yes
POSITION	Yes
EQUIPMENT	Yes
IMPLANTS	Yes
RELEVANT IMAGES	Yes
APPROPRIATE RESULTS	Not Applicable
SAFETY	Yes
ANTIBIOTIC	Yes
FLUIDS FOR IRRIGATION	Yes

TIMEOUT COMMENT:

PROCEDURE INFORMATION

PRIMARY PROCEDURE: DIRECT LATERAL INTERBODY FUSION, L1-L5; POSTERIOR L5-S1 TLIF
WITH INTRA-OP NEURO MONITORING
[ ] ACTUAL PROCEDURE SAME AS SCHEDULED
PROCEDURE START: 10/26/10 9:02 PROCEDURE STOP: 10/26/10 15:12
PRIMARY SURGEON: DENNING, JEREMY W
SURGEON / ASSISTANT: KIRBY, RANDALL P
SURGEON / ASSISTANT: COLEMAN, TINA
PROCEDURE SERVICE: NEURO
NURSE'S NOTES: REPOSITIONED PATIENT AT 1220. SECOND PAUSE TAKEN AT:1235
SURGERY
RESTARTED AT:1250

PROCEDURE POSITIONAL DEVICES

OUTCOME #3: PATIENT IS FREE OF SIGNS AND SYMPTOMS OF POSITIONING INJURY.

POSITION FOR SURGERY: LATERAL LEFT UP
POSITIONED BY: SURGICAL TEAM
RIGHT ARM PLACEMENT: ARM BOARD <90 , SECURED, PALM UP
LEFT ARM PLACEMENT: SUSPENDED, SECURED
[ ]STANDARD TABLE SPECIALTY TABLE: JACKSON TABLE
GENITALIA CHECKED PER POSITION: Yes
PULSES CHECKED PER POSITION: Yes
BREAST CHECKED PER POSITION: Yes
SAFETY STRAP: [X] MID THIGH [ ] ABDOMEN [X] CHEST
[ ] CALF [ ] OTHER - SEE NURSE'S NOTES

NAME: JONES, KATHRYN MARIE
GENDER: F BIRTHDATE: 3/1/50 AGE: 60 Y

ANTIBIOTIC

[ ] DECLINED
ANTIBIOTIC GIVEN: LEVOFLOXACIN (LEVAQUIN)
DOSE: 500 mg
ROUTE: IVPB - (PIGGYBACK)
GIVEN BY: BOEHLER, LILLIAN M
DATE/TIME: 10/27/10 7:50
PHASE: INTRAOP
NURSING NOTES:

10/28/10 9:28:17AM

NAME: JONES, KATHRYN MARIE
GENDER: F BIRTHDATE: 3/1/50 AGE: 60 Y
MEDICAL RECORD NUMBER: 1467727 ACCOUNT NUMBER: 4603201796
SURGERY DATE: 10/27/10 7:32

PATIENT BELONGINGS/DISPOSITION

BELONGING: NONE
DISPOSITION:
COMMENT:

CASE STAFF

NAME: COLE, TIMOTHY, RN
ROLE: CIRCULATOR
TIME IN: 10/27/10 7:32 TIME OUT:10/27/10 11:00
TIME IN: 10/27/10 11:30 TIME OUT:10/27/10 13:51
NAME: CUMBA, DARLA (EVOKE TECH)
ROLE: NEUROLOGIC MONITOR
TIME IN: 10/27/10 7:32 TIME OUT:10/27/10 13:51
TIME IN: TIME OUT:
NAME: SIRIVONGPAISAL, JITTREE; CST
ROLE: SCRUB
TIME IN: 10/27/10 7:32 TIME OUT:10/27/10 12:19
TIME IN: 10/27/10 12:49 TIME OUT:10/27/10 13:51
NAME: GAAB, MYRA RN
ROLE: CIRCULATOR
TIME IN: 10/27/10 7:35 TIME OUT:10/27/10 11:33
TIME IN: TIME OUT:
NAME: JOSH TSOKANAS (MEDTRONIC)
ROLE: VENDOR REPRESENTATIVE
TIME IN: 10/27/10 8:15 TIME OUT:10/27/10 9:00
TIME IN: TIME OUT:
NAME: JAMES SHERMAN (MEDTRONIC)
ROLE: VENDOR REPRESENTATIVE
TIME IN: 10/27/10 8:15 TIME OUT:10/27/10 13:51
TIME IN: TIME OUT:
NAME: ENTY, LORA JEAN (BUSINESS GROWTH)
ROLE: OBSERVER
TIME IN: 10/27/10 10:56 TIME OUT:10/27/10 12:57
TIME IN: TIME OUT:

DALLAS NEUROSURGICAL AND SPINE ASSOCIATES, P.A.

NOTICE OF PRIVACY PRACTICES

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

Protecting your privacy

Protecting your privacy and your medical information is at the core of our business. We recognize our obligation to keep your information secure and confidential whether on paper or the Internet. At **Dallas Neurosurgical and Spine Associates, P.A.** (hereinafter referred to as the "the Practice"), privacy is one of the highest priorities.

Keeping your information

Keeping the medical and health information we have about you secure is one of our most important responsibilities. We value your trust and will handle your information with care. Our employees access information about you only when necessary to provide treatment, verify eligibility, obtain authorization, process claims and otherwise meet your needs. We may also access information about you when considering a request from you or when exercising our rights under the law or any agreement with you.

We safeguard information during all business practices according to established security standards and procedures, and we continually assess new technology for protecting information. Our employees are trained to understand and comply with these information principles.

Working to meet your needs through information

In the course of doing business, we collect and use various types of information, like name, address and claims information. We use this information to provide service to you, to process your claims and bring you health information that might be of interest to you.

Keeping information accurate

Keeping your information accurate and up-to-date is very important. If you believe the health information we have about you is incomplete, inaccurate or not current, please call or write us at the telephone numbers or addresses below. We take appropriate action to correct any erroneous information as quickly as possible through a standard set of practices and procedures.

How-and why-information is shared

We limit who receives information and what type of information is shared.

- *Sharing information with the Practice.* We share information within our company to deliver you the health care services and related information and education programs specified to your plan.

- *Sharing information with companies that work for us.* To help us offer you our services, we may share information with companies that work for us, such as claim processing and mailing companies and companies that deliver health education and information directly

TEXAS HEALTH PRESBYTERIAN HOSPITAL DALLAS
8200 Walnut Hill Ln
Dallas, Texas 75231
Main Radiology 214-345-7770
Nuclear Medicine 214-345-2556
Womens Diagnostic and Breast Center 214-345-2598

Final

PATIENT: JONES,KATHRYN MARIE
DOB: [redacted]/1950
AGE/SEX: 60Y F
ADMIT MD: DENNING, JEREMY WAYNE
ORDER MD: BOEHLER, LILLIAN MARGARET
EXAM DATE: 10/26/2010 1559
ADMIT. DX: SCOLIOSIS
EXAM: CHEST 1 VIEW PORT MDX
REASON FOR EXAM: Post Line Placement
COMMENTS:

ROOM #: M21901
MR #: 1467727
ACCT #: 4603201796
PT TYPE:IP
ORD #:DDX56557-10

FINDINGS:

There is a right jugular line present, tip in the superior vena cava. There is a subtle linear radiopacity in the right apex that could possibly represent a tiny right apical pneumothorax. Otherwise, the visualized lungs are clear. There is no shift of mediastinal structures.

IMPRESSION:

Status post right jugular line placement.

Question tiny right apical pneumothorax. Recommend a repeat chest x-ray with end expiration.

Findings and recommendations were discussed with PACU staff caring for the patient at October 26, 2010, at 4:45 p.m.

Interpreted By: 114921 Scott Bundy, M.D.
Dictated on: 10/26/2010 16:46:45
Electronically Signed by: 114921 Scott Bundy, M.D.
Signed on: 10/26/2010 16:49:17

CareGate.Link

Jones, Kathryn Marie (MR # 1467727) H3NO-1011091

Author	Service	Author Type	Type	Filed	Note Time
Denning, Jeremy Wayne, MD	(none)	Physician	Op Report	11/05/10 1411	11/04/10 1809

Transcription ID
D013089246

Transcription Status
Available

Authorization Info
Authorized by Denning, Jeremy Wayne, MD at 11/10/10 1529

OPERATIVE REPORT

PATIENT: JONES, KATHRYN
DATE OF BIRTH: [redacted]/1950
ACCOUNT: 4603201796
MRN: 1467727
ADMISSION: 10/26/2010
DISCHARGE: 11/03/2010
AUTHOR: JEREMY W. DENNING, MD

CC:
JEREMY W. DENNING, MD, <Admitting>

DATE OF OPERATION:
October 27, 2010

PREOPERATIVE DIAGNOSES:
1. Thoracolumbar degenerative scoliosis.

2. L5-S1 isthmic spondylolisthesis, multilevel lumbar spondylosis, degenerative disk disease, and foraminal stenosis.

POSTOPERATIVE DIAGNOSES:
1. Thoracolumbar degenerative scoliosis.

2. L5-S1 isthmic spondylolisthesis, multilevel lumbar spondylosis, degenerative disk disease, and foraminal stenosis.

TITLE OF OPERATION:
1. Posterior T12 to L5 spinal osteotomies using the METRx tubes.

2. Posterior multilevel thoracolumbar fusion T12 to S1 using local bone and BMP.

3. Posterior segmental spinal instrumentation using the Medtronic Longitude percutaneous screw and rod system from T12 to S1 with AP and lateral fluoroscopy, somatosensory evoked potential, lumbosacral EMG and direct pedicle screw stimulation.

SURGEON:
Jeremy W Denning, MD

ASSISTANT:
Richard Jackson, MD

Stephanie M. Cracknell, RNFA, NP

ANESTHESIA:
General.

ESTIMATED BLOOD LOSS:
100 mL.

Printed by WASHINGTON, SONJA [WASHIS]

Jones, Kathryn Marie (MR # 1467727) H3NO-1011091

fluoroscopy down through the windows of each screw extender from T12 all the way down to S1. We then assessed that the rod was through the windows of each screw extender by confirming with a screw extender rod confirmation tool from T12 all the way to S1 and once we had confirmed showed and confirmed that we had good placement of the rod by AP and lateral fluoroscopy, we then placed the locking caps over the rod and down the screw extenders, and slowly by cantilevering the rod and screws, completely corrected the remainder of her spinal deformity.

Each cap was then locked and broken off with the counter-torque device, and the screw extenders removed. We then placed a 200 mm rod on the left side in a similar fashion, using a completely percutaneous technique and AP and lateral fluoroscopy. Once we had confirmed that the rod was passed through each screw extender window, we then cantilevered the rod down to the spine sequentially until it was completely reduced. The locking tool was then used to break off each cap and each screw extender removed.

Our final AP and lateral image then showed complete correction of her spinal deformity and good placement of the instrumentation percutaneously. We then each incision with 2-0 Vicryl suture through the fascia and Scarpa layer an inverted interrupted 2-0 Vicryl suture for the skin reapproximation, followed by Mastisol and Steri-Strips. There were no complications. However, the case, did require a lot of time, especially placing the screws and rods percutaneously with a lot of fluoroscopy. We had minimal blood loss and minimized the dissection through her muscles.

She was then positioned supine on the stretcher and extubated in the operating room and transported to the recovery room in good condition. The sponge, needle and instrument counts were correct at the end of the case as reported twice by the operating room personnel.

JEREMY W. DENNING, MD

JWD:cl
D: 11/04/2010 18:09:00
T: 11/05/2010 13:54:14
JOB: 15007861 / 238708

Electronically signed by Denning, Jeremy Wayne, MD at 11/10/10 1529

TEXAS HEALTH DALLAS JONES,KATHRYN MARIE
MRN: 1467727
Acct #: 4603201796
Admit Date: 10/26/2010
Page Printed By WASHIS at 6/24/11 3:19 PM

Printed by WASHINGTON, SONJA [WASHIS]

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2002

Richard W. Treharne, Ph.D.
Senior Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: P000058
InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device
Filed: January 12, 2001
Amended: January 12, March 19, May 9, July 31, August 24, September 25, October 9, November 21, and December 6, 7 and 26, 2001, January 22, February 8, March 19, April 2, 3, 12 (2), 15, 16, 17, 22, 26 and 30, May 9, 10, 14 and 28 and June 12 and 28, 2002
Procode: NEK

Dear Dr. Treharne:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device. This device is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L4-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, function deficit and/or neurological deficit and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis at the involved level. InFUSE™ Bone Graft/LT-CAGE™ devices are to be implanted via an anterior open or an anterior laparoscopic approach. Patients receiving the InFUSE™ Bone Graft/ LT-CAGE™ Lumbar Tapered Fusion Device should have had at least six months of nonoperative treatment prior to treatment with the InFUSE™ Bone Graft/LT-CAGE™ device. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions described below and in the "Conditions of Approval" (enclosed).

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

3. Perform post-approval studies which assess the effects of rhBMP-2 on tumor promotion. These studies will include *in vitro* studies with primary tumor cell isolates.

4. Perform post-approval studies to investigate the potential for an immune response to rhBMP-2 to interfere in embryonic development in rabbits. Observations from this investigation may indicate a necessity to create a pregnancy monitoring database and/or modify your labeling.

5. Develop and validate a new antibody ELISA for antibodies to rhBMP-2 that has the potential to detect all antibody isotypes.

6. Develop and validate a neutralization assay for antibodies to rhBMP-2.

Complete final reports addressing the requests identified in items 3-6 above should be submitted as the reports become available. If these reports have not been submitted by the time of submission of the first PMA annual report, you should include an approximate timeline for submission in the annual reports, as well as updates on the studies' progress.

7. Provide the results of three additional assays, *i.e.*, silver stained SDS-PAGE, Edmans test and glycoform analysis, on the release specifications for the drug substance. These should be submitted as PMA reports.

Expiration dating for this device has been established and approved at three years for the Small and Medium InFUSE™ Bone Graft components, two years for the Large and Large II InFUSE™ Bone Graft components and five years for the LT-CAGE™ Lumbar Tapered Fusion Device component.

CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Last Modified: 1-31-02

CONDITIONS OF APPROVAL

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e) or (f). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations that require a PMA supplement cannot be briefly summarized; therefore, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report (see below). FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

Alternate submissions permitted under 21 CFR 814.39(f) for manufacturing process changes include the use of a 30-day Notice. The manufacturer may distribute the device 30 days after the date on which the FDA receives the 30-day Notice, unless the FDA notifies the applicant within 30 days from receipt of the notice that the notice is not adequate.

3. Any significant chemical, physical or other change or deterioration in the device, or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc.

Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336)and FDA publications entitled "An Overview of the Medical Device Reporting Regulation" (FOD # 509) and "Medical Device Reporting for Manufacturers" (FOD #987) are available on the CDRH WWW Home Page. They are also available through CDRH's Fact-On-Demand (F-O-D) at 800-899-0381. Written requests for information can be made by sending a facsimile to CDRH's Division of Small Manufacturers International and Consumer Assistance (DSMICA) at 301-443-8818.

Medical Devices

InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device - P000058

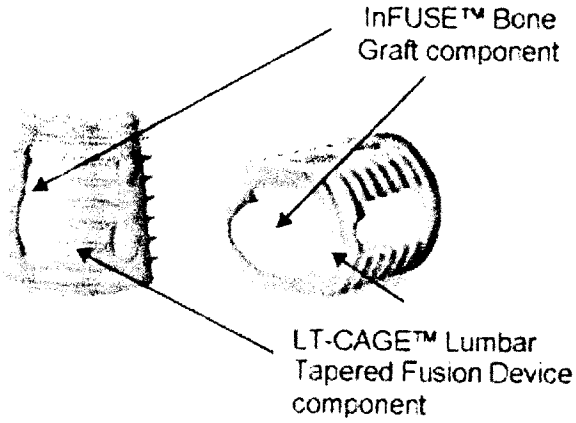
This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device
Manufacturer: Medtronic Sofamor Danek
Address: 1800 Pyramid Place Memphis, Tennessee 38132
Approval Date: July 2, 2002
Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf/P000058a.pdf[1]

What is it? A device to help fuse vertebrae in the lower spine in order to treat degenerative disc disease. It differs from other, similar devices in that it uses genetically engineered protein to help build bone tissue in the fusion process, instead of using a graft of the patient's own bone (an autograft).

The device consists of three components spilt among two parts -

1. a metallic tapered spinal fusion cage (known as the LT-CAGE™ Lumbar Tapered Fusion Device); and
2. a bone graft substitute (InFUSE™ Bone Graft) which consists of a genetically-engineered human protein (rhBMP-2) along with a carrier/scaffold for the protein (manufactured from bovine [cow] Type I collagen) that is placed inside the fusion cage.



How does it work? The fusion cage component maintains the spacing and temporarily stabilizes the diseased region of the spine, while the InFUSE™ Bone Graft component is used to form bone which would permanently stabilize (fuse) this portion of the spine.

When is it used? The device is used in the lower region of the spine (L4-S1) to treat degenerative disc disease.

What will it accomplish? A clinical study showed that the use of this device was as safe and effective in promoting spinal fusion as the same fusion cage component filled with autograft bone.

When should it not be used? This device should not be used for patients:

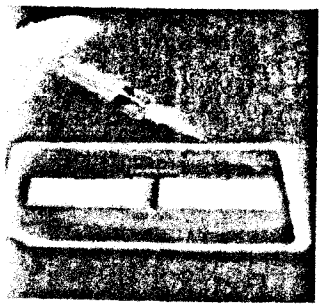
- who are pregnant or might be pregnant,
- who may be allergic to any of the materials contained in the device,
- who have an infection near the area of the surgical incision,
- who have had a tumor removed from the area of the implantation site or currently have a tumor in that area, or
- whose bones have not stopped growing.

In addition, it is not known if a woman who becomes pregnant after receiving the device could have a second immune reaction to the BMP-2 normally found in a developing fetus, which might harm either mother or fetus.

Medical Devices

INFUSE® Bone Graft - P050053

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.



Product Name: INFUSE® Bone Graft
PMA Applicant: Medtronic Sofamor Danek
Address: 1800 Pyramid Place, Memphis, Tennessee 38132
Approval Date: March 9, 2007
Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf5/p050053a.pdf[1]

What is it? INFUSE® Bone Graft is a bone filling material for dental use, and contains a bone protein. It is an alternative to grafting a patient's own bone.

How does it work? INFUSE® Bone Graft is used to fill space where bone is needed in order to place endosseous dental implants. Endosseous dental implants are inserted in the jaw and have an exposed head that can be used to secure dental devices like a crown, fixed bridge, or dentures.

When is it used? INFUSE® Bone Graft is used in making enough bone in the sinus area to place endosseous dental implants in the upper jaw. It is also used to increase bone in extraction sites prior to implant placement.

What will it accomplish? INFUSE® Bone Graft accomplishes almost the same clinical outcome as grafting a patient's own bone into these locations but without the difficulties of grafting bone from the hip and other sites. Grafting sites usually have many side effects including pain and long recovery times.

When should it not be used? INFUSE® Bone Graft should not be used:

- In patients with an active infection at the operative site
- In patients who are pregnant
- In patients who are hypersensitive to recombinant human Bone Morphogenic Protein-2, or bovine type I collagen.
- In an area where there was a tumor.

Additional information: The Summary of Safety and Effectiveness and labeling are available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p050053[2]

Other Resources

- Mayo Clinic - Dental Implant Surgery[3][4]

Page Last Updated: 06/29/2009
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

ELSEVIER

The Spine Journal 11 (2011) 471–491

THE SPINE JOURNAL

Review Article

A critical review of recombinant human bone morphogenetic protein-2 trials in spinal surgery: emerging safety concerns and lessons learned

Eugene J. Carragee, MD[a,*], Eric L. Hurwitz, DC, PhD[b], Bradley K. Weiner, MD[c]

[a]*Department of Orthopedic Surgery, Stanford Medicine Outpatient Center, Stanford University School of Medicine, 450 Broadway, Mail Code 6342, Redwood City, CA 94063, USA*

[b]*Office of Public Health, University of Hawaii, 1960 East-West Rd, Honolulu, HI, USA*

[c]*Department of Orthopaedic Surgery, The Methodist Hospital, 6565 Fannin St, Houston, TX, USA*

Received 18 February 2011; revised 5 April 2011 and 25 April 2011; accepted 27 April 2011

Abstract

BACKGROUND CONTEXT: Increasingly, reports of frequent and occasionally catastrophic complications associated with use of recombinant human bone morphogenetic protein-2 (rhBMP-2) in spinal fusion surgeries are being published. In the original peer review, industry-sponsored publications describing the use of rhBMP-2 in spinal fusion, adverse events of these types and frequency were either not reported at all or not reported to be associated with rhBMP-2 use. Some authors and investigators have suggested that these discrepancies were related to inadequate peer review and editorial oversight.

PURPOSE: To compare the conclusions regarding the safety and related efficacy published in the original rhBMP-2 industry-sponsored trials with subsequently available Food and Drug Administration (FDA) data summaries, follow-up publications, and administrative and organizational databases.

STUDY DESIGN: Systematic review.

METHODS: Results and conclusions from original industry-sponsored rhBMP-2 publications regarding safety and related efficacy were compared with available FDA data summaries, follow-up publications, and administrative and organizational database analyses.

RESULTS: There were 13 original industry-sponsored rhBMP-2 publications regarding safety and efficacy, including reports and analyses of 780 patients receiving rhBMP-2 within prospective controlled study protocols. No rhBMP-2–associated adverse events (0%) were reported in any of these studies (99% confidence interval of adverse event rate <0.5%). The study designs of the industry-sponsored rhBMP-2 trials for use in posterolateral fusions and posterior lateral interbody fusion were found to have potential methodological bias against the control group. The reported morbidity of iliac crest donor site pain was also found to have serious potential design bias. Comparative review of FDA documents and subsequent publications revealed originally unpublished adverse events and internal inconsistencies. From this review, we suggest an estimate of adverse events associated with rhBMP-2 use in spine fusion ranging from 10% to 50% depending on approach. Anterior cervical fusion with rhBMP-2 has an estimated 40% greater risk of adverse events with rhBMP-2 in the early postoperative period, including life-threatening events. After anterior interbody lumbar fusion rates of implant displacement, subsidence, infection, urogenital events, and retrograde ejaculation were higher after using rhBMP-2 than controls. Posterior lumbar interbody fusion use was associated with radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes. In posterolateral fusions, the risk of adverse effects associated with rhBMP-2 use was equivalent to or greater than that of iliac crest bone graft harvesting, and 15% to 20% of subjects

FDA device/drug status: Some rhBMP-2 uses in this article are approved; others are not. See text for details.

Author disclosures: ***EJC:*** Stock Ownership (options only): Intrinsic Spine, Cytonics, Simpirica (B); Private Investments: Simpirica (D); Consulting: US Department of Justice (D), Kaiser Permanente (D), US Army (Trips/Travel disclosed), US Department of Defense (Trips/Travel disclosed); Research Support (Investigator Salary): NIH (C, Paid directly to institution/employer); Other office: NASS The Spine Journal (E, Editor in Chief); Fellowship Support: OREF (E, Paid directly to institution/employer), AO Foundation (E, Paid directly to institution/employer); Trips/Travel: US Army (B), Department of Defense (A), Orthopedic Trauma Society (A), OREF (B), AAOS (A), NASS (A), The Spine Journal (A). ***ELH:*** Nothing to disclose. ***BKW:*** Nothing to disclose.

The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

* Corresponding author. Department of Orthopedic Surgery, Stanford Medicine Outpatient Center, Stanford University School of Medicine, 450 Broadway, Mail Code 6342, Redwood City, CA 94063, USA. Tel.: (650) 721-7616; fax: (650) 721-3470.

E-mail address: carragee@stanford.edu (E.J. Carragee)

doi:10.1016/j.spinee.2011.04.023

reported early back pain and leg pain adverse events; higher doses of rhBMP-2 were also associated with a greater apparent risk of new malignancy.

CONCLUSIONS: Level I and Level II evidence from original FDA summaries, original published data, and subsequent studies suggest possible study design bias in the original trials, as well as a clear increased risk of complications and adverse events to patients receiving rhBMP-2 in spinal fusion. This risk of adverse events associated with rhBMP-2 is 10 to 50 times the original estimates reported in the industry-sponsored peer-reviewed publications.

Keywords: Critical review; rhBMP-2 trials; Spinal fusion; Safety concerns; Conflict of interest

Introduction

Spinal fusion techniques have historically used autogenous bone grafting, either from local or distant sources, to augment the local techniques used to stimulate fusion. For long spinal fusions or spinal fusions in adverse metabolic or local conditions, traditional techniques of bone grafting can prove inadequate. Accordingly, bone graft substitutes and enhancers have been developed over time to address these needs. One such bone graft substitute, recombinant human bone morphogenetic protein-2 (rhBMP-2), was introduced commercially in 2002.

There has been an appreciation in the more recent spine surgery literature that frequent and occasionally catastrophic complications are associated with the use of rhBMP-2 in spinal fusion surgeries. Adverse events of this sort were not reported as being associated with rhBMP-2 application in multiple early industry-sponsored trials published in peer-reviewed journals. This article critically reviews the evolving safety profile of rhBMP-2; beginning with the original industry-sponsored publications and progressing to later independent assessments of the product and by independent reassessment of publicly available trial data.

In addition to giving perspective to the specific morbidities of rhBMP-2, it is hoped that lessons can be learned from this era in spinal research and publication. Such lessons might prove valuable in the future, allowing us to better serve not only our community of researchers and clinicians but especially our patients who rely on the expeditious but safe introduction of new technologies in health care.

Summary of events leading to the current review

Multiple studies in the 1990s suggested that bone morphogenetic protein-2 (BMP-2) could cause bone induction in various animal models. There was uncertainty, however, regarding appropriate dosing, appropriate carriers, and safety, all of which appeared to be highly variable depending on the species of animal and location of BMP application [1].

When the use later began in humans, there seemed little doubt that bone induction would be possible; but proper dosing and possible adverse reactions with various applications remained uncertain. Preliminary human trials for lumbar fusion were published beginning in 2000 [2] and 2002 [3]. It was clear at the time that the nature and diversity of adverse events could not be well predicted given that rhBMP-2 appeared to be involved in a multiplicity of physiological and pathological events including, but not limited to, the inflammatory response, bone induction and resorption pathways, abnormal growth signaling pathways, certain malignancy pathways, and induction of an altered immune response [1,4]. Accordingly, in a 2002 review article, Poynton and Lane [4] wrote:

> "Safety issues associated with the use of bone morphogenetic proteins in spine applications include the possibility of bony overgrowth, interaction with exposed dura, cancer risk, systemic toxicity, reproductive toxicity, immunogenicity, local toxicity, osteoclastic activation, and effects on distal organs."

The results of several small and large industry-sponsored trials were subsequently published [2,3,5–11]. These reported the use of rhBMP-2 in larger numbers of patients undergoing a variety of spinal fusion techniques, including anterior interbody lumbar fusion (ALIF), posterolateral lumbar fusion (PLF), posterior lumbar interbody fusion (PLIF), and anterior cervical discectomy and fusion (ACDF) (Table 1).

Notably, with each new industry-sponsored trial publication, the safety findings were identical: no adverse events associated with rhBMP-2 were reported to be observed. Given that 780 patients received rhBMP-2 in these industry-sponsored publications and that not a single adverse event had been reported, the estimated risk of rhBMP-2 use could be calculated to be less than 0.5% with 99% certainty. That is, the reported risk of an adverse event with rhBMP 2, based on the industry-sponsored data, was less than one-fortieth the risk of a course of commonly used anti-inflammatory or antibiotic medications [12].

Although initially contemplated as an adjunct to spine arthrodesis to be used in particularly adverse clinical situations, a generalized use of rhBMP-2 was observed [13]. In the United States alone, the usage of BMP increased from 0.7% of all fusions in 2002 to 25% of all fusions in 2006, with 85% being used in single- or two-level fusions [14]. By 2007, more than 50% of primary ALIF, 43% of PLIF/transforaminal lumbar interbody fusion (TLIF), and 30% of PLF were reported to use rhBMP-2 [15]. It has been suggested [16] that, at least in part, the documented rapid increase in rhBMP-2 use in spinal surgery was related to the industry-sponsored trials, which reported virtually no

Table 1
Original industry-sponsored or industry-associated author rhBMP-2 clinical studies and reported adverse event rates because of rhBMP-2

Authors	rhBMP-2 Placement	rhBMP-2, n	rhBMP-2 Adverse events (%)	Authors comment regarding rhBMP-2–related observed adverse events in study patients
Boden et al. [2]	Anterior interbody (LT-cage, lumbar, rhBMP-2)	11	0	"There were no adverse events related to the rhBMP-2 treatment"
Boden et al. [3]	Posterolateral (lumbar, ± instrumentation)	20	0	"There were no adverse effects directly related to the rhBMP-2..."
Burkus et al. [5]	Anterior interbody (LT-cage, lumbar, INFUSE)	143*	0	"There were no unanticipated device-related adverse events..."
Burkus et al. [6]	Anterior interbody (bone dowel, lumbar, INFUSE)	[24]‡	0	"There were no unanticipated adverse events related to the use of INFUSE Bone Graft." (2002)
Burkus et al. [39]		79	0	None reported (2005)
Burkus et al. [40]	Anterior interbody (LT-cage, lumbar, INFUSE)	277	0	None reported
Baskin et al. [7]	Anterior interbody (cervical, INFUSE)	18	0	"There were no device-related adverse events"
Haid et al. [8]	Posterior interbody fusion (lumbar, INFUSE)	34	0	"No unanticipated device-related adverse events occurred"
Boakye et al. [41]	Anterior interbody (cervical, INFUSE)	24	0	"Analysis of our results demonstrated the safety and efficacy of this combination of cervical spine fusion therapy.... a 100% fusion rate and nonsignificant morbidity"
Dimar et al. (2009)	Posterolateral (lumbar, INFUSE, pedicle screws)	53	0	None reported
Glassman et al. [42]	Posterolateral (lumbar, AMPLIFY, and pedicle screws)	[148]†	0	None reported
Dimar et al. [10]	Posterolateral (lumbar, AMPLIFY, and pedicle screws)	239	0	"No adverse event that was specifically attributed to the use of rhBMP-2 matrix in the study group was identified"
Dawson et al. [11]	Posterolateral (lumbar, INFUSE, and pedicle screws)	25	0	None reported
Total	All types	780	0	99% CI <0.5% adverse event rate

rhBMP-2, recombinant human bone morphogenetic protein-2; CI, confidence interval.
* Report patients as in Burkus 2003, not included in total rhBMP-2 calculation.
† Possible subgroup of Dimar et al., 2009, not included in total rhBMP-2 calculation.
‡ These patient reported again in Burkus 2005.

complications associated with the use of these powerful biologic products.

In 2002, the United States Food and Drug Administration (FDA) approval was obtained for a single narrow method of spinal fusion: single-level ALIF within specific threaded cages (LT-cage, Medtronic Sofamor Danek, Inc., Memphis, TN, USA). However, over the last 10 years, numerous industry-sponsored articles on rhBMP-2 documented the use for a far wider range of spinal applications. Vaidya [13] summarized the impact of these subsequent publications:

> "We have used it [rhBMP-2] in ways that were not originally approved by the FDA because we felt, if it works so well for one indication; why not try it for others. Many of us read early articles on off label use which showed the results were excellent in the c-spine and in PLIF or TLIF surgery."

Simultaneously, industry-sponsored trials also reported high rates of complications associated with iliac crest bone graft (ICBG) harvesting; the common, practical, and gold standard alternative to rhBMP-2 in most settings. Thus, although complications associated with the rhBMP-2 product were rarely reported, these subsequent publications presented a 40% to 60% morbidity rate with ICBG harvesting [5,8,10].

Beginning in 2006, however, there would be a series of studies detailing serious complications associated with rhBMP-2 use in all settings. Adverse event rates ranged from 20% to 70% in some studies. In June 2008, the FDA issued a Public Health Notification [17] of life-threatening complications associated with rhBMP-2 use:

> "These complications were associated with swelling of neck and throat tissue, which resulted in compression of the airway and/or neurological structures in the neck. Some reports describe difficulty swallowing, breathing or speaking. Severe dysphagia following cervical spine fusion using rhBMP products has also been reported in the literature.... Most complications occurred between 2 and 14 days post-operatively with only a few events occurring prior to day 2. When airway complications occurred, medical intervention was frequently necessary. Treatments needed included respiratory support with intubation, anti-inflammatory medication, tracheotomy and most commonly second surgeries to drain the surgical site [17]."

[26,36]. Roseman et al. [37] have recommended that industry relationships from original publications be clearly presented in systematic reviews or meta-analysis of those studies. Accordingly, these industry sponsorship and author's financial relationships are listed per study in the Supplementary Appendix to provide consistent potential conflict of interest data across a range of studies from different journals.

Statistical analysis

Recommendations of the CONSORT group regarding methods for the reporting of harms associated with clinical trials have been detailed and were followed as the data permitted in this critical review [38]. Statistical analyses of original or comparative data were performed and in most cases conformed to the statistical method used or recommended by the original study authors in their publications (eg, if a one-tailed Fisher test was used in the original study to analyze categorical outcome events, this test was also used in the critical review). Confidence intervals (CIs) were calculated for adverse events in rhBMP-2 and control groups. If there was a compelling methodological reason to use an alternate analysis, these are explained in the text. A set statistical significance for adverse events was not used for reporting harms—after the recommendations of the CONSORT group [38]. Instead for serious or catastrophic events (eg, sterility, neurologic injury, and malignancy) 90% CIs are reported, whereas less serious events (eg, osteolysis without loss of fixation) are reported at a 95% CI. In calculating the maximum estimated adverse event rate from the original peer-reviewed publications, a 99% CI for less than one event in 780 subjects was used. Additionally, the number needed to harm (NNH) was computed to determine the number of patients treated with rhBMP-2 to produce one patient suffering harm because of a specific rhBMP-2–associated adverse event treated (eg, if the risk of a certain adverse event in the treatment group is 10% vs. 0% in the control group, the NNH is 10).

Funding

No funds were received in support of this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.

Systematic review and comparison

The original industry-sponsored trials reported rhBMP-2 use in five primary methods of spinal fusion technique and location. Although there were a number of ancillary publications found with partial data sets, commentaries, and promotional material, there were 10 trials with more complete reporting of an identifiable cohort and outcomes. These were reported in 13 separate articles although some apparent overlap in study subjects remained. The five study areas included (Table 1):

1. Anterior lumbar interbody fusion using the INFUSE Bone Graft preparation (Medtronic Sofamor Danek, Memphis, TN, USA), which is rhBMP-2 on an absorbable collagen sponge within anterior threaded LT cages (Medtronic Sofamor Danek) or threaded bone dowels with or without supplemental posterior fixation [2,5,6,39,40].
2. Posterolateral lumbar fusion using a lower dose rhBMP-2 or INFUSE/carrier preparation (Medtronic Sofamor Danek) and pedicle-screw and rod implant (Medtronic Sofamor Danek) [3,9,11].
3. Posterior lumbar interbody fusion with an INFUSE preparation and two-paired INTER FIX devices (Medtronic Sofamor Danek) [8].
4. Anterior cervical discectomy and interbody fusion using an INFUSE preparation and an anterior cervical plate (ATLANTIS; Medtronic Sofamor Danek) [7,41].
5. A higher dose rhBMP-2 preparation (AMPLIFY; Medtronic Sofamor Danek) with posterolateral lumbar fusion using Cotrel-Dubousset Horizon pedicle screws and rods (Medtronic Sofamor Danek) [10,42].

Disclosures and conflicts of interest

Each of the 10 original rhBMP-2 trials discussed in the following sections were funded in whole or in part by the rhBMP-2 manufacturer, Medtronic, Inc. Consistent with recommendations by Roseman et al. [37] and *The Spine Journal* disclosure policies, the Supplementary Appendix contains the industry sponsorship and financial disclosures for all 13 peer-reviewed articles and as a range of total compensation for all authors of each study [33–35].

As of March 2011, of the 13 original studies, there was one study with no information available regarding the authors financial relationship with the rhBMP-2 manufacturer. Of the remaining 12 studies, the median-known financial association between the authors and Medtronic Inc. was found to be approximately $12,000,000–$16,000,000 per study (range, $560,000–$23,500,000). For all studies reporting on more than 20 patients receiving rhBMP-2, one or more authors were found to have financial associations with the sponsor of more than $1,000,000; for all studies reporting on more than 100 rhBMP-2 patients, one or more authors were found to have financial associations with the sponsor of more $10,000,000. See Supplementary Appendix.

Part 1: use of rhBMP-2 in PLF

Pilot study

Boden et al. [3], 2002, reported the first randomized controlled trial (RCT) of rhBMP-2 for PLF. This was a small

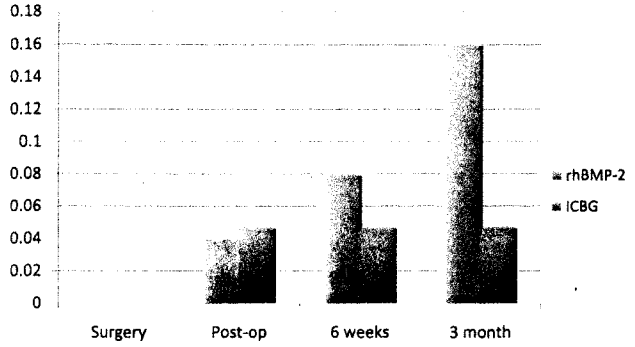


Fig. 2. Early adverse back and leg pain events adverse events (cumulative to the 3 months) after posterolateral fusion using recombinant human bone morphogenetic protein (rhBMP) (INFUSE Bone Graft MASTERCRAFT Granules) compared with iliac crest bone graft (ICBG). Expected outcome of study was less pain in the group without ICBG harvesting, instead paradoxical effect seen of greater back and leg pain morbidity with rhBMP-2 (rhBMP-2 16%, CI: 3.6, 28; ICBG 4.8, CI: −2.9, 12.4; Fisher exact p=.13).

These findings, from more than one RCT, suggest that rhBMP-2 causes equivalent or greater pain and functional impairment than ICBG harvesting in the early postoperative period (strong, Level 1 evidence). This observation was not discussed in any of the published studies despite being evident across multiple RCTs including (and to a larger degree) in the findings of the later higher dose rhBMP-2 study on AMPLIFY [27].

Part 2: use of rhBMP-2 in ALIF

There were five industry-sponsored peer-reviewed publications available on the use of rhBMP-2 in ALIF trials. In the pilot study, Boden et al. [2] reported, "there were no adverse effects directly related to the rhBMP-2..." In 2004, summarizing further industry-sponsored trials of rhBMP-2 use with ALIF, Burkus reported:

> "I have reported the clinical and radiographic results of three different interbody constructs in a single-level, stand-alone ALIF derived from several prospective multicenter studies....There were no adverse events due to rhBMP-2 [47]."

However, careful review of FDA data and subsequent documentation of the largest of these trials suggests osteolysis, subsidence, and adverse neurologic and urologic events were all more commonly seen with rhBMP-2 use.

Osteolysis, subsidence, and reoperation

Smoljanovic and Pecina [48] had noted that abnormal radiographic findings (end-plate resorption, osteolysis, and subsidence) were apparent in the original radiographs (Fig. 3) from the industry-supported RCT publication by Burkus et al. [6] reporting on rhBMP-2 use with bone dowels. That is, the radiograph presented as a model outcome depicts a loss of stability, collapse of the disc space by 50%, and large osteolytic cystic lesions—some extending 50% of the vertebral height. These findings were not commented on/recognized by the authors in the original publication [6]. In a follow-up publication in 2005, Burkus et al. [39] reported on a larger cohort of patients treated with ALIF and bone dowels and again reported no complications, such as end-plate fracture, collapse, and implant migration associated with rhBMP-2 despite the clear radiographic findings in at least the one presented case.

As reported by Burkus in 2004, industry-sponsored trials of ALIF with rhBMP-2 published from 2002 to 2004 found no adverse events associated with its use. However, FDA documents available as early as 2002 had already suggested that some of these findings were evident with those ALIF cases submitted to the FDA during the regulatory evaluation process. The FDA publication "Summary of Safety and Effectiveness Data" [28] concluded the following from the original data:

> "The incidence of adverse events that were considered device related, including implant displacement/loosening, implant malposition and subsidence were all greater in the investigational [rhBMP-2] groups compared to the control group [28]."

This effect was later corroborated in a 2007 nonindustry supported prospective cohort study of rhBMP-2 use in ALIF that found 70% (14 of 20) of levels showed signs of early lucency and more than 10% graft subsidence with a mean collapse of 27% [49]. Another study, this time

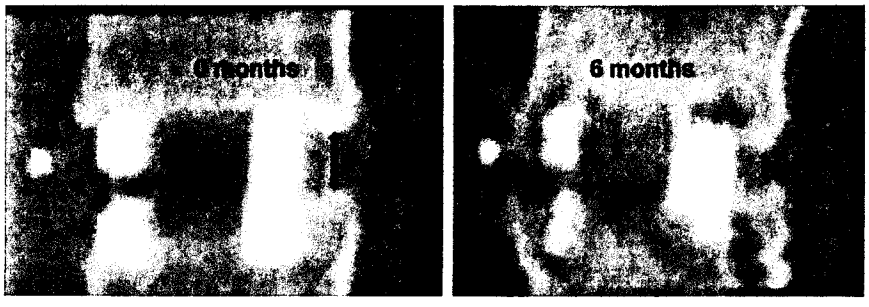


Fig. 3. Computed tomography reconstructions from Burkus et al., showing implant subsidence, disc space collapse (black arrows, 40%), and wide osteolysis (white arrows) with cyst formation extending caudally and around the implanted bone dowel. (From Burkus et al, Spine 2002;27:2396–408, [6], used with permission of publisher; dates and arrows added).

Further, the highest level of evidence from the RCT comparing the open use of rhBMP-2 versus autograft (ie, not laparoscopic), observed higher RE rates in male patients receiving rhBMP-2, 6.4% (5 of 78, 90% CI: 1.9, 11.0) than those receiving ICBG 1.4% (1of 68, 90% CI: −0.9, 3.9; NNH=20, p=.14). In both groups, the approach was retroperitoneal in the large majority of cases; the rate of transperitoneal approach was in fact slightly higher in the control group, which had less RE. That is, the rhBMP-2 group had more RE despite a slightly lower rate of transperitoneal approaches. Unfortunately, this finding was not published until 7 years after the original publications [5,6,40], and 8 years after FDA approval of this rhBMP-2 use in ALIF with the LT-cage [28].

Corroborating the finding of an approximately 6% to 7% rate of RE found with ALIF using rhBMP-2, Jarrett et al. [53] reported a 6.4% RE rate (90% CI: 2.5, 10.2) after anterior lumbar surgery, 98% of which used rhBMP-2. However, in ALIF surgery without rhBMP-2, Kang et al. [54], Sasso et al. 2004 [55], and Sasso et al. 2005 [56] reported an RE rate of less than 1% in nearly 1,000 patients, including those followed by FDA protocols. Similarly, Carragee et al. reported a retrospective cohort-controlled study of RE events after lower lumbar ALIF, using an open retroperitoneal approach by a single surgeon [57]. The findings were nearly identical to the eventually disclosed data of Burkus et al.: a 7.2% (90% CI: 2.1, 12.4) RE rate in the rhBMP-2 ALIF patients (n=69) compared with a 0.6% (90% CI: −0.4, 1.5) rate in non-rhBMP-2 patients (n=174). These findings of Carragee et al. were highly significant statistically, indicating a strong association of rhBMP-2 with RE events (Fisher exact test, p=.0025) with a risk ratio of 12.6 and a calculated NNH of 15 (Fig. 4).

In summary, multiple independent studies have found that the rate of RE in ALIF with rhBMP-2 is approximately 5% to 7% and possibly two to four times higher than the rate observed without rhBMP-2. These findings were consistent across multiple studies and designs, including an RCT [28,52], a cohort controlled trial [57], and large observation cohort with more than 1000 patients [52,54].

Urogenital/bladder retention

Other adverse early urogenital events were also more frequently reported in the rhBMP-2 group after ALIF by FDA Summary of Safety and Effectiveness Data: 7.9% of rhBMP-2 (90%: CI, 5.4–10.6) compared with 3.6% of control subjects (90% CI: 1.0, 6.2) and was statistically significant at p=.04 by chi-square test. Although these adverse events (mainly urinary retention after surgery) were documented in the FDA records as associated with rhBMP-2 (Fig. 5), this finding was not reported by the original study authors in their multiple publications: 2002 [5], 2003 [40], 2004 [47], and 2009 [51].

Infections

A "high" infection rate (39 infections in 35 of 288 rhBMP-2 patients, 12.2%) was reported in the FDA Summary of Safety and Effectiveness in the rhBMP-2 group of the FDA trial [44]. This finding was not reported in any of the publications by Burkus et al. [5,40,47,51].

Food and Drug Administration documents [28] indicate that early infections (less than 6 weeks postoperatively) were equivalent in rhBMP-2 (9.4%) and ICBG (9.4%) groups. However, delayed infections in the first year after surgery were much more common in patients treated with

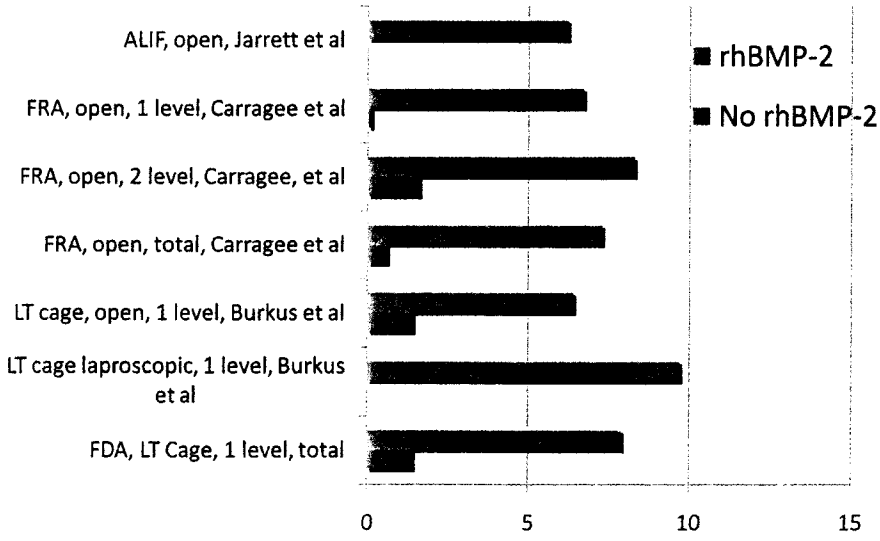


Fig. 4. Comparison of retrograde ejaculation rates (percent) in male patients after anterior interbody lumbar fusion (ALIF) from three studies: ALIF with recombinant human bone morphogenetic protein-2 (rhBMP-2) by Jarrett; femoral ring allograft/rhBMP-2 versus control group (single level and two levels) by Carragee et al., LT-cage/rhBMP-2 versus control (open) group, LT-cage/rhBMP-2 (laparoscopic) group by Burkus et al., and Food and Drug Administration data LT-cage versus control, total cases. See citations in text [28,52,53,57].

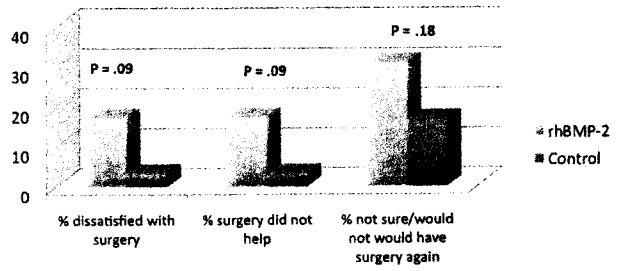


Fig. 6. Patient reported outcomes after posterior lumbar interbody fusion with and without rhBMP-2 from Haid et al. [8]. This industry-supported trial was discontinued with less than 50% enrollment limiting statistical power.

my patient, required two surgeries to clear excessive bone growth from his spinal canal [30]."

This observation was documented in the FDA record years before the Haid et al. study had been published, but these complications were not included in the authors' comments on unanticipated adverse events related to rhBMP-2 in PLIF surgery [8].

It was Dr Malone's opinion expressed to the FDA 2 years before the Haid et al. publication that "BMP may lead to excessive bone growth and may cause significant neural impingement if placed in posterior lumbar interbody type of device." The major adverse events in Dr Malone's patients resulting in reoperation were not included in the Haid et al. article.

Shortly after that Haid et al. publication, when off-label use of rhBMP-2 in PLIF surgery had begun, Wong et al. [61] reported on five patients with ectopic bone formation in the spinal canal after either PLIF or TLIF using rhBMP-2. These patients reported neurological complaints, and three patients underwent an extensive and "difficult" revision surgery [61]. Since then, more reports of serious adverse events associated with rhBMP-2 use in this setting have followed.

Radiculitis, osteolysis, and loss of alignment after PLIF using rhBMP-2

Adverse events associated with rhBMP-2 in PLIF or TLIF are now commonly recognized and are reported to occur in most patients, including osteolysis and end-plate resorption, increased rates of radiculitis or root injury, cage displacement, subsidence, wound infection, ectopic bone formation, and others [49,62–64]. The most common complications—postoperative radiculitis and osteolysis—have been reported to occur in between 20% and 70% of cases. Others have reported higher rates of subsidence when rhBMP-2 is used compared with other graft methods [49].

Recent close follow-up of the osteolytic defects associated with rhBMP-2 has shown that these findings are common and may result in massive bone loss and relative kyphosis because of collapse (see figures in Hegleson et al. [65] and Knox et al. [66]). Importantly, these defects have been shown to persist in most patients. Hegleson et al. reported that the incidence at 3 to 6 months was 56%; and 76% of these failed to resolve at long-term follow-up [57]. Subsidence of the anterior cage results in a loss of lordosis and relative flat back [66]; a problem associated with poorer outcomes and accelerated superior segment degeneration. At present, several investigators are exploring strategies to limit these complications of the use of rhBMP-2 in PLIF and TLIF approaches. Alternative technical methods (including atraumatic end-plate preparation, applying a sealant to the anulotomy site, and varying the dosage of rhBMP-2) have been suggested [51,54,57,58]; but none, thus far, has proven to be fully successful.

These frequent adverse events might help explain the finding in the original Haid et al. study that more patients in the rhBMP-2 group felt the surgery had not helped and were dissatisfied with the surgery (see Fig. 6).

Part 4: use of rhBMP-2 in anterior cervical interbody fusion

An initial small industry-sponsored RCT of rhBMP-2 in the cervical spine reported no adverse events and, specifically, none associated with the use of rhBMP-2 [58] (Table 4). Boakye et al. in 2005 similarly reported no swelling or wound complications, no reoperations, and no readmissions [41]. Some authors have stated that it was these reported findings coupled with the "perfect" [16] reports from use in other locations that led to more common use

Table 4
Late recognition and reporting of complications associated with rhBMP-2 use in the cervical spine

	Baskin et al. [7]	Boakye et al. [41]	Smucker et al. [70]	Tumialán and Rodts [71]
Patient number (n)	18	24	69	176
Dose per level	0.6 mg	2.1 mg	1.5 mg/ml	0.7–1.05
Dysphagia, n (%)	0	2 (11)	5 (7.2) "severe"	12 (7)
Required PEG placement, n (%)	0	0	1 (1.5)	4 (2)
Readmission, n (%)	0	0	2 (3)	3 (2)
Wound complication, n (%)	0	0	3 (4)	5 (3)
Early reoperation, n (%)	0	0	5 (7)	4 (2)

rhBMP-2, recombinant human bone morphogenetic protein-2; PEG, percutaneous endoscopic gastrostomy.

Although life-threatening events associated with rhBMP-2 use have been reported by the FDA, a precise estimate of excess mortality is not currently available to the public.

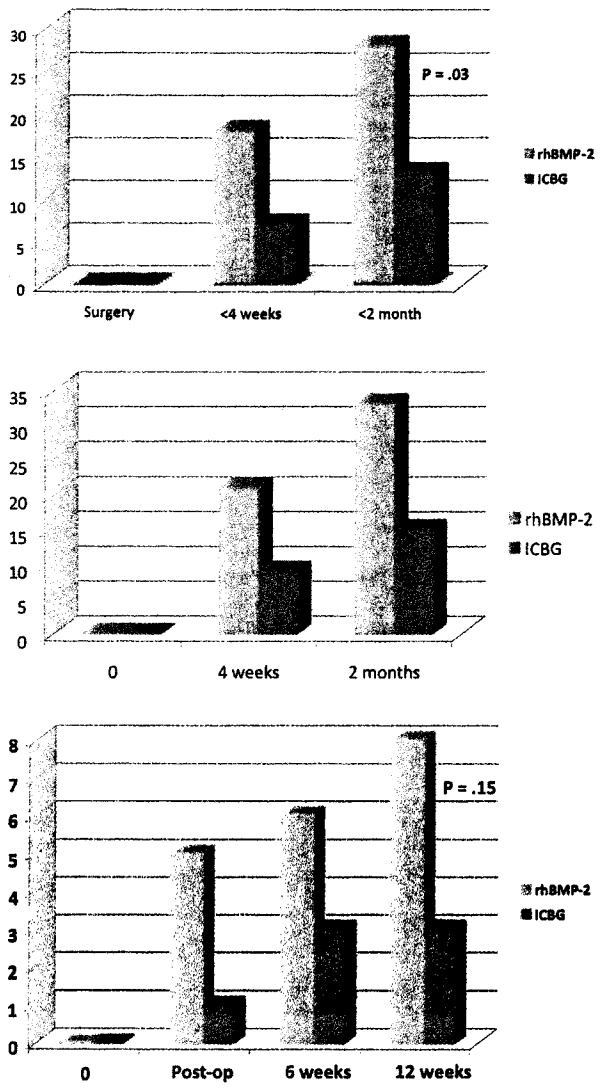


Fig. 7. Cumulative early postoperative complications: (Top) Adverse back and leg pain events in the AMPLIFY trial showing a significantly greater increase in major adverse back and leg pain events in patients receiving and not receiving the rhBMP-2 preparation. (p Values, chi-square test, two tail). (Middle) Combined back/leg pain events and arthritis/bursitis events. (Bottom) Serious back and leg pain events in each group.

Although the increased incidence of cancer was a serious enough observation to concern both the FDA and other groups [74,75], the company spokespersons stated that there is "no plausible biological mechanism for cancer induction" caused by rhBMP-2 [76]. However, the basic biology of growth factor signaling in carcinogenesis suggests that categorical denial is not supportable. A theoretical concern regarding malignancy risk with rhBMP-2 was clear when human trials began [4]. In March 2011, the *Wall Street Journal* reported that Medtronic received a "nonapprovable letter" from the FDA for the spine device known as Amplify, "amid outside concerns regarding whether an ingredient used in the product might be linked to cancer" [77].

Part 6: possible study design biases against the control groups

The study designs were examined to consider the possibility of design bias suggested by the media and other observers [23,24,46,78]. We considered whether the choice of fusion technique and ICBG morbidity assessment used in the control groups might have impacted the apparent competitiveness of rhBMP-2 fusion.

Control group technique in the PLF group

The biology of fusion promotion by rhBMP-2 and ICBG is inherently different. The rhBMP-2 product is known to work through bone induction in a variety of tissues and can be anticipated to perform well in a muscle bed, as would be the case of lateral intertransverse process fusion. In contrast, ICBG or other autogenous bone graft acts best locally, where the graft can be contained and packed, to bridge short distances between viable bones, such as a facet fusion. The basic techniques of posterolateral fusion [79,80] and posterolateral fusion with transpedicular fixation [81–83] as originally described include meticulous decortication of the bone surfaces and preparation of the facets. Curettage of the facets, removal of articular cartilage, and impaction of bone graft into the decorticated facet joint are fundamental parts of posterolateral fusion using autologous bone [83], although it may be less important with a primarily osteoinductive agent such as rhBMP-2.

The randomized trials comparing rhBMP-2 with ICBG in posterolateral fusion did not include facet preparation as part of the required surgical protocol but, instead, focused on the intertransverse process fusion. Specifically, the study authors indicate, "fusion of the facet joint was not specifically required by the protocol" [84]. Similarly, when evaluating the fusion radiologically, "the facet joints were not specifically evaluated for the presence of fusion" [84]. As a result, the study design may have biased the clinical outcomes against the ICBG group.

Similarly, the reported rate of radiographic fusion was based on "the presence of bilateral, continuous trabeculated bone connecting the transverse processes." [84] A solid facet fusion alone, often a primary intention of posterolateral fusion when autogenous bone is used, would not be reported as a solid fusion by study protocol.

The study protocols also allowed very small quantities of ICBG to be used as the sole grafting source. The studies indicate that ICBG volumes of as little as 7 cc were used in the control group [10]. At the same time, the local bone graft, which is readily harvested in during the surgery, was discarded. Other studies have shown the volume of local graft available ranges between 10 and 30 cc of bone and in some cases would have been greater than the total ICBG used [85,86]. Discarding local bone graft and failure to prepare facets for arthrodesis are not standard surgical procedures for posterolateral arthrodesis and may have

Estimates of long-term ICBG morbidity

The industry-sponsored trials made various estimates of morbidity in the control groups from the ICBG harvesting procedures for short-segment fusions. The rate of long-term harm was estimated to be 60%, according to the authors' method of assessment [10,84]. This was substantially higher (50–95% higher) than previous estimates [46,89–91]. The industry-sponsored authors' method of assessment ascribed 100% of any ongoing pain in the region of the iliac crest harvesting to be because of the harvesting alone.

Although this was an unusual assumption at the time, given most spine surgeons experience, subsequent studies have indicated that patients, more than 1 year after surgery, do not perceive more pain on the operative side of ICBG harvesting compared with the opposite side, as determined by two independent investigations [92,93]. That is, patients who have undergone posterolateral fusion of the lumbar spinal, commonly have pain around the site of potential ICBG graft harvesting, whether or not this harvesting was actually performed. Moreover, even when harvesting has occurred, patients cannot reliably discriminate which side had the bone graft procedure.

In summary, compared with the industry-sponsored original estimates of long-term ICBG harvesting morbidity, independent and more rigorous estimates appear to be much lower, if any measurable long-term morbidity can be detected at all [46,92,93]. An overestimation of harm in the control groups from the ICBG harvesting might have contributed to a perceived relative benefit of rhBMP-2 in that clinical situation.

Discussion and conclusion

The availability of rhBMP-2, and other bone graft substitutes, in the treatment of some patients with potential or demonstrated compromised fusion capacity can be a great medical advantage, particularly in patients with long or anatomically deficient fusion beds and other special circumstances.

Recent work by Cahill et al. [94] has shown that use of BMP in single-level lumbar fusion may decrease the need for repeat fusion by 1.1% (ie, at least 100 patients need to receive rhBMP-2 to possibly avoid one revision fusion; NNT=100), with an approximately 10% to 14% increase in costs across all patients. Deyo et al. [95] found no decrease at all in lumbar fusion revision rates after BMP use in older patients. Given these marginal benefits in many patients, the risks of using of a highly potent tissue-signaling drug must be carefully weighed against other options.

As described in the Summary of Events Leading to this Review, there had been wide-ranging allegations of possible underreporting of adverse events in this literature, as well as the suggestion that the original published studies lacked critical editorial oversight from the publishing journals. To critically assess those suggestions, we examined the evidence of whether there were any important omissions, discrepancies, or systematic bias in apparent reporting of possible adverse events between the original industry-sponsored peer-reviewed publication and concurrent or subsequent available data sources.

In this systematic review, we critically assessed the conclusions of authors in 13 published studies regarding the clinical safety and relative efficacy of rhBMP-2 in spinal fusion using CONSORT recommendations for assessing study design and adverse event reporting. Four findings from this review appear clear to us:

1. The estimates of rhBMP-2 safety from the original publications underestimated rhBMP-2–related adverse events of the product. In the small pilot studies [2,3,7], there was inadequate numbers to assess safety, but some suggestion of potential harms was seen in at least one study [3]. In the larger trials, there is evidence in each trial that rhBMP-2 complications may be common and may be serious; but in each publication these were unreported.
2. The presence and magnitude of conflicts of interest and the potential for reporting bias were either not reported or were unclear in each of the original industry-sponsored studies. Some of the conflict of interest statements reported appeared to be vague, unintelligible, or were internally inconsistent.
3. The original estimate of ICBG harvesting morbidity was based on invalid assumptions and methodology. This in turn may have exaggerated the benefit or underestimated the morbidity of rhBMP-2 in the clinical situations tested.
4. The control group methods and technique, as selected for both posterior approach methods (PLIF and PLF), were potentially handicapped by significant design bias against the controls.

As a consequence of these factors, the absolute and relative safety of the rhBMP-2 product was difficult or impossible for readers to ascertain from these original publications. The subsequent reporting of additional studies, the review of administrative, government documents, and subsequent follow-up cohort data have given a fundamentally different picture of morbidity associated with rhBMP-2 use in spinal surgery.

In retrospect, several prominent spine researchers were openly skeptical about the validity of the original publications. Inconsistencies in the data and study conclusions were raised by Smoljanovic et al. soon after the industry-sponsored studies were published. Others questioned the perspective and objectivity of the published presentations. Kahanovitz, commenting on the Haid et al. study, wrote, "Unfortunately, the authors of this study appear to have been overwhelmed by their enthusiasm of using recombinant human bone morphogenetic protein type 2 (rhBMP-2)..." Spengler, former Editor-in-Chief of the *Journal of Spinal Disorders*, commented that he doubted "the (Haid et al.)

this, the alpha level should be set higher (eg, 0.1 or 0.2, depending on the seriousness of the event), and CIs computed and shown to reflect that the data are consistent with the possible risk of adverse events. This was not done.

- There was a failure to analyze or report in publication the adverse events occurring during the main pharmacologically active period of the rhBMP-2 drug (weeks). This methodological problem is specifically commented on in the CONSORT recommendation: "Improperly handling or disregarding the relative timing of the events, when timing is an important determinant of the adverse event in question" [38]. Instead investigators followed a cumulative event analysis over years of observation, which is more appropriate to monitor long-term device failure. As a result, increased early adverse events such as urinary retention, radiculitis, and severe back pain episodes occurring during the pharmacologically active period were not reported. The statistical "noise" of random events over years may mask these important and significant complications if considered over an extended follow-up period.

- In those studies for which other data sources have been made available on the same patient sets (either FDA documents or subsequent reporting of follow-up data), serious contradictory findings have emerged. Major complications, additional surgeries, neurologic/urologic injury, and major back/leg pain events were apparently observed but not reported in the original articles. The authors have defended some of this failure to report by citing that their calculated p values did not reflect a 95% or 99% certainty of the effect. However, as described above, in safety assessments, an 80% to 90% confidence of increased risk of cancer or sterility or infections are all clinically significant findings that should have been fully reported in scientific publication.
- By reporting "perfect" of "near perfect" safety, the original studies might have led others to widespread off-label use of the product with some potentially catastrophic outcomes. With a wider range of reports and data available from both independent and industry-sponsored investigations, a revised estimate of adverse events associated with rhBMP-2 use in the spine can be made (Table 7):
  - Posterior lumbar interbody fusion techniques—25% to 50% risk of rhBMP-2–associated adverse events for PLIF techniques including osteolysis, subsidence, graft migration, cyst formation, neuritis, and other events.
  - Anterior lumbar interbody fusion—10% to 15% risk of rhBMP-2–associated adverse events including osteolysis, subsidence, graft migration, cyst formation, neuritis, urinary retention, and RE. This estimate is much higher if a greater requirement for supplemental fixation is included (10% to 15% more).
  - Anterior cervical fusion—40% greater risk of adverse events in the acute postoperative period after rhBMP-2 use including potentially life-threatening complications. Food and Drug Administration warnings regarding increased risks of catastrophic complications already exist. Adverse effects on spinal cord injury recovery is highly suspected but not well quantitated.
  - Posterolateral fusions with the INFUSE product—an equivalent or greater early postoperative risk of morbidity compared with ICBG harvesting for this dosage; 16% to 20% of rhBMP-2 subjects had adverse back and leg pain events, a probable two to threefold increase in the first 3 months after surgery over control subjects; as well as an undetermined increased risk of wound problems and inflammatory cyst formation.
  - Posterolateral fusions with the AMPLIFY product—The high-dose rhBMP-2 preparation in the AMPLIFY product was associated with adverse early back/leg pain and other nonspecific pain events in 14% of subjects, approximately twice as many as control subjects. Similarly, there were twice as many early serious back and leg pain events in the rhBMP-2 group in this period. There remains an unquantified increase risk of neuritis, wound problems, and inflammatory cyst formation. Most importantly, there was a greater rate of new malignancy occurrence in the AMPLIFY-exposed subjects, approximately 90% to 95% probability of this being a true effect.

In conclusion, it is important to consider that identification of problems during the early industry-sponsored lumbar trials may have averted (or at least raised concerns about) complications before significant morbidity and mortality were eventually seen with widespread use. As it was, the presentation of rhBMP-2 morbidity in the original industry-sponsored publications did not fully reflect the data available from those trials as reviewed in FDA documents and subsequent clinical reports.

Instead, we have found that trial design, particularly in the posterolateral fusion and PLIF trials, may have handicapped the control groups with unnecessary early morbidity and long-term clinical failure. Conversely, the reported extremely high-ICBG morbidity estimates in these studies were not determined with validated methods. Finally, retrospective review of complications and adverse events as reported in FDA and other documents suggests the true risk to patients receiving rhBMP-2 is conservatively 10 to 50 times the original estimates calculated from industry-sponsored publications.

Table 7 (*continued*)

Application	Industry-sponsored original assessment of rhBMP-2–associated adverse events	FDA data and subsequent publication assessment of rhBMP-2–associated adverse events
		hospitalization alone. (Level of evidence 2: analysis of large administrative database; multiple small prospective observational studies) Prolonged dysphagia requiring tube feeding: 2% of patients even at low-dose formulation: (Level of evidences 3–4, multiple observational studies, one comparative cohort study, large administrative database) End-plate resorption, subsidence and loss of alignment: >50% of patients treated with rhBMP-2 (Level of evidence 3) Spinal cord toxicity in the presence of cord injury: high-level animal data only at this point (preclinical data)

rHBMP-2, recombinant human bone morphogenetic protein-2; RCT, randomized controlled trial; ICBG, iliac crest bone graft; FDA, Food and Drug Administration; PLIF, posterior lumbar interbody fusion; ACDF, Anterior cervical discectomy and fusion; ALIF, anterior lumbar interbody fusion.

Supplementary material

Supplementary material can be found in the online version at www.TheSpineJournalOnline.com, and at 10.1016/j.spinee.2011.04.023.

References

[1] Martin GJ, Boden SD, Marone MA, et al. Posterolateral intertransverse process spinal arthrodesis with rhBMP-2 in a nonhuman primate: important lessons learned regarding dose, carrier, and safety. J Spinal Disord 1999;12:179–86.

[2] Boden SD, Zdeblick TA, Sandhu HS, Heim SE. The use of rhBMP-2 in interbody fusion cages. Definitive evidence of osteoinduction in humans: a preliminary report. Spine 2000;25:376–81.

[3] Boden SD, Kang J, Sandhu H, Heller JG. Use of recombinant human bone morphogenetic protein-2 to achieve posterolateral lumbar spine fusion in humans: a prospective, randomized clinical pilot trial: 2002 Volvo Award in clinical studies. Spine 2002;27:2662–73.

[4] Poynton AR, Lane JM. Safety profile for the clinical use of bone morphogenetic proteins in the spine. Spine 2002;27(16 Suppl 1):S40–8.

[5] Burkus JK, Gornet MF, Dickman CA, Zdeblick TA. Anterior lumbar interbody fusion using rhBMP-2 with tapered interbody cages. J Spinal Disord Tech 2002;15:337–49.

[6] Burkus JK, Transfeldt EE, Kitchel SH, et al. Clinical and radiographic outcomes of anterior lumbar interbody fusion using recombinant human bone morphogenetic protein-2. Spine 2002;27:2396–408.

[7] Baskin DS, Ryan P, Sonntag V, et al. A prospective, randomized, controlled cervical fusion study using recombinant human bone morphogenetic protein-2 with the CORNERSTONE-SR allograft ring and the ATLANTIS anterior cervical plate. Spine 2003;28:1219–24; discussion 1225.

[8] Haid RW, Branch CL, Alexander JT, Burkus JK. Posterior lumbar interbody fusion using recombinant human bone morphogenetic protein type 2 with cylindrical interbody cages. Spine J 2004;4:527–38; discussion 538–9.

[9] Dimar JR, Glassman SD, Burkus KJ, Carreon LY. Clinical outcomes and fusion success at 2 years of single-level instrumented posterolateral fusions with recombinant human bone morphogenetic protein-2/compression resistant matrix versus iliac crest bone graft. Spine 2006;31:2534–9; discussion 2540.

[10] Dimar JR, Glassman SD, Burkus JK, et al. Clinical and radiographic analysis of an optimized rhBMP-2 formulation as an autograft replacement in posterolateral lumbar spine arthrodesis. J Bone Joint Surg Am 2009;91:1377–86.

[11] Dawson E, Bae HW, Burkus JK, et al. Recombinant human bone morphogenetic protein-2 on an absorbable collagen sponge with an osteoconductive bulking agent in posterolateral arthrodesis with instrumentation. A prospective randomized trial. J Bone Joint Surg Am 2009;91:1604–13.

[12] Brunton L, Lawrence L, Parker KL. Goodman and Gilman's Manual of Pharmacology and Therpeutics. 12th ed. New York: McGraw Hill Medical, 2008:430–64; 730–53.

[13] Vaidya R. Transforaminal interbody fusion and the "off label" use of recombinant human bone morphogenetic protein-2. Spine J 2009;9:667–9.

[14] Cahill KS, Chi JH, Day A, Claus EB. Prevalence, complications, and hospital charges associated with use of bone-morphogenetic proteins in spinal fusion procedures. JAMA 2009;302:58–66.

[15] Ong KL, Villarraga ML, Lau E, et al. Off-label use of bone morphogenetic proteins in the United States using administrative data. Spine 2010;35:1794–800.

[16] Smoljanovic T, Cimic M, Bojanic I. Aggressive end plate decortication as a cause of osteolysis after rhBMP-2 use in cervical spine interbody fusion. Spine J 2010;10:187–8.

[17] Center for Devices and Radiological Health. Public Health Notifications (Medical devices)—FDA Public Health Notification: life-threatening complications associated with recombinant human bone morphogenetic protein in cervical spine fusion. Available at: http://wwwfda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062000.htm. Accessed March 1, 2011.

[18] Armstrong D, Burton T. Medtronic says device for spine faces probe. Wall Street J. November 19, 2008.

[19] Abelson R. Whistle-Blower suit says device maker generously rewards doctors. The New York Times 2006. Available at: http://www.nytimes.com/2006/01/24/business/24device.html?_r=2. Accessed March 1, 2011.

[20] Kuklo TR, Groth AT, Anderson RC, et al. Recombinant human bone morphogenetic protein-2 for grade III open segmental tibial fractures from combat injuries in Iraq. J Bone Joint Surg Br 2008;90:1068–72.

[21] Scott J. Withdrawal of a paper. J Bone Joint Surg Br 2009;91:285–6.

[22] Armstrong D, Burton T. Medtronic paid the surgeon accused of falsifying study nearly $800,000. Wall Street J. June 18, 2009.

[23] Fauber J. Doctors' financial stake in Medtronic product questioned. Milwaukee J Sentinel. September 5, 2010.

[24] Fauber J. Doctors question journal articles: Medtronic paid surgeons millions for other products. Milwaukee Wisconsin J Sentinel 2010. Available at: http://wwwjsonline.com/watchdog/watchdogreports/112487909.html. Accessed January 23, 2011.

[25] Meier B, Wilson D. Medtronic bone product faces pressure from U.S. The New York Times 2011. Available at: http://wwwnytimes.com/2011/04/12/business/12device.html?_r=1&ref=medtronicinc. Accessed April 22, 2011.

[26] Armstrong D. Medtronic product linked to surgery problems. Wall Street J 2008. Available at: http://wwwmemphisdailynews.com/editorial/Article.aspx?id=38479. Accessed February 18, 2011.

[68] Perri B, Cooper M, Lauryssen C, Anand N. Adverse swelling associated with use of rh-BMP-2 in anterior cervical discectomy and fusion: a case study. Spine J 2007;7:235–9.

[69] Shields LBE, Raque GH, Glassman SD, et al. Adverse effects associated with high-dose recombinant human bone morphogenetic protein-2 use in anterior cervical spine fusion. Spine 2006;31:542–7.

[70] Smucker JD, Rhee JM, Singh K, et al. Increased swelling complications associated with off-label usage of rhBMP-2 in the anterior cervical spine. Spine 2006;31:2813–9.

[71] Tumialán LM, Rodts GE. Adverse swelling associated with use of rh-BMP-2 in anterior cervical discectomy and fusion. Spine J 2007;7:509–10.

[72] Klimo P Jr, Peelle MW. Use of polyetheretherketone spacer and recombinant human bone morphogenetic protein-2 in the cervical spine: a radiographic analysis. Spine J 2009;9:959–66.

[73] Dmitriev AE, Farhang S, Lehman RA, et al. Bone morphogenetic protein-2 used in spinal fusion with spinal cord injury penetrates intrathecally and elicits a functional signaling cascade. Spine J 2010;10:16–25.

[74] Walker E. Not enough evidence to use BMP off-label, panel says. Medpage Today 2010. Available at: http://wwwmedpagetoday.com/PublicHealthPolicy/Medicare/22359. Accessed February 13, 2011.

[75] Dooren JC. Medtronic spine device draws concern. Wall Street J, July 23, 2010. Available at: http://onlinewsj.com/article/SB10001424052748703294904575385271544234334.html. Accessed February 13, 2011.

[76] Richwine L. FDA staff: cancer a concern with Medtronic device. Reuters 2010. Available at: http://wwwreuters.com/article/2010/07/23/us-medtronic-spine-idUSTRE66M2U820100723. Accessed April 22, 2011.

[77] 2nd UPDATE: FDA rejects Medtronic spine device. Wall Street J, March 10, 2011. Available at: http://onlinewsj.com/article/BT-CO-20110310-713347.html. Accessed March 23, 2011.

[78] Smoljanovic T, Bojanic I, Pecina M. The confusion of important literature review. Spine J 2009;9:427–8. author reply 428–9.

[79] Watkins MB. Posterolateral fusion of the lumbar and lumbosacral spine. J Bone Joint Surg Am 1953;35:1014–8.

[80] Watkins MB. Posterolateral bonegrafting for fusion of the lumbar and lumbosacral spine. J Bone Joint Surg Am 1959;41(3):388–96.

[81] Steffee AD, Biscup RS, Sitkowski DJ. Segmental spine plates with pedicle screw fixation. A new internal fixation device for disorders of the lumbar and thoracolumbar spine. Clin Orthop Relat Res 1986;(203):45–53.

[82] Roy-Camille R, Saillant G, Mazel C. Internal fixation of the lumbar spine with pedicle screw plating. Clin Orthop Relat Res 1986;(203):7–17.

[83] Dickman CA, Fessler RG, MacMillan M, Haid RW. Transpedicular screw-rod fixation of the lumbar spine: operative technique and outcome in 104 cases. J Neurosurg 1992;77:860–70.

[84] Dimar JR, Glassman SD, Burkus JK, et al. Two-year fusion and clinical outcomes in 224 patients treated with a single-level instrumented posterolateral fusion with iliac crest bone graft. Spine J 2009;9:880–5.

[85] Carragee EJ, Comer G, Smith MW. Local bone graft harvesting and volumes in posterolateral lumbar fusion: a technical report. Spine J 2011;11:540–4.

[86] Ohtori S, Suzuki M, Koshi T, et al. Single-level instrumented posterolateral fusion of the lumbar spine with a local bone graft versus an iliac crest bone graft: a prospective, randomized study with a 2-year follow-up. Eur Spine J 2011;20:635–9.

[87] Inage K, Ohtori S, Koshi T, et al. Single-, 2-, and 3-Level instrumented posterolateral fusion of the lumbar spine with a local bone graft: a prospective study with a 2-year follow-up. Spine 2011 Jan 10. [Epub ahead of print].

[88] Kim D-H, Jeong S-T, Lee S-S. Posterior lumbar interbody fusion using a unilateral single cage and a local morselized bone graft in the degenerative lumbar spine. Clin Orthop Surg 2009;1:214–21.

[89] Ahlmann E, Patzakis M, Roidis N, et al. Comparison of anterior and posterior iliac crest bone grafts in terms of harvest-site morbidity and functional outcomes. J Bone Joint Surg Am 2002;84:716–20.

[90] Cammisa FP, Lowery G, Garfin SR, et al. Two-year fusion rate equivalency between Grafton DBM gel and autograft in posterolateral spine fusion: a prospective controlled trial employing a side-by-side comparison in the same patient. Spine 2004;29:660–6.

[91] Delawi D, Dhert WJA, Castelein RM, et al. The incidence of donor site pain after bone graft harvesting from the posterior iliac crest may be overestimated: a study on spine fracture patients. Spine 2007;32:1865–8.

[92] Howard JM, Glassman SD, Carreon LY. Posterior iliac crest pain after posterolateral fusion with or without iliac crest graft harvest. Spine J 2011;11:534–7.

[93] Merritt AL, Spinnicke A, Pettigrew K, Alamin TF. Gluteal-sparing approach for posterior iliac crest bone graft: description of a new technique and assessment of morbidity in ninety-two patients after spinal fusion. Spine 2010;35:1396–400.

[94] Cahill KS, Chi JH, Groff MW, et al. Outcomes for single-level lumbar fusion. Spine 2011. [Epub ahead of print].

[95] Deyo RA, Ching A, Matsen L, et al. Use of bone morphogenetic proteins in spinal fusion surgery for older adults with lumbar stenosis. Spine 2011. [Epub ahead of print].

[96] Carreyrou J, McGinty T. Top spine surgeons reap royalties, Medicare bounty. Wall Street J, December 20, 2010. Available at: http://onlinewsj.com/article/SB10001424052748703395204576024023361023138.html?mod=WSJ_business_whatsNews. Accessed January 19, 2011.

CLYDESDALE® Spinal System
510(k) Summary
August 2012

SEP 18 2012

I. COMPANY:

Medtronic Sofamor Danek USA, Inc
1800 Pyramid Place
Memphis, Tennessee 38132

II. CONTACT:

Becky Ronner
Regulatory Affairs Specialist
Telephone: (901) 399-2757
Fax: (901) 346-9738

III. PROPRIETARY TRADE NAME:

CLYDESDALE® Spinal System

IV. CLASSIFICATION NAMES:

Intervertebral Body Fusion Device

COMMON NAME:

Intervertebral Fusion with Bone Graft, Lumbar

CLASS:

II

PRODUCT CODE:

MAX (21 CFR 888.3080)

V. PRODUCT DESCRIPTION:

The CLYDESDALE® Spinal System is intended to help provide support in the intervertebral body space during fusion of vertebral bodies in the lumbar spine. This system is intended to be used with supplemental fixation.

The CLYDESDALE® Spinal System consists of PEEK cages of various widths and heights, which include tantalum markers. These devices can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allow them to be packed with autogenous bone graft.

VI. INDICATIONS FOR USE:

The CLYDESDALE® Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Incorporated
% Ms. Becky Ronner
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

SEP 18 2012

Re: K122591
Trade/Device Name: Clydesdale® Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: August 23, 2012
Received: August 24, 2012

Dear Ms. Ronner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

510(k) Number (if known): K122591

Device Name: CLYDESDALE® Spinal System

Indications for Use:

The CLYDESDALE® Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CLYDESDALE® Spinal System is used for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a minimally invasive lateral approach.

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122591

CAPSTONE® Spinal System
510(k) Summary – K082342
September 2008

I. **Company:** **Medtronic Sofamor Danek**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

SEP 1 2 2008

Contact: **Chris McKee**
Sr. Regulatory Affairs Specialist

II. **Proprietary Trade Name: CAPSTONE® Spinal System**

III. **Classification Name: Intervertebral Body Fusion Device (21 CFR 888.3080)**

IV. **Product Code: MAX**

V. **Product Description**

The CAPSTONE® Spinal System consists of PEEK cages and titanium alloy cages of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft.

VI. **Indications**

The CAPSTONE® Spinal System is indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

VII. **Substantial Equivalence**

Documentation, including mechanical test result, was provided which demonstrated that the subject CAPSTONE® Spinal System devices are substantially equivalent to the predicate CAPSTONE® Spinal System devices (K073291 SE 04/24/08) as well as the VERTE-STACK® Spinal System (K043566 SE 01/07/05, K043561 SE 12/29/04).

510(k) Number (if known): K082342

Device Name: CAPSTONE® Spinal System

Indications for Use:

The CAPSTONE® Spinal System is indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

Prescription Use ___x__ OR Over-The-Counter Use _____

Per 21 CFR 801.109

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous K082342

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K082342

INFUSE® Bone Graft

Medtronic

Back

BRIEF SUMMARY OF INDICATIONS, CONTRAINDICATIONS, AND WARNINGS FOR.
INFUSE® BONE GRAFT/LT-CAGE® LUMBAR TAPERED FUSION DEVICE
INFUSE® BONE GRAFT/INTER FIX™ THREADED FUSION DEVICE
INFUSE® BONE GRAFT/INTER FIX™ RP THREADED FUSION DEVICE

The INFUSE® Bone Graft/Medtronic Titanium Threaded Interbody Fusion Device is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L_2-S_1, who may also have up to Grade I spondylolisthesis or Grade 1 retrolisthesis at the involved level. The INFUSE® Bone Graft/LT-CAGE® Lumbar Tapered Fusion Device is to be implanted via an anterior open or an anterior laparoscopic approach. INFUSE® Bone Graft with either the INTER FIX™ or INTER FIX™ RP Threaded Fusion Device is to be implanted via an anterior open approach.

The INFUSE® Bone Graft/Medtronic Titanium Threaded Interbody Fusion Device consists of two components containing three parts– a metallic spinal fusion cage, a recombinant human bone morphogenetic protein and a carrier/scaffold for the bone morphogenetic protein and resulting bone. **These components must be used as a system for the prescribed indication described above. The bone morphogenetic protein solution component must not be used without the carrier/scaffold component or with a carrier/scaffold component different from the one described in this document. The INFUSE® Bone Graft component must not be used without the Medtronic Titanium Threaded Interbody Fusion Device component.**

NOTE: The INTER FIX™ Threaded Fusion Device and the INTER FIX™ RP Threaded Fusion Device may be used together to treat a spinal level LT-CAGE® Lumbar Tapered Fusion Device implants are not to be used in conjunction with either the INTER FIX™ or INTER FIX™ RP implants to treat a spinal level.

The INFUSE® Bone Graft/Medtronic Titanium Threaded Interbody Fusion Device is contraindicated for patients with a known hypersensitivity to recombinant human Bone Morphogenetic Protein-2, bovine Type I collagen or to other components of the formulation and should not be used in the vicinity of a resected or extant tumor; in patients with any active malignancy or patients undergoing treatment for a malignancy; in patients who are skeletally immature; in pregnant women; or in patients with an active infection at the operative site or with an allergy to titanium or titanium alloy.

There are no adequate and well-controlled studies in human pregnant women. In an experimental rabbit study, rhBMP-2 has been shown to elicit antibodies that are capable of crossing the placenta. Women of child bearing potential should be warned by their surgeon of potential risk to a fetus and informed of other possible orthopedic treatments. The safety and effectiveness of this device has not been established in nursing mothers. Women of child-bearing potential should be advised to not become pregnant for one year following treatment with this device.

Please see the package insert for the complete list of indications, warnings, precautions, adverse events, clinical results, definition of DDD, and other important medical information. The package insert also matches the sizes of those sized devices that are indicated for use with the appropriate INFUSE® Bone Graft kit.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training or experience.

Medical Devices

FDA Public Health Notification: Life-threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion

Issued: July 1, 2008

Dear Healthcare Practitioner:

This is to alert you to reports of life-threatening complications associated with recombinant human Bone Morphogenetic Protein (rhBMP) when used in the cervical spine. **Note that the safety and effectiveness of rhBMP in the cervical spine have not been demonstrated and these products are not approved by FDA for this use.**

The following information provides the adverse events reported to the FDA, the risks associated with the use of rhBMP products in the cervical spine, recommendations for mitigating those risks and the current regulatory status of rhBMP products in the U.S.

Public health concerns: Adverse events and risks to health

FDA has received at least 38 reports of complications during the last 4 years with the use of rhBMP in cervical spine fusion. These complications were associated with swelling of neck and throat tissue, which resulted in compression of the airway and/or neurological structures in the neck. Some reports describe difficulty swallowing, breathing or speaking. Severe dysphagia following cervical spine fusion using rhBMP products has also been reported in the literature.

Anatomical proximity of the cervical spine to airway structures in the body has contributed to the seriousness of the events reported and the need for emergency medical intervention. The mechanism of action is unknown, and characteristics of patients at increased risk have not been identified.

Most complications occurred between 2 and 14 days post-operatively with only a few events occurring prior to day 2. When airway complications occurred, medical intervention was frequently necessary. Treatments needed included respiratory support with intubation, anti-inflammatory medication, tracheotomy and most commonly second surgeries to drain the surgical site.

Mitigating the risks

Since the safety and effectiveness of rhBMP for treatment of cervical spine conditions has not been demonstrated, and in light of the serious adverse events described above, **FDA recommends that practitioners either use approved alternative treatments or consider enrolling as investigators in approved clinical studies.**

Patients treated with rhBMP in the cervical spine should know:

- the signs and symptoms of airway complications, including difficulty breathing or swallowing, or swelling of the neck, tongue, mouth, throat and shoulders or upper chest area
- that they need to seek medical attention immediately at the first sign of an airway complication
- that they need to be especially watchful 2 -14 days after the procedure when airway complications are more likely to occur

Regulatory Status of rhBMP

FDA has approved the use of two rhBMPs for well-defined medical conditions in limited patient populations:

- rhBMP-2 (contained in InFuse Bone Graft) has received premarket approval for fusion of the lumbar spine in skeletally mature patients with degenerative disc disease (DDD) at one level from L_2-S_1 and for healing of acute, open tibial shaft fractures stabilized with an IM nail and treated within 14 days of the initial injury. rhBMP-2 is also approved for certain oral and maxillofacial uses.
- rhBMP-7 (referred to as OP-1 and contained in OP-1 Implant and OP-1 Putty) has received humanitarian device exemption approval as an alternative to autograft in recalcitrant long bone nonunions where use of autograft is unfeasible and alternative treatments have failed. It is also approved as an alternative to

INFUSE® BONE GRAFT/LT-CAGE® Device

Medtronic

Home About INFUSE® Bone Graft Clinical Research Am I A Candidate?

Now in Smaller Sizes!

Product Information

INFUSE® Bone Graft

Important Safety Information

Reimbursement Center

News and Articles

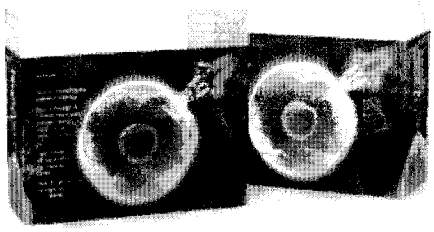
Your Path to Treatment

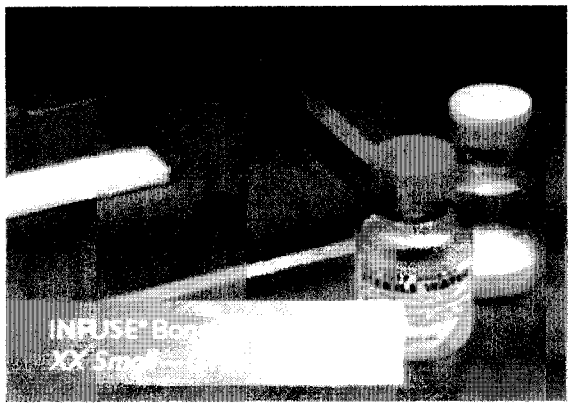
Treatment Options

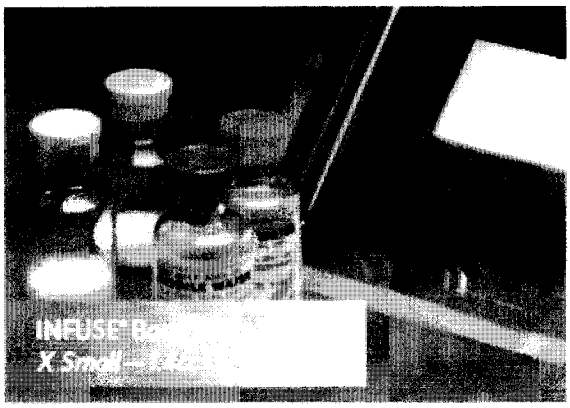
Anatomy

FAQs

Patient Stories







Kit Configurations

	Description	Item #	Dual Chamber	rhBMP-2	Volume of Collagen Sponge (Hydrated Dimensions)
NEW SIZE!	INFUSE Bone Graft – XX Small	7510050	0.7cc	1.05mg	One (1) ½" × 2" Sponge
	INFUSE Bone Graft – X Small	7510100	1.4cc	2.10mg	One (1) 1" × 2" Sponge
	INFUSE Bone Graft – Small	7510200	2.8cc	4.2mg	Two (2) 1" × 2" Sponges
	INFUSE Bone Graft – Medium	7510400	5.6cc	8.4mg	Four (4) 1" × 2" Sponges
	INFUSE Bone Graft – Large	7510600	8.0cc	12.0mg	Six (6) 1" × 2" Sponges
	INFUSE Bone Graft – Large II	7510800	8.0cc	12.0mg	One (1) 3" × 4" Sponge

For more information please call (800) 876-3133

Important Safety Information for Oral Maxillofacial Indications

Printed on [illegible]

Updated [illegible]

Visit our Websites:
Back.com iScoliosis.com MatureSpine.com NeckSurgery.com

MICHELSON TECHNOLOGY AT WORK

A W Jones

From: Sandra Chavez [SChavez@dallasneuro.com]
Sent: Wednesday, September 26, 2012 11:50 AM
To: awj
Subject: RE: Post-surgery Complications

Mrs. Jones,

Dr. Denning dictated his response to me, and yes he did use INFUSE in your spine surgeries. As you have requested a letter will be mailed to you with Dr. Denning signature
please allow 2-3 days for all records to arrive.

Thanks,
SC

From: awj [mailto:[redacted]]
Sent: Wednesday, September 26, 2012 10:31 AM
To: Sandra Chavez
Subject: RE: Post-surgery Complications

Hi Sandra –

Thanks for the reply. I am somewhat confused. Did Dr. Denning himself dictate the response? It does not quite sound like him, and appears to be a general statement, not specifically about me. Is the response confirmation that Dr. Denning used INFUSE in my spine surgeries?

Please ask Dr. Denning to sign and mail a copy of his response to me. Thanks.

Kathryn Marie Jones

From: Sandra Chavez [mailto:SChavez@dallasneuro.com]
Sent: Wednesday, September 26, 2012 8:04 AM
To: A W Jones
Subject: RE: Post-surgery Complications

Mrs. Jones,

See below for Dr. Denning's response.

We have use INFUSE in all of our fusions for 6 years and continue to use this technology if insurance carriers cover it, because it has worked and studies have proven its effectiveness.
We place it only inside cages or spacers, where it is contained and never in the anterior cervical area. It is not exposed to nerves in any of our surgeries, We have never seen any serious complications from its use, specifically no bladder/urinary complications.
The alternative to INFUSE is to take bone from the hip, which we haven't done for years because of the chronic pain it can cause afterward and because the studies that were done showed INFUSE to be as effective. The other option is to use donor or cadaver bone which does not heal as well and can be rejected by the body.

SC

From: A W Jones [mailto:[redacted]]
Sent: Tuesday, September 25, 2012 12:34 PM

Progress Notes (continued)

Vitals (last recorded):
Temp: 98.1 °F (36.7 °C) Pulse: 89 Resp: 19 BP: 120/70 mmHg SpO2: 98 % Weight: 62 kg (136 lb 11 oz)
Temp (24hrs), Avg:99.9 °F (37.7 °C), Min:98.1 °F (36.7 °C), Max:100.6 °F (38.1 °C)

Intake/Output Summary (Last 24 hours) at 10/29/10 0753
Last data filed at 10/29/10 0530

	Gross per 24 hour
Intake	1774.5 ml
Output	1365 ml
Net	409.5 ml

Labs (last 24 hours)
Results for orders placed during the hospital encounter of 10/26/10 (from the past 24 hour(s))

POTASSIUM, BLOOD

Collection Time	*10/28/10 7:38 PM*
Component	Value
• Potassium	3.6

MAGNESIUM

Collection Time	*10/28/10 7:38 PM*
Component	Value
• Magnesium	1.7

BASIC METABOLIC PANEL

Collection Time	*10/29/10 3:45 AM*
Component	Value
• Calcium	8.4
• Glucose	120 (*)
• BUN	10
• Creatinine	0.57
• Sodium	133 (*)
• Potassium	3.4 (*)
• Chloride	95 (*)
• CO2	31
• AGap	7
• BUN/Creat Ratio	17.5
• Osmolality calc	276 (*)

MAGNESIUM

Collection Time	*10/29/10 3:45 AM*
Component	Value
• Magnesium	1.8

Subjective: POD # 3. Lying flat in bed. Was uncomfortable in bed during the night and required multiple repositioning. Pain controlled on Morphine drip. Persistent nausea, but no vomiting. C/O spitting up thin phlegm. Denies chest pain/SOB/abd pain/visual problems. Was out of bed briefly yesterday and tolerated fair with some increase in pain. Nurse reports patient had episode of atrial fib/flutter during the night.

Objective: NAD, VSS
Heart: Atrial flutter per monitor this am

Progress Notes (continued)

Lungs: Respirations even and unlabored
Abdomen: Soft and nontender to palpation
Extremities: SCDs on LE, no edema noted
Neuro: Alert and oriented x 3. Speech clear and fluent. Comprehension good. Memory intact both recent and remote. PERRL, EOMI, no nystagmus noted. MAE with good strength. Sensation intact. Cranial nerves II-XII grossly intact.
Incision: Left flank dressing intact with minimal drainage noted. JP and marcaine pump in place. Drainage 15 mL. Lumbar dressings clean and dry.

Assessment/Plan: Making progress after ant/post spinal reconstruction T12-S1.
1. Will DC morphine drip, MS Contin
2. Continue mobilization
3. IS every 2 hours
4. Atrial fib/flutter reported. Per Dr. Williams
5. Transfer to floor soon if okay with Dr. Williams/Kirby

Tina Coleman, ACNP 10/29/2010 7:53 AM

Coleman, Tina Ford, ACNP

Progress Notes signed by Kirby, Randall Parker, MD at 10/29/10 1127

Author:	Kirby, Randall Parker, MD	Specialty:	Surgery / Vascular Surgery.	Author Type:	Physician
Filed:	10/29/10 1127	Note Time:	10/29/10 1127		

Vascular/General Surgery
POD#3
Drain, On-Q pulled
RPK

Kirby, Randall Parker, MD

Progress Notes signed by Denning, Jeremy Wayne, MD at 10/29/10 1226

Author:	Denning, Jeremy Wayne, MD	Specialty:	Neurological Surgery.	Author Type:	Physician
Filed:	10/29/10 1226	Note Time:	10/29/10 1222		

She is doing well; got up to chair already
Tm100.6 vss
Labs reviewed
Awake and alert
No significant pain complaints
Lying flat in bed
Moves all ext's with normal strength,sensation
scd's on and no leg swelling, redness, pain
Wounds cdi

A/p
Making good progress after major spinal surgery
Appreciate Dr. Williams following her medically
Talked to blood bank and they do not recommend transfusing her auto-donated blood back (last hgb 11.6)
Continue to mobilize/PT
To floor later today

Progress Notes (continued)

Denning, Jeremy Wayne, MD

Progress Notes signed by Gunn, Kimberly, RN at 10/29/10 1520

Author:	Gunn, Kimberly, RN	Specialty:		Author Type:	Registered Nurse
Filed:	10/29/10 1520	Note Time:	10/29/10 0853		
Related Notes:	Original Note by: Gunn, Kimberly, RN filed at 10/29/10 1450				

0730am assessment done Mae to commandPt states she feels comfortable Feet warm pulses present. HOB up 30 tolerating well
0845 Dr williams notified Heart Rhythm Rate 80-110 irregular.
0850 husband in room
1000 seems to be comfortable Tolerated up in chair 20min with brace on Back to bed Husband combing pt hair wearing gloves in room and picking up hair from Bed
1330 pt given tomato soup Husband states there was hair in soup long grey dark hair Nurse looked at soup did not see hair. Nutrion manager notified reordered soup here at 1400 pt eating soup. Frank notified to see pt.
Report called to room 314 sealed room.1500 to room on bed husband at bedside call bell in reach low postion instructed on use.neuros intact mae to command feet warm

Gunn, Kimberly, RN

Gunn, Kimberly, RN

10/29/10 1450 Progress Notes addendum by Gunn, Kimberly, RN

Progress Notes signed by Shipman, Kristin Michelle at 10/29/10 1529

Author:	Shipman, Kristin Michelle	Specialty:		Author Type:	Dietitian
Filed:	10/29/10 1529	Note Time:	10/29/10 1525		

Nutrition Note

Nutrition Services is following. I spoke with the patient yesterday and provided her with my card. Menus have been created for the weekend that are compliant with a <1000 mg Na diet as well as her allergies to corn, shellfish and peanuts. She will not receive menus as even our 2g Na diet is not low enough in sodium for this patient. For any concerns over the weekend please call the kitchen or page the on- call Dietitian 214-759-1856.

Kristin Shipman, MPH, RD, LD

Shipman, Kristin Michelle

Progress Notes signed by Amelunxen, Franchesca Carolina, RN at 10/29/10 1834

Author:	Amelunxen, Franchesca Carolina, RN	Specialty:		Author Type:	Registered Nurse
Filed:	10/29/10 1834	Note Time:	10/29/10 1530		

Patient arrived from 2icu in bed. Alert, states pain 5/10. Has many questions regarding med regiman, explained will attempt to keep her on same shedule, i.e compazine as close as possible with her scheduled po morphine. Husband at bedside. Call light in reach.

TEXAS HEALTH DALLAS

JONES,KATHRYN MARIE
MRN: 1467727
Acct #: 4603201796
Adm: 10/26/2010, D/C:

Transcription

Type	ID	Present Time	Author
Consults	D01297588 4-1	10/29/2010 4:32 PM	Williams, Phillip Earle III, MD

Authenticated by Williams, Phillip Earle III, MD on 11/01/10 at 1037
This document replaces document D012975884

Document Text

CONSULTATION

PATIENT: JONES, KATHRYN
DATE OF BIRTH: [redacted]/1950
ACCOUNT: 4603201796
MRN: 1467727
ADMISSION: 10/26/2010
DISCHARGE:
AUTHOR: PHILLIP E. WILLIAMS, III, MD

CC:
JEREMY W. DENNING, MD, <Admitting>

DATE OF CONSULT

CONSULTING PHYSICIAN:
Phillip E. Williams, III, MD

REFERRING PHYSICIAN:
Jeremy W. Denning, MD

REASON FOR CONSULTATION:
Medical management during her hospital stay.

HISTORY OF PRESENT ILLNESS:
The patient is a very pleasant 60-year-old white female from Arizona who came to our institution for long-standing scoliosis. The patient states that she has had chronic back pain for years, and it has progressively increased over the last several months to where it was unbearable and not well-treated medically as an outpatient or conservatively with physical therapy. The patient decided to undergo corrective surgery.

PAST MEDICAL HISTORY:
The patient does have a past medical history of proximal SVT, hypertension, GERD, Meniere's disease, scoliosis, pernicious anemia, Von Hippel-Lindau disease, asthma, headaches.

PAST SURGICAL HISTORY:
She has had a tubal ligation, D and C, left elbow surgery, lower left lobectomy, right foot surgery. She has had numerous cosmetic surgeries, including face lift, breast reduction, liposuction, and nasal reconstruction.

SOCIAL HISTORY:
She is married. She occasionally uses alcohol. She has never smoked. She denies ever using drugs.

MEDICATIONS:
Medications she takes at home:
1. B12 injections once per month.

2. Vitamin D 400 international units 1 tablet daily.

3. Transdermal estradiol patch daily.

4. Ferrous sulfate 325, 1 tablet p.o. daily.

5. Zantac 75 mg 1 tablet p.o. daily.

6. Vitamin E 400 units 1 tablet p.o. daily.

7. Forecasted 1 mg, 1 tablet p.o. daily.

8. Ascorbic acid 500 mg 1 tablet p.o. daily.

ALLERGIES:
She has multiple allergies:
1. FLUCONAZOLE causes a rash.

2. FENTANYL, severe itching.

3. DILAUDID projectile vomiting.

4. PERCOCET projectile vomiting,

5. DARVOCET, projectile vomiting.

6. TRAMADOL, projectile vomiting,

7. OXYCODONE, projectile vomiting,

8. SHELL FISH, itching.

9. She has a food allergy to PEANUTS that causes shortness of breath.

10. She is allergic to ADHESIVE TAPE, which causes rashes and skin tears.

11. Adverse reactions to AMBIEN.

12. She is allergic to all PPIs.

13. She is allergic to all CEPHALOSPORINS.

REVIEW OF SYSTEMS:
The patient states that her pain is well-controlled. She denies fevers, chills, cough, shortness of breath, chest pain, dizziness, palpitations, or any other problems right now. She states that she does feel a little bloated.

PHYSICAL EXAMINATION:
VITAL SIGNS: Temperature 100.2, blood pressure 128/81. Pulse 100, respiratory rate of 24. She is 98 percent on room air.

GENERAL: She is awake. She is alert, oriented to person, place, time and event. She is a little drowsy but seems to be in no acute distress.

HEENT: PERRL. EOMI. Moist mucous membranes.

NECK: Neck is supple. There is no lymphadenopathy. No JVD. No bruit. She has a right IJ catheter in place. She has no erythema.

CARDIOVASCULAR: Regular rate and rhythm. S1, S2.

CHEST: Clear to auscultation bilaterally.

ABDOMEN: Soft, mildly distended. Positive bowel sounds. It is tympanic to palpation in all 4 quadrants. Nontender. No signs of organomegaly.

EXTREMITIES: No clubbing, cyanosis, or edema.

NEUROLOGIC: Grossly intact.

TEXAS HEALTH DALLAS

JONES,KATHRYN MARIE
MRN: 1467727
Acct #: 4603201796
Adm: 10/26/2010, D/C:

LABORATORY:
WBC is 15.6, hemoglobin 11.6, hematocrit 34.4, MCV of 90.6, platelet count of 274. Sodium 141, potassium 2.9, chloride 99, CO2 31, BUN 10, creatinine 0.6, glucose 148, calcium 8.8, osmolarity 294.

IMPRESSION AND PLAN:
1. The patient is a very pleasant 60-year-old female, status post posterior lumbar fusion by
Dr. Jeremy Denning. The patient is currently stable. She did have a small pneumothorax after a right jugular line was placed. The patient has a history of PSVT, hypertension, gastroesophageal reflux disease, Meniere's disease, pernicious anemia, Von Hippel-Lindau disease. The patient's pain is well-controlled. Repeat chest x-ray shows expansion of a small pneumothorax. Will continue oxygen therapy. She is currently on telemetry and we will watch her closely.

2. White count is a little high. It could be secondary to atelectasis. She is currently on Levaquin. There is no evidence of an infection.

3. Will resume her home medications. She has been told it is okay for her to take her Zantac, as it is not formulary here at the hospital.

4. Thank you for this consultation. I will be happy to follow the patient daily while she was in the hospital.

PHILLIP E. WILLIAMS, III, MD

PEW:nt
D: 10/29/2010 16:32:27
T: 10/29/2010 21:05:49
JOB: 14885836 / 236297

Transcription CC Recipients

Recipient	Type
PHD CC POOL	Pool

A2450

HOME HEALTH CERTIFICATION AND PLAN OF CARE

1.Patient's HI Claim No.	2.Start Of Care Date	3.Certification Period	4.Medical Record No.	5.CCN
W15[redacted]	111510	From: 111510 To: 011311	00020379-00008769	HH9753

6.Patient's Name and Address

JONES, KATHRYN
HYATT - DALLAS PARK CENTRAL
12411 N. CENTRAL EXPWAY
DALLAS, TX 75243
972 458 1224

7.Provider's Name, Address and Telephone Number

Texas Health Presbyterian Home Care
8140 WALNUT HILL LANE
SUITE 925
DALLAS, TX 75231
214 345 4663

8.Date of Birth 030150 | 9.Sex M X F

10. Medications: Dose/Frequency/Route (N)ew (C)hanged

ZANTAC 75 75 mg TABLET
1 tab ORAL 2 times daily

BENADRYL 25 mg CAPSULE
1 cap ORAL Daily

DYAZIDE 37.5 mg-25 mg CAPSULE
1 cap ORAL Daily
(See Addendum)

11.ICD-9-CM V571	Principal Diagnosis PHYSICAL THERAPY NEC	Date 111510	O
12.ICD-9-CM	Surgical Procedure (See Addendum)	Date	
13.ICD-9-CM V5878	Other Pertinent Diagnoses SURG AFTERCARE-MS SY	Date 111510	O
7812	ABNORMALITY OF GAIT	102610	E
2810	PERNICIOUS ANEMIA (See Addendum)	010105	O

14.DME and Supplies:

Has - Single point cane Has -(See Addendum)

15.Safety Measures:

1 - Establish emergency plan 2 -(See Addendum)

16.Nutritional Req.: Regular

17.Allergies: HYDROMORPHONE(See Addendum)

18.A. Functional Limitations

1	Amputation	5	Paralysis	9	Legally Blind		
2	Bowel/Bladder (Incontinence)	6	X Endurance	A	Dyspnea With Minimal Exertion		
3	Contracture	7	X Ambulation				
4	Hearing	8	Speech	B	X Other (Specify) POST(See Addendum)		

18.B. Activities Permitted

1	Complete Bedrest	6	Partial Weight Bearing	A	Wheelchair
2	Bedrest BRP	7	Independent At Home	B	X Walker
3	X Up As Tolerated	8	Crutches	C	No Restrictions
4	Transfer Bed/Chair	9	Cane	D	Other (Specify)
5	X Exercises Prescribed				

19.Mental Status:	1	X Oriented	3	Forgetful	5	Disoriented	7	Agitated
	2	Comatose	4	Depressed	6	Lethargic	8	Other
20.Prognosis:	1	Poor	2	Guarded	3	Fair	4 X	Good 5 Excellent

21.Orders for Discipline and Treatment (Specify Amount/Frequency/Duration)

PT 3 Week 1;2 Week 1

PT
PT ORDERS:
OTHER PHYSICIANS INVOLVED IN PATIENTS CARE ARE RANDALL KIRBY
EVALUATION, HOME SAFETY CHECKOUT, ASSESS HOME EQUIPMENT NEEDS.
ASSESS THE FOLLOWING: VITAL SIGNS, PAIN, INCISION SITE. PERFORM AND INSTRUCT PATIENT/CAREGIVER IN THE FOLLOWING:
THERAPEUTIC EXERCISES, ACTIVE-ASSISTIVE EXERCISES, PROPRIOCEPTIVE NEUROMUSCULAR FACILITATION, ENDURANCE ACTIVITIES,
TRANSFER TRAINING, RESISTIVE EXERCISES, STRETCHING EXERCISES, ACTIVE EXERCISES, BALANCE AND COORDINATION ACTIVITIES,
HEP, PAIN MANAGEMENT, SIGNS AND SYMPTOMS OF DVT, SIGNS AND SYMPTOMS OF INFECTION, SIGNS AND SYMPTOMS OF UTI, PROPER USE
OF ANTICOAGULATION MEDS, SIGNS AND SYMPTOMS RELATED TO ANTICOAGULATION MEDS, CONSTIPATION.
GAIT TRAINING: WITH APPROPRIATE ASSISTIVE DEVICE ON LEVEL SURFACES, UNLEVEL SURFACES, AND SINGLE STEP (AND/OR) STAIRS.
PROGRESSIVE GAIT TRAINING WITH ASSISTIVE DEVICES AS APPROPRIATE. INSTRUCT PATIENT/CAREGIVER IN: JOINT CARE AND
PRECAUTIONS, BED MOBILITY, EDEMA CONTROL, BACK(See Addendum)

FILE COPY

22. Goals/Rehabilitation Potential/Discharge Plans

Goals: (See Addendum)

23. Nurse's Signature and Date of Verbal SOC Where Applicable:

25. Date HHA Received Signed POT

MULRY, RANDALL PT/ MK 111510

24. Physician's Name and Address

DENNING, JEREMY WAYNE MD MD
8230 WALNUT HILL LN
STE 220
DALLAS, TX 75231
214 750 3646

26. I certify/recertify that this patient is confined to his/her home and needs intermittent skilled nursing care, physical therapy and/or speech therapy or continues to need occupational therapy. The patient is under my care, and I have authorized the services on this plan and will periodically review the plan.

27.Attending Physician's Signature and Date Signed

28. Anyone who misrepresents, falsifies, or conceals essential information required for payment of Federal funds may be subject to fine, imprisonment, or civil penalty under applicable Federal Laws.

ADDENDUM TO: X PLAN OF TREATMENT MEDICAL UPDATE

ient's HI Claim	2. Start Of Care	3. Certification Period		4. Medical Record No.	5. CCN
[redacted]	111510	From: 111510	To: 011311	00020379-00008769	HH9753

atient's Name
NES, KATHRYN

7. Provider Name
Texas Health Presbyterian Home Care

Item
o.

10

OXYBUTYNIN CHLORIDE ER 5 mg TAB ER 24
1 tad ORAL Daily

MORPHINE SULFATE 15 mg TABLET (N)
1 tab ORAL Every 12 hours

MORPHINE SULFATE 15 mg TABLET SA (N)
1 tab ORAL 2 times daily as needed; as needed for breakthrough pain

PROCHLORPERAZINE MALEATE 5 mg TABLET (N)
1 tab ORAL 3 times daily

BACTROBAN 2 % OINT.(GM) (N)
topical TOPICAL Daily; for irritated incision and tape burn

12
1. 8105 POSTERIOR DORSAL FUS 102710
2. 8104 ANTERIOR DORSAL FUSI 102610

13
(b) Etiology - 73730
5. 38600 MENIERES DISEASE NO 010107 O
6. 4019 HYPERTENSION NOS 110107 O

14 Wheeled Walker Has - Raised toilet seat Has - Grab bars (toilet/shower/tub) Has - Hand held shower Has - Shower chair

15 Establish fire response plan 3 - Establish emergency disaster plan 4 - Implement a falls prevention program (e.g., remove throw rugs, teach safe use of assist/safety devices) 5 - Teach weight-bearing precautions 7 - Teach appropriate cleaning of equipment 8 - Teach proper/safe use of medications 9 - Teach standard precautions (e.g., handwashing, safe disposal of contaminated sharps and supplies)

17 HCL DARVOCET A500 LANOLIN NEXIUM ZOLPIDEM TARTRATE CEPHALEXIN FENTANYL FLUCONAZOLE TRAMADOL HCL PERCOCET OXYCODONE HCL Adhesives

18A OP BACK RPECAUTIONS

21 CARE AND PRECAUTIONS, RELAXATION TECHNIQUES, FALL PREVENTION, HOME SAFETY, GAIT TRAINING WITH/WITHOUT ASSISTIVE DEVICE, BODY MECHANICS, USE OF HOME EQUIPMENT, POSITIONING/PRESSURE RELIEF, PROPER BREATHING TECHNIQUE. CHECK O2 SATS VIA PULSE OX ON EVALUATION VISIT AND THEN AS NEEDED TO ASSESS EXERCISE/ACTIVITY TOLERANCE. NOTIFY MD IF O2 SAT IS LESS THAN 88%.

22

PT Patient/caregiver will demonstrate knowledge of disease process, treatment goals and self-care management. Patient/caregiver will demonstrate self-management of incision/wound. Patient/caregiver will verbalize adverse signs and symptoms to report. Patient will achieve adequate symptom control through use of medications or other therapies/treatments. Patients reported pain level will decrease to 0 on a 0 to 10 scale. Patient will demonstrate safe mobility and transfers independently. Patient will demonstrate improved standing balance to good.. Patient will ambulate with as normal a gait pattern as possible for a functional distance independently using appropriate assistive device on level surfaces, unlevel surfaces and/or steps. Patient will demonstrate increased activity tolerance. Patient will demonstrate independence with home exercise program. Patient will demonstrate adequate nutrition/hydration status. Patient will remain safe in home environment without injury/falls. Patient will demonstrate safe use of adaptive equipment/assistive devices. Patient will demonstrate increased self-care skills. Patient will verbalize potential consequences of noncompliance with plan of care. Patient will demonstrate compliance with treatment, diet, medication, exercise, other. Patient will verbalize community services available and how to contact them.

Rehab Potential: Good

Discharge Plans:PATIENT/FAMILY TO ASSUME RESPONSIBILITY FOR CARE AFTER DISCHARGE FROM AGEMCY

Discharge summary available upon request

9. Signature of Physician

10. Date

11. Optional Name/Signature of Nurse/Therapist

12. Date

111510

MULRY, RANDALL PT/MK

TEXAS HEALTH PRESBYTERIAN HOME CRE
UNIVERSAL CONSENT FOR TREATMENT

I understand that my health condition requires home health services. I consent to and authorize testing, home health treatment as ordered by my doctor and his/her consultants, associates and assistants. I authorize Texas Health Presbyterian Home Care nurses, employees and others as necessary to carry out the instructions of my doctor(s) with respect to the home health services they have ordered. I understand that photos may be taken if relevant to my care and treatment and will become a part of my medical record.

ACKNOWLEDGEMENT:

1. I understand that the first visit is an evaluation visit to find out if I am eligible for home health services based on admission criteria and does not require Texas Health Presbyterian Home Care to admit me for services.
2. I have received a copy of my rights and responsibilities as a patient including OASIS Privacy Rights, THR Notice of Privacy Practices, personal emergency information and have been informed and received a copy of Texas Health Presbyterian Home Care's home safety measures and policy on reporting abuse, neglect and/or exploitation. I have also been informed of Presbyterian Home Health's grievance procedure.
3. Communicable disease testing. I acknowledge that Texas Law provides if any health care worker is exposed to my blood or other bodily fluid, the agency may perform tests, without my consent, on my blood or other bodily fluid to determine the presence of hepatitis B and C and HIV. I understand that such testing is necessary to protect those who will be caring for me while I am a patient. I understand that the results of tests taken under these circumstances are confidential and do not become a part of my patient record.
4. **I acknowledge that the doctors who ordered home health care for me do not work for Texas Health Presbyterian Home Care. They are not employees, servants or agents of the Hospital.**
5. I understand that Texas Health Presbyterian Home Care is a department of Texas Health Presbyterian Hospital Dallas.

NO GUARANTEE: I acknowledge that no guarantees or warranties have been made to me with respect to treatment to be provided by Texas Health Presbyterian Home Care. I understand that all supplies, medical devices and other goods sold or furnished to me by Texas Health Presbyterian Home Care are sold or furnished on an "AS IS" basis, and Texas Health Presbyterian Home Care and its parent company, Texas Health Resources, do not provide any expressed or implied warranties with respect to them.

If the person signing this form is not the patient, please give full name, phone number and address:

I HAVE READ AND UNDERSTAND THIS INFORMATION:

Signature of Patient or Legally Authorized Representative	Relationship to Patient	Reason Patient Unable to Sign
Witness	Title	Date of Signature

(Continued from page 1)

PATIENT NAME: _____ Last First	I.D. Number:

AGENCY RATES PER VISIT

SN	PT	OT	ST	MSW	AIDE	OTHER

θ **Medicare No.:**	Exact Name On Card:	
Hospital (Part A)/Effective Date:	Medical (Part B)/Effective Date:	[ ] Primary [ ] Photo ID viewed [ ] Secondary [ ] Photo ID not viewed *

- Are you or your spouse still working? [ ] Yes [ ] No
- Is the reason for home care related to an accident or injury? [ ] Yes [ ] No
- If yes, is an insurance co. other than Medicare responsible for payment (e.g. worker's comp, auto insurance)? [ ] Yes [ ] No
- Is the reason for home care related to Federal Black Lung Program or ESRD? [ ] Yes [ ] No
- Are you currently receiving outpatient rehab/therapy services? [ ] Yes [ ] No
- Are you receiving services from another Home health agency? [ ] Yes [ ] No
- Are you receiving services from a hospice agency? [ ] Yes [ ] No

NOTE: If yes to above, contact supervisor immediately.

I understand that I have the right to change home health agencies. I understand that if I am transferring to Presbyterian Home Health from another agency, the other agency can no longer provide Medicare covered services or bill Medicare for services after the date of transfer.

θ **Medicaid No.:**	θ Application Pending:	Effective Date:
Exact name per card:	Copy of Card Viewed [ ] Yes [ ] Not available	*Photo ID Viewed [ ] Yes [ ] Not available

θ PRIVATE HEALTH INSURANCE

Insurance Company:	Insurance Phone #:
Policy Number:	Group Number:
Employer Name:	Insurance Contact:
Policy Holder (If other than patient):	*Photo ID viewed: [ ] Yes [ ] Not available

POLICY BENEFITS

Deductible: $ Lifetime Maximum Benefit: $ Year: _____ to _____

Nursing Visit Maximum: _____ Visits per policy year. Other Visit Maximum: _____ Visits per policy year.

After meeting your deductible, the insurance company will pay _____% of eligible charges until you have met your required "Out-of-Pocket Expense" of $_____. After you have met your required out-of-pocket expenses, insurance will pay eligible charges at _____% until you reach your lifetime maximum benefits.

Be aware that cost of services may vary according to insurance coverage, medical necessity and eligibility.

PATIENT RESPONSIBILITY (other than listed above)

Per Visit $: RN_____ PT_____ OT_____ ST_____ MSW_____ HHA_____

Supplies: $_____ or _____% Per Dose: $_____ Other:_____

If you have further questions, contact our office at (214) 345-4663.

θ PRIVATE PAY

I agree to pay for all services and supplies provided. Payment in full is due upon receipt of invoice unless prior arrangements have been made.

_____ Date

Billing address & phone number

SIGNATURES

_____

Signature of ☐ Patient ☐ Legal Representative ☐ Financially Responsible Party

_____ Date

Staff Signature/Title

***If Photo ID not available, contact a manager**

PRESBYTERIAN HOME HEALTH
RELEASE OF INFORMATION

Patient Name: _____ ID # _____
Last First

RELEASE OF INFORMATION: I consent and authorize Presbyterian Home Health **("Agency")** to release all information contained in my medical and billing records, including diagnoses and test results, to (a) any of my treating practitioners, (b) my insurance company or health plan, (c) any other person or entity that is responsible for paying or processing for payment of any portion of my Agency bill, (d) for any Agency audit, or (e) any government or accrediting agency. This consent applies to all records created in the course of and relating to my care by Agency, including those related to chemical dependency or mental health treatment and/or treatment for any communicable disease, including HIV/AIDS. I consent to the Agency leaving telephone messages for me at home.

I also consent and authorize any health care provider to release to any employee or agent of Agency who treats me, all information contained in my medical records from prior treatment that is relevant to my current care and treatment.

I also consent to the release of billing and medical records to my primary care physician and his/her medical group. I also consent to the release of a copy of the physician treatment plan and discharge summary from my medical records upon transfer to or from another health care facility or agency.

The agency may verbally release medical information about my condition and treatment to:

☐ Spouse _____ ☐ Parents _____
☐ Children _____ ☐ Other _____

This release shall remain valid until I notify Agency, in writing, of my desire to revoke it. I understand there are times when the law allows Agency to release information regardless of whether or not I give my consent. For example, the Agency may release information to doctors, nurses and others who provide me with health care or are prospective health care providers; to government agencies as authorized by law; to insurance companies or others who are responsible for paying my medical bills; or to a court of law that issues a subpoena or court order. I understand this information may be released either orally or in document form whether or not I withdraw my consent.

This authorization for verbal release of medical information will expire at the time of discharge if not revoked in writing prior to that time.

I have received a copy of the THR Notice of Privacy Practices statement.

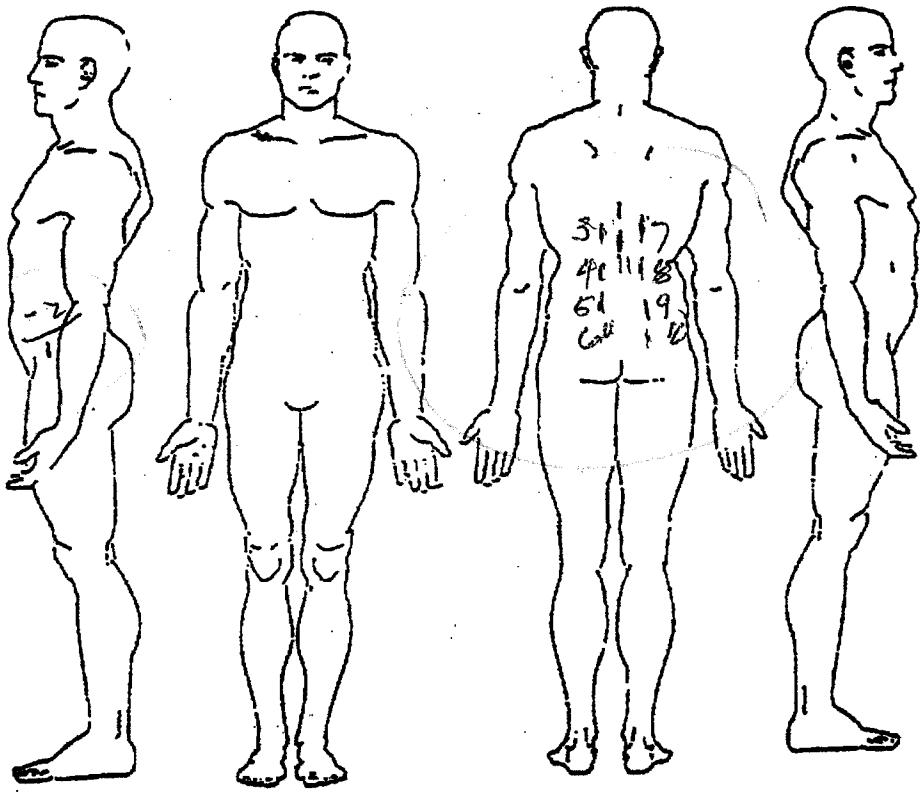
If the person signing this form is not the patient, please give full name, phone number and address:

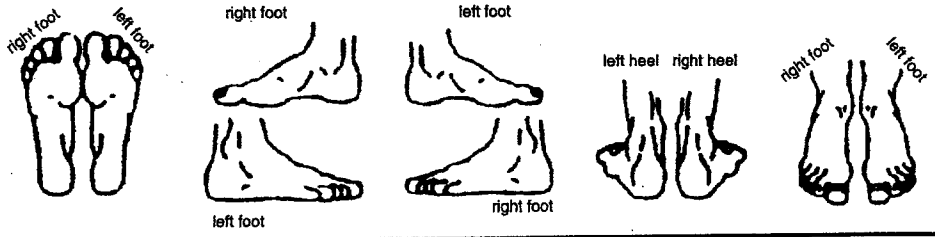
I HAVE READ AND UNDERSTAND THIS INFORMATION:

Signature of Patient or Legally Authorized Representative	Relationship to Patient	Reason Patient Unable to Sign
Witness	Title	Date of Signature

Presbyterian Home Care
In-Home Wound Communication Log

Patient Name: Kathryn Jones ID#: _____





Date	Wound #	Dimensions	Comments (Tunnels, Drainage, Infection, Odor)
11/15/10	1	2.0 x 0.2 x 0.0	
"	2	1.9 x 0.1 x 0.0	
8	3	2.0 x 0.2 x 0.0	
4	4	2.0 x 0.2 x 0.0	
5	5	2.0 x 0.2 x 0.0	
6	6	2.0 x 0.2 x 0.0	
7	7	2.0 x 0.2 x 0.0	
8	8	2.0 x 0.2 x 0.0	
9	9	2.0 x 0.2 x 0.0	
10	10	2.0 x 0.2 x 0.0	

Date	Wound #	Dimensions	Comments (Tunnels, Drainage, Infection, Odo
	10	2.0 x 0.2 x 0.0	
	11	2.0 x 0.2 x 0.0	Red. [illegible] at Distal end

FOOD AND DRUG INTERACTION SHEET

Combination of the right foods and medicines plays a very big part in getting well and staying well. Some foods and medicines, however, should not be mixed. Use these guidelines to get the most from the medicines your doctor has prescribed. *This sheet contains general guidelines, and may not apply to all patients and all situations. This sheet does not contain a complete list of medications. Contact your Doctor if you have questions.*

FOLLOW THESE GENERAL RULES WHENEVER TAKING MEDICATIONS:

1. Know the names of all medications you are taking, including over-the-counter medications.
2. Be sure to tell your doctor if you are allergic to any medication, if you are on a special diet, if you are pregnant or planning to become pregnant, if you are breast feeding and if you have other medical problems.
3. Take your medications exactly as prescribed. Do not increase or decrease the dose of your medication without first contacting your doctor. Do not stop taking your medication without contacting your doctor. In the event you take the wrong dose or miss a dose of medication notify your doctor and follow his/her exact instructions.
4. If you notice troubling symptoms that you think may be related to your medication, contact your doctor.
5. Do not store capsules or tablets in the bathroom or in damp places.
6. Keep all medicine out of the reach of children and in the original container.
7. Do not take medicines in the dark and always read the label before taking any medication.
8. Never crush, chew or break a medicine without first checking with your doctor or pharmacist.
9. Never give your medication to anyone else or take anyone else's medication.
10. Use only one pharmacy so that all of your medication records are in the same place. Your pharmacy will assist you with refill information.
11. It is best to avoid alcohol while taking medication.
12. Discard all medications that are no longer prescribed by your doctor.

Medication	Special Instructions
Coumadin (Warfarin)	Limit alcohol intake to no more that 1-2 ounces per day. Avoid extreme changes in your diet and very large amounts of food high in Vitamin K such as beef liver, broccoli, brussel sprouts, cabbage, collards, green leafy vegetables, green tea, kale, mustard greens, turnip greens and spinach.
Cipro (Ciprofloxacin) Noroxin (Norfloxacin) Tetracycline, Doxycycline (Vibramycin)	Avoid taking milk or other dairy products, antacids or calcium, iron or zinc supplements within two hours before or after taking these medications.
Precose (Acarbose)	Take with the first bite of each meal (up to three times a day).
Fosamax (Alendronate sodium)	Take with a full glass of plain water at least 30 minutes before your first meal, beverage or any other medication. Do not lie down for at least 30 minutes after taking Fosamax.
Iron Supplements (Feosol, Fergon, etc.)	Do not eat or drink dairy products (milk, cheese, yogurt, etc.) eggs, coffee, or take calcium supplements at the same time you take an iron supplement. Wait one or two hours after these foods or drinks before taking iron. Orange juice is the best drink to use when taking an iron pill. Don't lie down for 30 minutes after taking an iron supplement.
Lithium	Avoid extreme changes in diet, salt intake or fluid intake.
Flagyl (Metronidazole) Antabuse (Disulfiram)	Alcohol must be avoided when taking these medications.
Monoamine Oxidase (MAO) Inhibitors e.g., Parnate Nardil (Phenelzine)	Foods high in tyramine must be avoided while taking Monoamine Oxidase Inhibitors. Avoid the following: acidophilus milk, Chinese pea pods, cheese (except cottage and cream cheese), anchovies, Italian green beans, liver, beer, sauerkraut, wine (especially Chianti, sherry, vermouth), olives, meat extract.

TEXAS HEALTH PRESBYTERIAN HOME CARE
PATIENT GRIEVANCE PROCEDURE

Any person(s) who believes that he/she or any class of individuals has been subjected to discrimination prohibited by Section 504 of the Rehabilitation Act of 1973 may file a complaint on his/her own behalf or on behalf of another person or on behalf of handicapped persons as a class. The procedure below has been developed for this purpose.

All persons are free to and encouraged to use this procedure for handling problems and filing complaints. Your filing a complaint will not result in any form of adverse personnel action, reprimand, retaliation or otherwise negative treatment by the agency or its staff.

STEP 1	A person who has a complaint concerning any matter which affect him/her, directly or indirectly, should contact the **Home Care Manager** Michelle MiKovic (Name) **at 214-345-4663.** Patti Mize
STEP 2	If the complaint is not resolved satisfactorily within 10 days after the matter has been presented, the Home Care Manager will arrange for you to talk to the Home Care Director.
STEP 3	If the complaint is not satisfactorily resolved by the Home Care Director within 20 days after presentation, you may request a hearing with the Administrator for a final determination. The final determination will be made within 30 days of presentation.
STEP 4	Any time at the client's discretion, the Texas Department of Aging and Disability Services may be contacted at: Texas Department of Aging and Disability Services (DADS) DADS' Consumer Rights and Services Division P.O. Box 149030 Austin, Texas 78714-9030 DADS' at 1-800-458-9858 Department of Family and Protective Services Toll Free 24 hour Hotline number: 1-800-252-5400
STEP 5	Texas Health Presbyterian Home Care is accredited by The Joint Commission. Unannounced triennial surveys are conducted by The Joint Commission to ensure that quality care, treatment and service are consistently provided. The public may contact the Joint Commission's Office of Quality Monitoring to report any concerns or register complaints about a Joint Commission-accredited health care organization by either calling 1-800-994-6610 or emailingcomplaint@jointcommission.org

Texas Health Resources

TEXAS HEALTH RESOURCES
NOTICE OF PRIVACY PRACTICES

This Notice describes how medical information about you may be used and disclosed, and how you can get access to this information. Please review it carefully.

Understanding Your Health Information

Each time you visit a hospital, physician or other health care provider, a record of your visit is made in order to manage the care you receive. The Texas Health Resources entities listed on this document understand that the medical information that is recorded about you and your health is personal. The confidentiality of your health information is also protected under both state and federal law.

This Notice of Privacy Practices describes how Texas Health entities may use and disclose your information and the rights that you have regarding your health information. The Notice applies to all of Texas Health's health care facilities (both inpatient and outpatient). It also applies to physicians and allied health professionals with staff privileges at Texas Health facilities[1], for hospital-based episodes of care conducted in cooperation with Texas Health facilities.

Texas Health is in the process of transitioning from a paper-based health record to an electronic health record.

Your Health Information Rights

Although your health information is the physical property of the facility or practitioner that compiled it, the information belongs to you, and you have certain rights over that information. You have the right to:

- Request, in writing, a restriction on certain uses and disclosures of your health information. However, agreement with the request is not required by law, such as when it is determined that compliance with the restriction cannot be guaranteed;
- Inspect or obtain a copy of your health record as provided by law;
- Request, in writing, that your health record be amended as provided by law, if you feel the health information we have about you is incorrect or incomplete. You will be notified if the request cannot be granted;
- Request that we communicate with you about your health information in a specific way or at a specific location. Reasonable requests will be accommodated;
- Obtain an accounting of disclosures of your health information as provided by law;
- Obtain a paper copy of this Notice of Privacy Practices on request.

You may exercise these rights by directing a request to the Privacy Officer Contact listed on this Notice.

Our Responsibilities

Texas Health has certain responsibilities regarding your health information, including the requirement to:

- Maintain the privacy of your health information;
- Provide you with this Notice that describes Texas Health's legal duties and privacy practices regarding the information that we maintain about you;
- Abide by the terms of the Notice currently in effect.

[1] Doctors on the medical staff practice independently and are not employees or agents of the hospital except for resident doctors in the hospital's graduate medical education program.

Texas Health entities reserve the right to change these information privacy policies and practices and to make the changes applicable to any health information that we maintain. If changes are made, the revised Notice of Privacy Practices will be made available at each Texas Health facility, posted on each entity Web site, and will be supplied when requested.

Uses and Disclosures of Health Information without Authorization

When you obtain services from any Texas Health entity, certain uses and disclosures of your health information are necessary and permitted by law in order to treat you, to process payments for your treatment and to support the operations of the entity and other involved providers. The following categories describe ways that Texas Health entities use or disclose your information, and some representative examples are provided in each category. All of the ways your health information is used or disclosed should fall within one of these categories.

Your health information will be used for treatment.

For example: Disclosures of medical information about you may be made to physicians, nurses, technicians, medical residents or others who are involved in taking care of you at a Texas Health facility. This information may be disclosed to other physicians who are treating you or to other health care facilities involved in your care. Information may be shared with pharmacies, laboratories or radiology centers for the coordination of different treatments.

In addition, if you receive treatment from a Texas Health entity that participates in a health information exchange, the entity may share your health information with the health information exchange in an information system for the purposes of diagnosis and treatment. Other health care providers may access your health information through this system as part of your treatment. You will be provided the opportunity to opt in to this form of data exchange at the time of admission.

Your health information will be used for payment.

For example: Health information about you may be disclosed so that services provided to you may be billed to an insurance company or a third party. Information may be provided to your health plan about treatment you are going to receive in order to obtain prior approval or to determine if your health plan will cover the treatment.

Your health information will be used for health care operations.

For example: The information in your health record may be used to evaluate and improve the quality of the care and services we provide. Students, volunteers and trainees may have access to your health information for training and treatment purposes as they participate in continuing education, training, internships and residency programs.

Business Associates: There are some services that we provide through contracts with third-party business associates. Examples include transcription agencies and copying services. To protect your health information, Texas Health entities require these business associates to appropriately protect your information.

Directory: Unless you give notice of an objection, your name, location in the facility, general condition and religious affiliation will be used for patient directories, in those entities where such directories are maintained. This information may be provided to members of the clergy. This information, except for religious affiliation, may also be provided to other people who ask for you by name.

Continuity of Care: In order to provide for the continuity of your care once you are discharged from one of our facilities, your information may be shared with other health care providers such as home health agencies. Information about you may be disclosed to community services agencies in order to obtain their services on your behalf.

Disclosures Requiring Verbal Agreement

Unless you give notice of an objection, and in accordance with your *Authorization to Verbally Release Health Information*, medical information may be released to a family member or other person who is involved in your medical care or who helps pay for your care. Information about you may be disclosed to notify a family member, legally authorized representative or other person responsible for your care about your location and general condition. This may include disclosures of information about you to an organization assisting in a disaster relief effort, such as the American Red Cross, so that your family can be notified about your condition. You will be given an opportunity to agree or object to these disclosures except as due to your incapacity or in emergency circumstances.

Disclosures Required by Law or otherwise Allowed without Authorization or Notification

The following disclosures of health information may be made according to state and federal law without your written authorization or verbal agreement:

- When a disclosure is required by federal, state or local law, judicial or administrative proceedings or for law enforcement. Examples would be reporting gunshot wounds or child abuse, or responding to court orders;
- For public health purposes, such as reporting information about births, deaths and various diseases, or disclosures to the FDA regarding adverse events related to food, medications or devices;
- For health oversight activities, such as audits, inspections or licensure investigations;
- To organ procurement organizations for the purpose of tissue donation and transplant;
- For research purposes, when the research has been approved by an institutional review board that has reviewed the research proposal and established guidelines to provide for the privacy of your health information; or the disclosure is that of a limited data set, where personal identifiers have been removed;
- To coroners and funeral directors for the purpose of identification, the determination of the cause of death or to perform their duties as authorized by law;
- To avoid a serious threat to the health or safety of a person or the public;
- For specific government functions, such as protection of the President of the United States;
- For workers' compensation purposes;
- To military command authorities as required for members of the armed forces;
- To authorized federal officials for national security and intelligence activities as authorized by law;
- To correctional institutions or law enforcement officials concerning the health information of inmates, as authorized by law.

Other Allowable Uses and Disclosures without Authorization.

Other uses or disclosures of your health information that may be made include:

- Contacting you to provide appointment reminders for treatment or medical care, as well as to recommend treatment alternatives;
- Notifying you of health-related benefits and services that may be of interest to you;
- Use of your health information for the purposes of fundraising for a Texas Health entity. You will have the opportunity to opt out of any future communications. Contact the Privacy Officer on this Notice for instructions on opting out.

Required Uses and Disclosures

Under the law we must make disclosures when required by the Secretary of the U. S. Department of Health & Human Services to investigate or determine our compliance with federal privacy law.

Uses and Disclosures Requiring Authorization

Any other uses or disclosures of your health information not addressed in this Notice or otherwise required by law will be made only with your written authorization. You may revoke such authorization at any time.

Privacy Complaints

You have the right to file a complaint if you believe your privacy rights have been violated. This complaint may be addressed to the Privacy Contact listed in this Notice, or to the Secretary of the U. S. Department of Health & Human Services. There will be no retaliation for registering a complaint.

Privacy Contact

Address any questions about this Notice or how to exercise your privacy rights to the applicable Privacy Officer Contact listed below.

Effective Date

July 16, 2007

Entity Privacy Officer Contacts

- Texas Health Arlington Memorial Hospital
  817-807-7429
- Texas Health Harris Methodist Hospital
  Azle
  817-250-4683
- Texas Health Harris Methodist Hospital
  Cleburne
  817-556-5516
- Texas Health Harris Methodist Hospital
  Fort Worth
  817-250-4683
- Texas Health Harris Methodist Hospital
  Hurst-Euless-Bedford
  817-685-4472
- Texas Health Harris Methodist Hospital
  Southwest Fort Worth
  817-433-6206
- Texas Health Harris Methodist Hospital
  Stephenville
  254-965-1542
- Texas Health Presbyterian Hospital Allen
  972-747-1000
- Texas Health Presbyterian Hospital Dallas
  214-345-4557
- Texas Health Presbyterian Hospital Kaufman
  972-932-7292
- Texas Health Presbyterian Hospital Plano
  972-981-3734
- Texas Health Presbyterian Hospital Winnsboro
  903-342-3963
- Texas Health Specialty Hospital
  817-250-4683
- Texas Health
  Springwood Hospital
  817-685-4472
- Deuteronomy Practice
  214-345-6311

Texas Health
Presbyterian Home Care

Relieving Your Pain

The nurses and therapist at Texas Health Presbyterian Home Care have written this information sheet for you to answer common questions about pain and to help assure that you have good pain relief while you are receiving services from Presbyterian Home Care. If you have any questions about this information, or want more information, be sure to let us know.

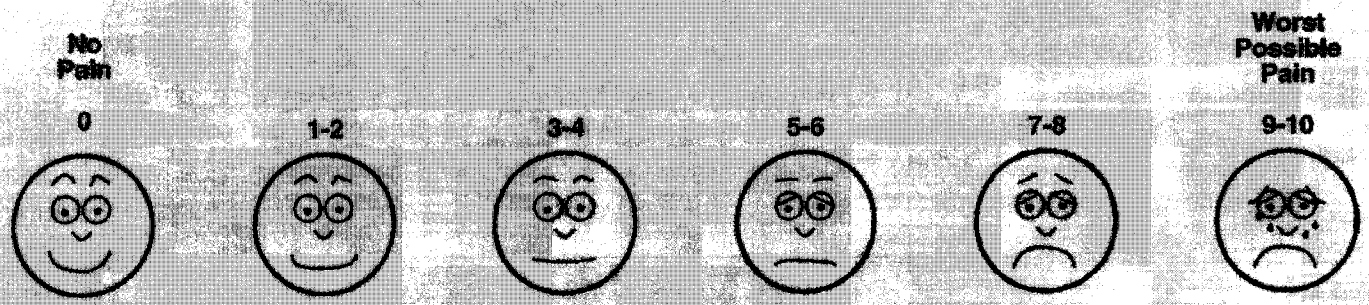
• Why is pain relief important?
Pain causes suffering and can delay recovery. Relieving pain can improve your sleep, appetite, mood, energy, and activity level. Therefore, relieving pain can help you to heal faster and become independent sooner.

• What should I do if I have pain? Who can help me?
Tell your nurse or therapist when you have pain. Don't worry about "being a bother". The nurses and therapists cannot help you unless you tell them about your pain. Do not wait until your pain is severe because then it is harder to relieve. Your nurse or therapist may ask you several questions about your pain so they can better help your doctor treat your pain

• What questions are the nurse/therapist likely to ask me about my pain?
- Where is your pain?
- When did your pain start?
- How does the pain feel?
  For example, is it sharp, dull, achy, throbbing, burning, stabbing?
- What tends to make the pain better or worse?
  For example, does a certain position help? Does a warm or cold compress help?
- Does your pain limit any of your activities?
- How much do you hurt?
  Is your pain mild, moderate, or severe?

• Have you had Pain since our last visit?
- What did you do?
- How long did you have pain relief?

Using the scale below, what number shows how much pain you are having?



• What can be done to relieve my pain?
People used to think they had to "put up with pain". This is no longer true. Today's new treatments enable doctors, nurses and therapists to control your pain. You will be given pain medicines to relieve your pain. Pain medicines are called "analgesics". These may not get rid of all your pain but they should lower your pain to a level you can handle. Other treatments also can be used to reduce your pain.

• What pain medicines will be used?
There are many types of pain medicines. The type used depends on the kind of pain. Opioids (also called narcotics) are often used for severe or moderate pain. Non-opioid medicines such as Tylenol® and non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin or Advil® can also be used. Other drugs such as muscle relaxants and antidepressants often are helpful. Your nurse or therapist will work together with your doctor to determine what medicine or therapy is best for your pain.

• How long will it take to relieve my pain?
This depends on the medicine used and how severe the pain is when the medicine is taken. Most medicines take 30 minutes or more to work, but the more serve the pain, the longer the medication may take to work. Your nurse or therapist can tell you when the medicine is likely to start working.

• How long will the medicine work?
This depends on the medicine used. Some medicines work for a short time. Other medicines work for 12 hours or more. Tell your nurse or therapist when your pain starts to come back so your medications can be adjusted, or you can take more, if necessary.

• Do pain medicines have any side effects?
All medicines can have side effects. Constipation, upset stomach, and drowsiness are common side effects of opioid drugs. If you get these or other side effects, tell your nurse or doctor so these can be treated.

• If I take opioids (narcotics) will I get addicted to them?
The chance of getting addicted is very rare, about 1 in 10,000 people. Unless you have a previous problem with drug abuse, you should be able to stop your pain medicine when your pain is controlled.

• Is it better to tough it out as long as I can?
No, pain can delay recovery. Also, if you wait until the pain is severe, it may take more medicine to control your pain.

• If I take pain medicine regularly, will it lose its effect?
Your body can slowly develop "tolerance" to some pain medicines. This means you need to take more medicine to get the same effect. This is a natural, normal response of the body. This is not addiction. If this occurs, the dose can be increased, or another medicine can be added or used.

• What else can help relieve pain in addition to pain medicine?
Many other approaches can help control pain such as massage, positioning, applying heat or cold, relaxing, and listening to music. Ask your nurse or doctor about these approaches.

Remember: Pain relief is important to your recovery. Tell your nurse or doctor when you have pain so your pain can be treated.

Patient Name: _____ **Patient ID #:** _____

Guarding Your Independence

Most falls occur because people do not call for help or they step away from their walker.

Level of Mental State

- o Increase level of supervision

History of Falls

- o Remove throw rugs
- o Remove clutter
- o Watch oxygen tubing
- o Use proper transfer movements
- o Keep cords away from walkways
- o Use staircase handrails
- o Label first and last step
- o Control or kennel pets
- o Increase lighting
- o Do not wax floors

Ambulation and Balance Status (Including possible blood pressure drop with position changes)

- o Limit fluids after ____pm
- o Wear pad or underwear briefs
- o Go to the bathroom more often
- o Use bedside or elevated commode
- o Clear pathways
- o Use gait belt as instructed
- o Use walker/cane as instructed
- o Change position from sitting to standing slowly
- o Use shower chair
- o Get up slowly and pause before walking to prevent dizziness.
- o Use tub transfer bench
- o Use/install grab bars in shower
- o Wear properly fitting non-skid shoes
- o Watch for door threshold or surface changes
- o Avoid furniture walking
- o Lock wheelchair brakes for sitting or standing
- o Use transfer techniques as instructed
- o Call or ask for help with walking
- o Use bathmat in shower
- o Use a Reacher to pick up items from the floor.

Vision Status

- o Make visit to eye doctor for exam
- o Wear glasses when walking
- o Increase lighting

Medicines

- o Keep items used daily within arms reach.
- o Do not combine pain medication with alcohol.
- o Practice good drinking/eating habits.
- o Use caution with medications that can cause dizziness or drowsiness

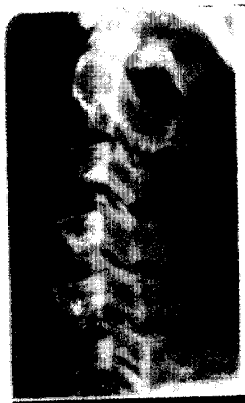
Medical History

- o Some conditions such as hypotension (low blood pressure), vertigo (dizziness), CVA (stroke), Parkinsons, loss of limb(s), seizures, arthritis, osteoporosis, and fractures can increase the risk of falling.
- o Follow the items marked on this teaching sheet to help decrease the risk of falling.

Recommendations: Obtain Medical Alert Button, plan fire escape route, notify fire department of bedbound patient, and take medications as prescribed. This is not meant to be all-inclusive. Good common sense helps reduce unexpected falls!

Patient Signature: _____ Date: _____

Kathryn M. Jones
Dr. Jeremy W. Denning
TX Health Presby Dallas
10-26-10
•DLIF L1-L5, Posterior
INFUSE, PEEK, BMP •T12-S1 Fusion
•TLIF L5-S1
Medtronic



Medtronic

The holder of this card has a Medtronic spine implant which may activate a metal detection device.

Came 10-1-12 with records

JEREMY W. DENNING, M.D.
DALLAS NEUROSURGICAL & SPINE ASSOCIATES, P.A.

8230 WALNUT HILL LANE, SUITE 220
DALLAS, TEXAS 75231
PHONE (214) 750-3945
FAX (214) 691-5992

4708 ALLIANCE BLVD, SUITE 620
PLANO, TEXAS 75093
PHONE (972) 665-4810
FAX (972) 665-4815

FOR Kathryn Jones

ADDRESS [redacted] 11/22/63

Ms. Jones has had major Spinal Surgery for Scoliosis and has Spinal implants made of titanium that could set off alarms at Airport Security.

MD

REPT. UT. DICT.
1 2 3 4 TIMES
P.R.N. ☐ NON-REP. ☐

B09736270
DPS # Y0146191

M.D
Dr. Signature - product selection permitted

M.D.
Dr. Signature - dispense as written

Dallas Neurosurgical & Spine

dallasneurosurgical.com

Jeremy W. Deming, MD
J. Michael Desaloms, MD
Richard H. Jackson, MD
Jon A. Krumerman, MD
Richard L. Weiner, MD, FACS
Gary C. Hutchison, MD, FACS

January 27, 2011
ESTABLISHED/ FOLLOW UP PATIENT VISIT

PATIENT: Jones, Kathryn

SUBJECTIVE: Ms. Jones returns to the office today three months postoperative after an anterior/posterior spinal reconstruction operation for scoliosis and spondylolisthesis at L5-S1. She had previously had complete resolution of her preoperative leg pain, but she is now complaining of a circumferential band of pain in her right leg. It started about six weeks after surgery. She says is comes and goes. Sometimes it can be quite severe. However, she is taking no pain medications for this and takes no routine pain medication at all anymore. She continues to use a walker when she is outside of her home, but she uses no walker inside. She has had no balance problems and has not noticed any strength issues in her legs. She continues to wear her lumbosacral brace that she was given at the time of her surgery. The one thing that she did report was that she has been unable to drive at home because she cannot get into any of her personal vehicles without assist. Upon more careful questioning it was discovered that the Jones' have two vehicles that are quite high off the ground, a Jeep vehicle and a big truck that require a very high step-up and use of a hand rail to get up into the vehicle and she has been unable to do that maneuver as her legs and arms have not been strong enough. When is asked if they were planning on replacing any of these vehicles they indicated they were not.

RADIOGRAPHIC TESTS:
AP and lateral x-rays of the thoracolumbar spine done at Southwest Diagnostic Imaging Center on January 27, 2011 show all hardware to be in excellent position with no residual scoliosis. Implants are well positioned and there are no complicating features on the film.

PHYSICAL EXAMINATION:
Ms. Jones has a normal gait without her walker. Her incisions are all well healed. Motor function in the lower extremities is graded 5/5 to manual testing. No heel or toe-drop is noted on examination today.

IMPRESSION:
Ms. Jones continues to do very well after her extensive scoliosis surgery, but she has now developed a circumferential pain around the right thigh that various anywhere from a 1 out of 10 to a, 5 out of 10 in severity.

I told Ms. Jones that she was still healing after her surgery and could expect to have some odd sensations like this up to a year after her surgery as things were continuing to settle.

RECOMMENDATIONS:
I told Ms. Jones that she is healed enough that she can begin to wean out of her lumbar brace and this process was explained to her at present. I was a little concerned that she has not been driving yet because she cannot get into her cars and I suggested to Ms. Jones and her husband that she go to physical therapy specifically to work on leg and upper body strength so she can get in and out of her vehicles as they have no plans to replace these vehicles. She was somewhat resistant to this idea as she has had some negative encounters with physical therapy in the past, but as we continue to discuss this she became more agreeable.

We have asked to see Ms. Jones in another three months. We will get another x-ray at that time. We will continue to follow her as she heals.

Ms. Jones was also seen and examined by Dr. Jeremy Denning who agrees with this impression and management plan.

TColeman RN, ACNP
Tina Coleman, RN, ACNP

Jeremy W. Denning, M.D.

TC/MW
D: 1/27/2011 @ 5:15 PM
T: 1/28/2011 @ 8:12 AM
J: 4909608

☐ J. MICHAEL DESALOMS, M.D.
☐ RICHARD H. JACKSON, M.D.
☐ JON A. KRUMERMAN, M.D.
☐ RICHARD L. WEINER, M.D.
☐ JEREMY W. DENNING, M.D.
☐ MICHELLE L. FULLER, NP-C
☐ CHERYL RUBNER, NP-C
☒ TINA COLEMAN, NP-C
☐ STEPHANIE CRACKNELL, NP-C

NEUROLOGICAL SURGERY
DALLAS NEUROSURGICAL AND SPINE ASSOCIATES, P.A.
PRESBYTERIAN PROFESSIONAL BLDG. III
SUITE 220
8230 WALNUT HILL LANE
DALLAS, TEXAS 75231
OFFICE PHONE (214) 750-3646
FAX (214) 739-6815

PATIENT NAME: Kathryn Jones DATE: 1-27-2011

DIAGNOSIS: s/p scoliosis surgery 10/26/2010

☒ EVALUATE AND TREAT bilateral leg weakness

MODALITIES	THERAPEUTIC PROCEDURES	RETURN TO WORK PROGRAM
☐ HOT PACKS	☐ McKENZIE METHOD	☐ WORK HARDENING
☐ COLD PACKS	☐ SPINE STABILIZATION	☐ WORK CONDITIONING
☐ ULTRASOUND	☐ BODY MECHANICS/ POSTURAL TRAINING	☐ PAIN MANAGEMENT
☐ MASSAGE	☒ STRENGTHENING EXERCISE LE + UE	☐ FUNCTIONAL CAPACITY EVALUATION
☐ CERVICAL TRACTION	☐ RANGE OF MOTION EXER.	☐ IMPAIRMENT RATING
☐ HOME TRACTION (if effective)	☒ HOME EXERCISE PROGRAM	☒ Needs work to get in & out of her car
☐ AQUATIC THERAPY	☐ EXERCISES __FLEXION __EXTENSION	
☐ E STIM	☒ No back exercises!	
☐ _____	_____	
_____		

FREQUENCY: 2 TIMES PER WEEK DURATION: 4 WEEKS

SIGNATURE: T Coleman RN, ACNP

THIS TREATMENT IS MEDICALLY NECESSARY

Dallas Neurosurgical & Spine

dallasneurosurgical.com

Jeremy W. Denning, MD
J. Michael Dessloens, MD
Richard H. Jackson, MD
Jon A. Kramerman, MD
Richard L. Weiner, MD, FACS
Gary C. Hutchison, MD, FACS

April 28, 2011
ESTABLISHED/ FOLLOW UP PATIENT VISIT

PATIENT: **Jones, Kathryn**

DIAGNOSIS: Degenerative scoliosis with lumbar stenosis and radiculopathy on the right.

OPERATION: DATE: 10/27/2010 PROCEDURE: Direct lumbar interbody fusion at L1-L5.

SUBJECTIVE: Ms. Jones comes to the office today accompanied by her husband approximately six months after the above surgery. She reports that she is getting along fairly well. She does still have occasional back pain and right leg pain, which vary with her level of activity. She is walking on a treadmill daily. At her last office visit we gave Ms. Jones a prescription for physical therapy, but she reports that she decided not to pursue that. She is not taking any prescription medications, but she will take an occasional extra strength Tylenol for her back pain.

PHYSICAL EXAMINATION: Her lateral flank and posterior lumbar incisions are well healed with no redness, drainage, or swelling noted. The lateral incision still can be a little tender to palpation. The patient has a normal gait with an upright posture. No heel or toe-drop is noted. Good strength is demonstrated in the lower extremity to manual testing and sensation is intact.

RADIOGRAPHIC TESTS: An AP and lateral x-ray of the lumbar spine done at Southwest Diagnostic Imaging Center on April 28, 2011 show intervertebral hardware to be in good position. All pedicle screws are in place with no evidence of any lucency or loosening. The bilateral rods are intact with no evidence of any hardware failure.

IMPRESSION: Ms. Jones continues to make slow, but steady progress after her extensive lumbar fusion surgery for scoliosis and right radicular pain. She still has some difficulties with some day to day activities, but she is doing well overall and has continued to make steady progress.

Dallas
8230 Walnut Hill Lane
Prof. Bldg. III, Suite 220
Dallas, Texas 75231
t 214.750.3646
f 214.739.6815

Allen/McKinney
1105 N. Central Expwy
Suite 2310
Allen, Texas 75013
t 972.747.6393
f 214.363.2351

Denton
3537 S. I-35E
Suite 220-B
Denton, Texas 76210
t 940.484.8800
f 940.384.4770

Plano
4708 Alliance Blvd
Suite 620
Plano, Texas 75093
t 972.665.4810
f 972.665.4815

Rockwall/Rowlett
7801 Lakeview Parkway
Suite 130
Rowlett, Texas 75088
t 972.475.2150
f 214.987.4865

RECOMMENDATIONS: I have told Ms. Jones that at this point we can lift her weight lifting restriction to 40 lbs and there is really no further restrictions on her. I did encourage her to continue using proper body mechanics, such as bending at her knees and not bending at the waist, as well as limiting the amount of twisting that she does to protect the levels adjacent to her construct. I told Ms. Jones that after a surgery of this magnitude that it is a reasonable long term expectation that she might have a small degree of back pain with certain activities and that there would be some activities that would always bother her such as off-road riding in a jeep. Ms. Jones and her husband voiced understanding of this.

I have asked to see Ms. Jones back in the office on the anniversary of her surgery. At that time, we will get another AP and lateral x-ray of her lumbar spine so we can continue to assess the status of this fusion, as well as to make sure she continues to make expected progress.

Ms. Jones was also seen and examined by Dr. Jeremy Denning who agrees with this impression and management plan.

T Coleman RN, ACNP
Tina Coleman, RN, ACNP

Jeremy W. Denning, M.D.

TC/MW
D: 4/28/2011 @ 3:29 PM
T: 4/28/2011 @ 7:00 PM
J: 5508890

Quick Note

Patient Name:	Kathryn Jones	**Visit Date:**	September 21, 2011
Patient ID:	34538	**Provider:**	Jeremy W. Denning, MD
Sex:	Female	**Location:**	DNSA - Plano
Birthdate:	March 1, 1950		

History Of Present Illness

Mrs. Jones returns with chief complaint of left lower lumbar pain and some swelling in the area and below. This started after she squatted down one day a month and a half ago. She felt a "pulling" sensation and some pain then subsequently some swelling. They saw their PCP who ordered an MRI of hip which was negative then US which showed some edema. She saw a plastic surgery for the swelling as this was thought to be possible fat, as well. She then had a CT of her lumbar spine which I looked as well and showed no significant abnormalities with alignment anatomic and post op fusion changes from T12-S1. The T12-L1 level is not fused, but the screws and rods are positioned well and have not pulled out.

On exam
She has upright posture that is perfect coronally and sagitally
Her back was inspected and if anything it appears her right side of her back is more prominent than left; palpation over the left lower paraspinal area produces some tenderness but I don't palpate any bony or soft tissue abnormality; Her left lateral incision is well healed and there is no bulge or hernia through this; palpation at the top of her construct also doesn't produce any tenderness, nor do I palpation any hardware prominence.

Her gait and station is normal as is strength.

Assessment:
Given her pain and the pulling sensation she experience plus the fact that there is no bony abnormality, I think she has lumbar strain.

I have given her a referral for PT to use heat, massage, TENS, US and back strengthening
If this doesn't help then trigger point injection may be next step but no surgery is necessary
She will FU in 6 months.

Assessment

- Lumbago 724.2
- Scoliosis 737.43

Plan

Instructions

- Nonoperative back pain: The patient is neurologically intact and ambulatory, and the patient has been advised that surgical treatment is not the most appropriate intervention at this time. The treatment options have been discussed with the patient.
- I have recommended that the patient undergo physical therapy. We discussed that almost 2/3 of people will have a favorable response to physical therapy alone, that means that 1/3 will not. Multiple courses of physical therapy do not tend to provide any additional benefit.

Electronically Signed by: Jeremy W. Denning, MD -Author on September 21, 2011 02:42:59 PM

[Digital Signature Validated]
10-1-12

☐ J. MICHAEL DESALOMS, M.D.
☐ RICHARD H. JACKSON, M.D.
☐ JON A. KRUMERMAN, M.D.
☐ RICHARD L. WEINER, M.D.
☒ JEREMY W. DENNING, M.D.

☐ MICHELLE L. FULLER, NP-C
☐ CHERYL RUBNER, NP-C
☐ TINA COLEMAN, NP-C

NEUROLOGICAL SURGERY
DALLAS NEUROSURGICAL AND SPINE ASSOCIATES, P.A.
PRESBYTERIAN PROFESSIONAL BLDG. III
SUITE 220
8230 WALNUT HILL LANE
DALLAS, TEXAS 75231

OFFICE PHONE (214) 750-3646
FAX (214) 739-6815

PATIENT NAME: Kathryn Jones DATE:

DIAGNOSIS:

☒ EVALUATE AND TREAT

MODALITES	THERAPEUTIC PROCEDURES	RETURN TO WORK PROGRAM
☒ HOT PACKS	☒ McKENZIE METHOD	☐ WORK HARDENING
☐ COLD PACKS	☒ SPINE STABILIZATION	☐ WORK CONDITIONING
☒ ULTRASOUND	☒ BODY MECHANICS/ POSTURAL TRAINING	☐ PAIN MANAGEMENT
☒ MASSAGE	☒ STRENGTHENING EXERCISE	☐ FUNCTIONAL CAPACITY EVALUATION
☐ CERVICAL TRACTION	☐ RANGE OF MOTION EXER.	☐ IMPAIRMENT RATING
☐ HOME TRACTION (if effective)	☒ HOME EXERCISE PROGRAM	☐ _____
☒ AQUATIC THERAPY	☐ EXERCISES ___FLEXION ___EXTENSION	
☒ E STIM	☐ _____	
☐ _____		

FREQUENCY: 2 TIMES PER WEEK DURATION: _____ WEEKS

SIGNATURE:

THIS TREATMENT IS MEDICALLY NECESSARY

Aetna Life Insurance Company
P.O. BOX 981106
EL PASO, TX 79998-1106

000507 J280EVBC 001010

EXPLANATION OF BENEFITS

THIS IS NOT A BILL

Please Retain for Future Reference

Date Printed: 10/11/11

KATHRYN JONES
[redacted]

QUESTIONS? *Contact us at* **aetnanavigator.com**
1-866-565-1236
Or write to the address shown above.

Notes:

Thanks to you, our Explanation of Benefits will soon have a new look. You told us you had a hard time understanding it, and we listened. Arriving this Fall, you will see a simpler, easier-to-read statement. It is designed to give you the information you need quickly and at a glance.

Member: KATHRYN JONES
Group Name: AETNA ADVANTAGE PPO -ARIZONA

Member ID [redacted]
Group Number: 0888105-10-001 BV DB"610

All Remarks Appear After Final Claim

Claim Activity for KATHRYN JONES (self)

DATE AND TYPE OF SERVICE	SUBMITTED CHARGES	NEGOTIATED OR ALLOWED	Patient Responsibility (shaded columns): PENDING OR NOT PAYABLE	SEE REMARKS	YOUR COPAY	YOUR DEDUCTIBLE	AMOUNT REMAINING	PAID AT	PLAN PAYS	YOUR SHARE OF AMOUNT REMAINING	Total Patient Responsibility
	A	B	C		D	E	F		G	H	I
This is the claim detail for the bills **received on 09/28/11**						Claim ID: EFPATJFTT00					
FOOTHILLS SPORTS MEDICINE 09/26/11											
97140 *MANUAL THERAPY*	50.00	17.05					17.05	80%	13.64	3.41	3.41
97110 *THERAPEUTIC EXERCISES*	110.00	36.18					36.18	80%	28.94	7.24	7.24
97001 *PT EVALUATION*	100.00	44.30					44.30	80%	35.44	8.86	8.86
Column Totals	260.00	97.53					97.53		78.02	19.51	19.51
This is the claim detail for the bills **received on 09/30/11**						Claim ID: EJFATKD4N00					
FOOTHILLS SPORTS MEDICINE 09/28/11											
97140 *MANUAL THERAPY*	100.00	34.11					34.11	80%	27.29	6.82	6.82
97112 *NEUROMUSCULAR REEDUCATION*	120.00	37.84					37.84	80%	30.27	7.57	7.57
Column Totals	220.00	71.95					71.95		57.56	14.39	14.39
This is the claim detail for the bills **received on 10/06/11**						Claim ID: ESPAS8SXZ00					
FOOTHILLS SPORTS MEDICINE 10/03/11											
97112 *NEUROMUSCULAR REEDUCATION*	120.00	37.84					37.84	80%	30.27	7.57	7.57

Continued on Next Page

CONSENT

Patient Name: Jones, Kathryn

FOOTHILLS SPORTS MEDICINE AND REHABILITATION
CONSENT

CONSENT FOR CARE AND TREATMENT

I hereby give my agreement and consent to Foothills Sports Medicine and Rehabilitation to furnish appropriate rehabilitative care and treatment, as considered necessary and in the best interest in order to attend to the physical condition. I understand that the benefits and risks to all interventions will be explained and that the patient holds the final judgment in such matters.

Patient: Kathryn Marie Jones Signature Date: 9-26-11

Parent/Guardian: _____ Signature Date: _____

FINANCIAL CONSENT

KMJ X I understand it is the policy of Foothills Sports Medicine and Rehabilitation to collect co-pays, co-insurance, and deductibles at the time of service. As a courtesy we verified your benefits with your insurance company. The following benefits were given to us by your insurance company and are therefore an **estimate** of your responsibility. Plan benefits given to us are as follows:

Plan: AETNA Deductible: 1500 Met: 1500 Due: 0

Co-Insurance % 20 % of plan allowance Co-pay $ —

Note: RX REQD; 24 visits per cal year; $35 co-pay for IE then 20% co-insurance

[ ] *Deductible*: I agree to pay $_____ per visit toward the amount allowed by my plan at the time of service until my remaining deductible has been met.

KMJ X *Co-Insurance*: I agree to pay the **estimated** co-insurance allowed by my plan at the time of service.
Estimated Co-insurance per visit: $ 20

KMJ X *Co-pay*: I agree to pay my co-pay of $ 35 ~~per visit~~ IE.

I understand I will be billed for any remaining balance after all insurance companies have paid.

[ ] I will not be using any type of insurance coverage; my cost for treatment will be $100 for the Initial Evaluation and $90 for each additional visit. **I understand that my insurance will NOT be billed for my treatment now or in the future.**

I agree to the above financial terms

Patient: Kathryn Marie Jones Signature Date: 9-26-11

Parent/Guardian: _____ Signature Date: _____

Benefits Explained by: Kaetlyn S. Pasquale Date: 9/26/11

4-3-12 10:51 AM

From: awj [mailto:[redacted]]
Sent: Tuesday, April 03, 2012 10:51 AM
To: 'Sandra Chavez'
Subject: RE: ALAN JONES NECK SPINE MRI & NERVE TESTING
Importance: High

Email and response

Patient Name: Kathryn Jones
Patient ID: 34538
Sex: Female
Birthdate: [redacted]1950

Create Date: April 24, 2012

The following email was sent to the office requesting some information. Ms. Jones underwent a DLIF L1-2, L2-3, L3-4, L4-5 on 10/26/2010 for thoracolumbar degenerative scoliosis. She had done very well with resolution of her preoperative leg and back pain. She developed some perineal pain approximately 4-5 months ago. We recommended she see a local urologist for evaluation.

Hi Sandra –

I am puzzled by the lack of response from Dr. Denning. My urologist has put me through every possible diagnostic test (a 3D CT scan with and without contrast, a urinary scope, a uroflow, an MRI with and without contrast, and many urinalysis tests – including one to identify cancer markers). He can find no reason for the severe pain that I am experiencing. He does not want me to continue to take the hyoscyamine sulfate, as it interferes with my balance, and contributed to my bad fall in January. So yesterday he referred me to a pain specialist. My urologist has recommended that I receive injections/nerve blocks.

Please ask Dr. Denning to respond to my questions. Can this severe pain in my urethra and bladder in any way be related to my spinal surgery? Can the cause of the pain be repaired? I do not want to destroy any nerves if it is possible to fix them instead. Are there any further tests that would identify the cause of the pain?

Please respond quickly. If Dr. Denning does not want to answer my questions, please let me know.

Thank you,

Kathryn Marie Jones

After speaking to Dr. Denning, I called Ms. Jones and left a message on her answering machine. I apologized for any previous lack of response from our office and told her Dr. Denning did not believe her current pain is a result of or caused by her spine surgery. I explained to her that if the nerves which enervate her perineum were damaged during surgery, she would have had problems with this pain long before now as her surgery was over 1 1/2 years ago. Our recommendation is that she follow-up with the pain management physician her urologist referred her to. Unfortunately, Dr. Denning has no insight as to the cause of her pain and has no recommendations regarding additional testing.

I asked her to call us back if she had any further questions regarding this matter.

Electronically Signed by: Tina F. Coleman, NP -Author on April 24, 2012 03:58:46 PM

[Digital Signature Validated]

May 9, 2012

Dr. Jeremy Denning
8230 Walnut Hill Lane
Professional Bldg. III
Suite 220
Dallas, TX 75231

7010 2780 0000 3765 6392

Dear Dr. Denning,

As previously stated in e-mails to Sandra, I have been experiencing severe, stabbing pains in my urethra. These pains began right after Thanksgiving, and resulted in two ER visits.

My urologist has done extensive diagnostic tests, but has not found a urological cause for my pain. Unfortunately, the medicine that he has prescribed (Hyoscyamine Sulfate) has caused me to be uncoordinated, and contributed to a serious fall in mid-January. So my urologist recommended that I see a pelvic pain specialist at the Pain Center of Arizona. The goal is to be pain-free and able to stop the Hyoscyamine Sulfate.

I saw the pain specialist yesterday. His proposed treatment plan is to do a nerve block of the Hypogastric Plexus. The doctor will insert a needle into my back, "work around" my hardware, and inject steroids and pain killer in front of my L-5 vertebrae. The procedure will be performed without anesthesia. The doctor warned that I could suffer nerve damage or "burn" that would result in increased pain and would be permanent. If the nerve block is successful, the doctor would then do a radio frequency ablation. I scheduled the procedure for next week.

But then I decided that I would make one more attempt to contact you. Before I proceed with a risky

procedure by a doctor who is unfamiliar with my back, I need answers from you. Could my urethra pain be a post-surgery complication? If so, could you perform further surgery to repair the damaged nerve? If not, then should you (the expert on my back) be the doctor who does a nerve block? I have postponed the procedure, waiting for these answers.

To date, the only response from your office has been a confusing voice mail from Tina, instructing me to see the pelvic pain specialist. I have done so. Now I need to hear from you. Or have I been terminated as your patient, and you are no longer concerned with my health? If so, please send me a letter stating that, and I will no longer attempt to contact you.

Sincerely,

Kathryn Marie Jones
PO Box 72107
Phoenix, AZ 85050
[redacted]cox.net
[redacted]4767

PO Box 72107
Phoenix, AZ
85050

CERTIFIED MAIL™

7010 2780 0000 3765 6392

Dr. Jeremy Denning
8230 Walnut Hill Lane
Professional Bldg III
Suite 220
Dallas, TX 75231

Personal and Confidential

7010 2780 0000 3765 6392

U.S. Postal Service™
CERTIFIED MAIL™ RECEIPT
(Domestic Mail Only; No Insurance Coverage Provided)

For delivery information visit our website at www.usps.com®

Postage	$
Certified Fee	
Return Receipt Fee (Endorsement Required)	
Restricted Delivery Fee (Endorsement Required)	
Total Postage & Fees	$

Postmark Here

Sent To: Dr Jeremy Denning
Street, Apt. No.; or PO Box No.: 8230 Walnut Hill Lane Bldg 3 Suite 220
City, State, ZIP+4: Dallas, TX 75231

PS Form 3800, August 2006 — See Reverse for Instructions

DAISY MOUNTAIN MPO
PHOENIX, Arizona
850879998
0363680092 -0095
05/09/2012 (877)275-8777 04:22:43 PM

Sales Receipt

Product Description	Sale Qty	Unit Price	Final Price
DALLAS TX 75231 Zone-5 First-Class Letter 0.50 oz. Expected Delivery: Sat 05/12/12			$0.45
Certified Label #: 70102780000037656392			$2.95
Issue PVI:			$3.40
Total:			$3.40
Paid by: Cash Change Due:			$20.00 -$16.60

Order stamps at usps.com/shop or call 1-800-Stamp24. Go to usps.com/clicknship to print shipping labels with postage.
For other information call 1-800-ASK-USPS.
****
****
Get your mail when and where you want it with a secure Post Office Box. Sign up for a box online at usps.com/poboxes.
****
****

Bill#: 1000501812456
Clerk: 09

All sales final on stamps and postage
Refunds for guaranteed services only
Thank you for your business
****
****
HELP US SERVE YOU BETTER

Go to: https://postalexperience.com/Pos

TELL US ABOUT YOUR RECENT POSTAL EXPERIENCE

YOUR OPINION COUNTS
****
****

7010 2780 0000 3765 6392

U.S. Postal Service
CERTIFIED MAIL RECEIPT
(Domestic Mail Only; No Insurance Coverage Provided)

For delivery information visit our website at www.usps.com

DALLAS TX 75231

Postage	$ $0.45	0092
Certified Fee	$2.95	09
Return Receipt Fee (Endorsement Required)	$0.00	Postmark Here
Restricted Delivery Fee (Endorsement Required)	$0.00	
Total Postage & Fees	$ $3.40	05/09/2012

Sent To: Dr Jeremy Dennim
Street, Apt. No.; or PO Box No.: 8230 Walnut Hill Lane Bldg 3 Suite 220
City, State, ZIP+4: Dallas, TX 75231

PS Form 3800, August 2006 See Reverse for Instructions

GLENDALE, AZ 85308-9998

05/22/2012 04:47:06 PM

Track & Confirm Delivery Status

You entered 7010 2780 0000 3765 6392

Your item was delivered at 1:33 pm on May 14, 2012 in DALLAS, TX 75231.

For additional information, visit our Track & Confirm website at USPS.com, or call us at 1-800-222-1811.

I you.

June 21, 2012

Dr. Jeremy Denning
8230 Walnut Hill Lane
Professional Bldg. III
Suite 220
Dallas, TX 75231

7011 1150 0002 1728 1458

Dear Dr. Denning,

I wrote a letter to you on May 12, 2012. In that letter, I asked for your medical advice, your opinion, regarding an injection procedure that had been recommended to treat the urethra/bladder pain that I have been experiencing.

I asked if you, as my neurosurgeon, thought that you might be able to take a different approach to treat my urethra/bladder pain. I asked if you could perform the nerve block. And I asked if the pain could be a complication from my spinal reconstruction surgery.

I did not ask for your opinion regarding the effectiveness of the proposed nerve block procedure. I did not ask for your opinion regarding the expertise of the pain doctor. Nor did I ask for your opinion regarding the likelihood that I could suffer permanent nerve damage or burn from a radio frequency ablation.

I also asked if you had terminated me as your patient.

It is now six weeks since I wrote my letter. I have my answer. Clearly, you no longer consider me to be your patient, and will not provide me with follow-up care or advice. I regret my decision to undergo extensive and arduous spinal reconstruction

surgery in Dallas. A decision based on you and your staff leading me to believe that I could trust that you would be there to provide me with long-term guidance.

But instead you have allowed me to suffer severe pain for six more weeks, waiting for your response. A response that never came.

Kathryn Marie Jones

Kathryn Marie Jones
PO Box 72107
Phoenix, AZ 85050

44047 N 43RD AVE
PHOENIX, AZ 85087-9998

06/21/2012 04:24:19 PM

Sales Receipt

Product Description	Sale Qty	Unit Price	Final Price
DALLAS, TX 75231			$.45
Zone-5 First-Class Mail® Letter			
0 lb. 0.50 oz.			
* Expected delivery Monday, June 25.			
Certified Mail™			$2.95
%% Label #: See Attached Form			
Issue Postage:			$3.40
Total:			$3.40

Paid by:
MasterCard $3.40
Account #: XXXXXXXXXXXX6050
Approval #: 05109P
Transaction #: 682
23-902380435-99

APC Transaction #: 55
USPS® # 036392-9550

%% To check on the delivery status of this article, visit our Track & Confirm website at USPS.com, use this Automated Postal Center™ (or any Automated Postal Center™ at other Postal locations) or call 1-800-222-1811.

Please retain all receipts from affixed forms. For inquiries, both the sales receipt and the customer copy from the affixed form shall be required.

Thanks.
It's a pleasure to serve you.

ALL SALE ND POSTAGE.
REFUNDS ICES ONLY.

7011 1150 0002 1728 1458

U.S. Postal Service™
CERTIFIED MAIL™ RECEIPT
(Domestic Mail Only; No Insurance Coverage Provided)

For delivery information visit our website at www.usps.com®

Postage	$
Certified Fee	
Return Receipt Fee (Endorsement Required)	
Restricted Delivery Fee (Endorsement Required)	
Total Postage & Fees	$

Postmark Here

Sent To: Dr Jeremy Denning
Street, Apt. No., or PO Box No.: 8230 Walnut Hill Lane Bldg 3 Suite 320
City, State, ZIP+4: Dallas TX 75231

PS Form 3800, August 2006 See Reverse for Instructions

ATION
EN LN
PHOENIX, AZ 85050-9998

06/27/2012 07:02:07 PM

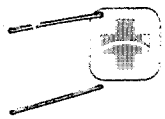
Track & Confirm Delivery Status

You entered 7011 1150 0002 1728 1458

Your item was delivered at 1:01 pm on June 25, 2012 in DALLAS, TX 75231.

For additional information, visit our Track & Confirm website at USPS.com, or call us at 1-800-222-1811.

It' you.



Dallas Neurosurgical & Spine

May 24, 2012

Katherine Marie Jones
P.O. Box 72107
Phoenix, AZ 85050

REMAILED CERTIFIED 6/27/12

Dear Mrs. Jones:

First of all, I apologize for not getting back to you sooner regarding the symptoms that you have been experiencing and specifically stabbing pains in your urethra. I received your recent correspondence regarding these symptoms. I think seeing the urologist was a good move on your part to try to define the pain. The pain that you are experiencing is quite an unusual one and I certainly have not seen this in any of my patients postoperatively.

To perform scoliosis surgery through an anterior approach to the spine basically involves two avenues, one is a direct anterior approach called a lumbar interbody fusion, and the other is extreme lateral or direct lateral transpsoas approach. The lateral approach is the procedure that we elected to use and involved a less invasive procedure, and one in which we do not manipulate the autonomic nerves, specifically, the hypogastric plexi that reside in the anterior lumbar spine.

The traditional way of performing the surgery, approaching the spine anteriorly, does manipulate the autonomic plexus that sits in front of the spine and in males there can be a complication referred to as retrograde ejaculation, which can occur in a small portion of individuals as a complication of the procedure. However, we did not approach your spine through this route, but again, elected to perform a less morbid approach, which basically does not involve manipulating those nerves at all.

If your urologist has done extensive testing and has found no source of the pain, then I think it is a reasonable approach to see the pain specialist who specializes in pelvic pain. Again, this symptom is quite unusual and I really do not have any experience with patients having these sort of symptoms before or after surgery. I do not perform injections, although we do have a pain management in our group. If there is a pelvic pain specialist in your area, then I think that would

Dallas
8230 Walnut Hill Lane
Prof. Bldg. III, Suite 220
Dallas, Texas 75231
214.750.3646
214.739.6815

Allen / McKinney
1105 N. Central Expwy
Suite 2310
Allen, Texas 75013
972.747.6393
214.363.2351

Denton
3537 S. I-35E
Suite 220-B
Denton, Texas 76210
940.484.8800
940.384.4770

Plano
4708 Alliance Blvd
Suite 620
Plano, Texas 75093
972.665.4810
972.665.4815

Rockwall / Rowlett
7801 Lakeview Parkway
Suite 130
Rowlett, Texas 75088
972.475.2150
214.987.4865

be a more practical approach.

Again, I am sorry that I do not have any solid answers for you, but I can tell you that the autonomic plexus that sits in front of the spine was not manipulated at all during your surgery, and that is the advantage of approaching the spine through this lesser invasive manner. If you have any further questions please do not hesitate to write again or contact Sandra. Again, I apologize for not getting back to you sooner and I promise to be more prompt in the future.

Sincerely,

Jeremy W Denning, MD

JWD/WY
D: 5/24/2012 @ 1:52 PM
T: 5/24/2012 @ 3:27 PM
J: 18678738

CERTIFIED MAIL

7010 1870 0000 9123 8423

Dallas Neurosurgical & Spin

8230 Walnut Hill Lane
Professional Bldg. III, Suite 220
Dallas, Texas 75231

7/2
7/7

Katherine Marie Jones
P.O. Box 72107
Phoenix, AZ 85050

A85050$1019 B011

I signed for this Cert receipt
7-5-12

ELSEVIER

The Spine Journal 11 (2011) 511–516

THE SPINE JOURNAL

Clinical Study

Retrograde ejaculation after anterior lumbar interbody fusion using rhBMP-2: a cohort controlled study

Eugene J. Carragee, MD[a,*], Kyle A. Mitsunaga, MD[a], Eric L. Hurwitz, DC, PhD[b], Gaetano J. Scuderi, MD[a]

[a]*Stanford University School of Medicine, 450 Broadway St, Redwood City, CA 94063, USA*
[b]*Department of Public Health, John Burns School of Medicine, University of Hawai'i, Honolulu, HI 96813, USA*

Received 14 February 2011; revised 16 March 2011; accepted 30 April 2011

Abstract

BACKGROUND CONTEXT: The commercially available growth factor recombinant bone morphogenic protein-2 (rhBMP-2) used in spinal fusion has been associated with numerous adverse reactions, including inflammatory reactions in soft tissue, heterotopic bone formation, radiculitis, osteolysis, and cage or graft subsidence. The original Food and Drug Administration Summary of anterior lumbar interbody fusion (ALIF) reported 12 retrograde ejaculation (RE) events (8%) in the rhBMP-2 groups compared with (1.4%) in the control group. It had been debated whether this finding was related to rhBMP-2 use.
PURPOSE: To compare the incidence of RE after ALIF in patients with and without rhBMP-2 use.
STUDY DESIGN: Retrospective analysis of prospectively gathered outcomes data on consecutive subjects having ALIF with and without rhBMP-2 use.
PATIENT SAMPLE: Male patients with lumbar spondylosis or spondylolisthesis having ALIF of the lowest one or two lumbar levels with and without rhBMP-2.
OUTCOME MEASURE: Report of RE as a new finding after ALIF.
METHODS: From the comprehensive outcome database at a high-volume university practice, male subjects having ALIF for one- (L5/S1) or two-level (L4/L5, L5/S1) lumbar fusion were identified. Retrograde ejaculation events were recorded and comparative incidence compared.
RESULTS: The two groups were comparable for age and additional procedures performed. There were 69 L5/S1 ALIFs performed with rhBMP-2 and 174 ALIFs performed without rhBMP-2 during the study period. Of those, 24 and 64 were two-level ALIFs performed with and without rhBMP-2, respectively. There were five RE events (7.2%) reported in the rhBMP-2 group and 1 (0.6%) in the control group. Comparing single-level L5/S1 ALIF, there was a 6.7% and 0% rate of RE in the rhBMP-2 versus control groups, respectively. At 1 year after surgery, three of six affected subjects reported resolution of the RE.
CONCLUSION: This study confirms previous reports of a higher rate of RE in ALIF procedures using rhBMP-2. This may be an important consideration in subjects concerned with sterility after surgery.

Keywords: Anterior lumbar interbody fusion; Retrograde ejaculation; Growth factor rhBMP-2

FDA device/drug status: Not approved for this indication (rhBMP-2 and FRA).

Author disclosures: ***EJC:*** Stock Ownership: Intrinsic Spine (<1% ownership), Simpirica (stock options), Cytonics (Unknown number of options); Private Investments: Simpirica (Unknown number of stocks, D); Consulting: US Department of Justice (D), Kaiser Permanente (D), US Army (Trips/Travel disclosed), US Department of Defense (Trips/Travel disclosed); Research Support (Investigator Salary): NIH (C, Paid directly to institution/employer); Other office: NASS The Spine Journal (E, Editor in Chief); Fellowship Support: OREF (E, Paid directly to institution/employer), AO Foundation (E, Paid directly to institution/employer); Trips/Travel: US Army (B), Department of Defense (A), Orthopaedic Trauma Society (A), OREF (B), AAOS (A), NASS (A), The Spine Journal (A). ***KAM:*** Nothing to disclose. ***ELH:*** Consulting: Society for Chiropractic Orthospinology, Inc. (B), Western University of Health Sciences, (B), National Institutes of Health (A); Trips/Travel: World Spine Care (B); Other relationships: Palmer Center for Chiropractic Research (B). ***GJS:*** Stock Ownership: Cytonics Corp. (4,000,000 shares); Private Investments: K2 Medical; Board of Directors: Cytonics (50,000 shares, 001%, <1% ownership); Scientific Advisory Board: Cytonics (none); Other office: Chairman (none); Grants: SBIR (F).

The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

* Corresponding author. Department of Orthopaedic Surgery, Stanford Medicine Outpatient Center, Stanford University School of Medicine, 450 Broadway St, Pavilion C–MC 6342, Redwood City, CA 94063, USA. Tel.: (650) 721-7616; fax: (650) 721-3470.

E-mail address: carragee@stanford.edu (E.J. Carragee)

1529-9430/$ - see front matter
doi:10.1016/j.spinee.2011.02.013

EVIDENCE & METHODS

Context
Retrograde ejaculation (RE) is a known complication of the anterior approach to the lumbar spine, particularly for interbody fusion at L5–S1. Previous reports have suggested that ALIF using rhBMP-2 might increase the risk of RE when compared to procedures in which BMP is not used. This study sought to confirm or contest these findings.

Contribution
In this retrospective case series report, the authors found that 7.2% of patients in whom BMP was used during ALIF had resultant RE, versus 0.6% in those in whom BMP was not used.

Implication
With the limitations of the study acknowledged, these data are similar to previous reports suggesting increased risk of RE with use of BMP during ALIF at L5–S1. These findings are likely to be important when discussing the risks and complications of this type of surgery with patients.

—The Editors

Introduction

Anterior lumbar interbody fusion (ALIF) may be complicated by retrograde ejaculation (RE) in male patients. The autonomic plexus coordinating bladder sphincter control during ejaculation is intimately associated with the aortic and vena cava and drapes down over the bifurcation and ventral surface of disc and sacral body. This area is necessarily manipulated during an approach to the lower lumbar segments, particularly L5/S1. The reported rates of RE have varied and can be associated with the magnitude of the dissection, the number of levels exposed, and possible soft-tissue debridement necessary in revision, infection, or tumor surgery [1–4].

The commercial human recombinant bone morphogenic protein-2 product (rhBMP-2), INFUSE (Medtronic Inc., Memphis, TN, USA), has been approved for use in the lumbar spine in association with ALIF with an LT-cage (Medtronic Inc.) [5]. The LT-cage is a threaded wedge-shaped cage that engages and distracts the disc space on application. Since its introduction, rhBMP-2 has been associated with multiple serious adverse effects, including soft-tissue swelling, local inflammation, sterile cyst formation, osteolysis, and implant migration, as well as possible increased risk of malignancy in the high-dose AMPLIFY formulation (Medtronic Inc.) [6–22].

The original publications of rhBMP-2 with the LT-cage for ALIF reported no adverse events associated with rhBMP-2. Food and Drug Administration (FDA) documents [23] reported more RE events in the rhBMP-2 group as compared with a control receiving iliac crest bone graft (ICBG) and no rhBMP-2. Smoljanovic et al. [17,24,25] have suggested this effect may be because of either ectopic bone formation in the area ventral to the disc or an inflammatory reaction associated with rhBMP-2. Burkus et al. have denied any association of the RE events with rhBMP-2 [17].

The senior surgeon began using rhBMP-2 in 2003 as a substitute for or augmentation to other fusion techniques for ALIF. We had collected a prospective database on all surgical cases, complications, and outcomes before and after this period of rhBMP-2 introduction. Some of these data have been previously published [26–28]. To investigate the possible effects of rhBMP-2 on the rate of RE after ALIF, we have retrospectively analyzed the data from three years, 2002 to 2004. During this time we began to use rhBMP-2. In this study, we compared the rate of RE in patients who did and did not receive the rhBMP-2.

Methods

Study design and patient selection

Patients of the senior author (EJC) who underwent surgery on investigational protocols for disc herniation, spondylosis, and spondylolisthesis were prospectively enrolled, and preoperative clinical data, operative details, postoperative complications, and postoperative outcomes were recorded by independent research assistants in a deidentified database. Details of the enrollment and data collection protocols have been previously published [26–28]. Specific data collection on RE was included for follow-up of all subjects undergoing anterior lumbar surgery.

From this database during the years 2002 to 2004, patients having one- or two-level ALIF for degenerative spondylolisthesis, low-grade isthmic spondylolisthesis, recurrent lumbar disc herniation, or presumed discogenic pain were identified. Patients were included if the lumbar fusion crossed one- or two-disc levels and included the L5/S1 level. The L5/S1 level was operationally defined for this study as the lowest mobile segment of the lumbar spine with its disc below the aortic bifurcation. That is, regardless of the number of anatomic lumbar vertebrae, the lowest mobile disc below the bifurcation (which determined the dissection) was considered L5/S1.

The 2002 to 2004 time period was selected to include a mix of cases before and after rhBMP-2 was introduced while the surgical indications and technique would have been relatively constant. In 2005, the senior author (EJC) temporarily left his usual university practice for active duty with the US military, and this provided a natural time break for this analysis.

From the data set, a retrospective analysis of the prospectively gathered outcomes data on consecutive subjects

having ALIF with and without rhBMP-2 use was performed regarding the complication of RE.

Purpose

To compare the incidence of RE after ALIF in patients with common lumbar pathology undergoing an ALIF, which included L5/S1 with and without rhBMP-2 use.

Hypothesis

Patients undergoing one-or two-level ALIF including L5/S1 via an open retroperitoneal approach would report RE at the same rate whether rhBMP-2 had been used in the ALIF or not.

Surgical technique

The senior author (EJC) did all the surgical approaches. He had extensive experience with the anterior and anterior-lateral approaches to the spine and trained at the University of Hong Kong and Duchess of Kent Children's Hospital specifically in this technique (1989). At the start of this study, he had 12 years experience doing his own anterior surgical approaches to the spine (1,000 cases or more).

The lower lumbar spine was exposed using a retroperitoneal approach. Depending on the patient's weight and abdominal obesity, either a medial transrectus approach (if thin) or less commonly an anterior-lateral muscle–splitting approach was used. Blunt dissection to the lower one or two discs was performed, and the iliolumbar vessels ligated and transected when necessary to approach L4/L5. No electrocautery was used in male patients at the level of bifurcation of the deep vessels or around the L5/S1 disc. At L5/S1, the middle sacral vessels were ligated and transected or sometimes swept bluntly to the side. The delicate autonomic plexus was divided with a sharp vertical incision in the midline from the bifurcation of the aorta caudally and retracted to either side using a dental roll blunt dissector. If the plexus appeared densely adherent to the disc or bone, several cubic centimeters of sterile saline was injected just ventral to the anterior longitudinal ligament with a long 25-gauge needle to create a dissectible plane in which mobilizes the plexus.

Once the exposure was achieved, it was maintained with a self-retaining retractor. The disc edges were incised off bone with a long scalpel, and the disc was removed piecemeal. End plates were perforated in their center with punctures from a small curette, and a femoral ring allograft (FRA) or titanium mesh cage was placed with the disc space under tension. If rhBMP-2 was not used, local osteophytes or ICBG were used as autograft often along with demineralized bone matrix grafting material. If rhBMP-2 was used, two sponges (Small Kit, 4.2 mg rhBMP-2; Medtronic Sofamor Danek, Memphis TN) were placed inside the FRA central canal. Unless a four-hole plate was used in a stand-alone configuration, a buttress screw was placed, usually, into the caudal vertebrae just below the end plate. Posterior instrumentation, either unilateral or bilateral, was placed as deemed necessary by the pathologic instability of the segment or bone quality.

Statistical analysis

Fisher exact test was used to compare binomial data in which low-frequency events (eg, RE) were anticipated. Statistical significance for complications was determined according to the severity of event, and the potentially serious or catastrophic events (eg, sterility, neurologic injury) were considered significant at a p value of less than 0.2. Number needed to harm (NNH) was computed to determine the number of patients treated with rhBMP-2 to produce one patient suffering harm due to a specific rhBMP-2–associated adverse-event treated (eg, if the risk of a certain adverse event in the treatment group is 10% vs. 0% in the control group, the NNH is 10).

Funding

No funds were received in support of this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.

Results

There were 174 patients identified as receiving an ALIF without rhBMP-2 and 69 receiving an ALIF with rhBMP-2 by the inclusion criteria. The groups were well matched for age, diagnoses, and number of levels fused (Table 1). Most surgeries were performed using a direct anterior approach

Table 1
Demographic and clinical data

	rhBMP-2	Control
n	69	174
Age (SD, range)	42.4 (10.3, 22–65)	40.9 (9.9, 25–65)
Smoker (%)	18 (28)	42 (24)
Weight, kg (SD)	81 (12.1)	79 (13.4)
Diagnoses %		
Degenerative spondy	48	46
Recurrent herniation/DDD	19	23
Isthmic spondy	33	31
One-level ALIF (%)	45 (65)	110 (59)
FRA	68	172
Mesh cage	1	2
Local autograft	6	15
ICBG	0	3
Demineralized bone matrix	0	138
Transrectus retroperitoneal approach (%)	59 (86)	150 (86)
'Anterior-lateral retroperitoneal approach (%)	10 (14)	24 (14)

Spondy, spondylolisthesis; DDD, low back pain illness presumed from degenerative disc disease; ALIF, anterior lumbar interbody fusion; ICBG, iliac crest bone graft; FRA, femoral ring allograft.

(medial transrectus), and virtually all received an FRA structural allograft. Only three mesh cages were used.

There were 45 single-level L5/S1 ALIFs performed with rhBMP-2 and 110 performed without rhBMP-2 during the study period; there were 24 and 64 two-level ALIF's performed respectively.

There were six RE events noted. All occurred after ALIF with FRA spacers, which were overwhelmingly most common spacer used. There was no association with diagnosis (p>.2): in the rhBMP-2 group, two had isthmic spondylolisthesis, two had degenerative spondylolisthesis, and one had presumed discogenic pain.

There were five RE events (7.2%) reported in the rhBMP-2 group and one (0.6%) in the control group (p=.0025). Comparing single-level L5/S1 ALIF, there was an RE rate of 6.7% and 0% in the rhBMP-2 versus control groups, respectively (p=.0233). There were relatively few patients having a two-level ALIF including L5/S1, and there were two RE events in the rhBMP-2 group and one in the control (p=.179) (Table 2).

Of the five patients having an RE event in the rhBMP-2 group, three had some apparent early osteolysis appreciable by plain radiograph in the early postoperative period. One patient had an extensive osteolysis with a fracture of the anterior half of the sacral body. This healed in time without gross displacement (there had been supplemental fixation at the first surgery). The RE was appreciated before the fracture was apparent on radiographs.

At 1 year after surgery, three of six affected subjects reported resolution of the RE: two in the rhBMP-2 group and one in the control group. The two oldest subjects reporting RE, aged 48 and 53 years, did not recover.

During the same study period, one patient having an L4/5 ALIF alone (ie, not included in this analysis but previously reported by this group) for isthmic spondylolisthesis may also have had RE [29]. This patient was diabetic with preexisting neuropathy and erectile dysfunction before surgery. It was difficult to be sure the complaint was in fact RE because of other neuropathic issues. At 6 months after surgery, this patient reported his sexual function had returned to his preoperative status. This was the only possible RE event in an ALIF patient having a lumbar level fusion excluded from this study. He had not received rhBMP-2.

Discussion

Anterior fusion with restoration of disc space height and lordosis may preserve better sagittal alignment and perhaps be associated with a more rapid recovery compared with posterolateral fusion techniques [29]. However, both anterior approaches and posterior lumbar interbody fusion approaches have risk of injury to intervening structures. Retrograde ejaculation is an uncommon complication of anterior fusion of the lower lumbar spine. The mechanism of the injury as a complication of anterior spinal surgery is thought to be a disruption of the superior hypogastric plexus in the retroperitoneal space around the level of the bifurcation of the aorta and the lumbosacral junction [30].

Estimates of incidence of RE after anterior lumbar surgery vary widely [3]. Kaiser et al. [1] reported a 45% incidence of RE after laparoscopic approach to the lumbar spine. At the other extreme, Kang et al. [4] report no RE after 412 minilaparotomic approaches to the lumbosacral spine. It is likely that both the true incidence and detection of RE after spinal surgery may vary by approach, technical expertise, concomitant pathology, and the intensity of the surveillance method.

The use of rhBMP-2 has been associated with various early inflammatory reactions, including soft-tissue swelling and sterile cyst formation. In the neck, these may result in life-threatening complications. In bone, rhBMP-2 may cause early osteolysis and can be associated with implant dislodgment, subsidence, and loss of alignment [6–22]. Obviously any of these events can theoretically affect the autonomic plexus.

Food and Drug Administration documents [23] and Smoljanovic et al. [17,24,25] also reported a high rate of RE associated with rhBMP-2 use in the LT-cage/rhBMP-2 trial (7.9%, rhBMP-2 group vs. 1.4%, ICBG group), overall (NNH=15, Fisher exact p=.05). With the laparoscopic approach, more than 9% of the patients in the FDA trial receiving rhBMP-2 and an LT-cage reported RE. In the randomized controlled trial phase of the FDA trial, there was an incidence of RE in 6.4% of male patients having an open ALIF with rhBMP-2 compared with 1.5% in the control (ICBG) group (NNH 20; Fisher exact p=.14).

Reporting on anterior interbody fusion in the setting of rhBMP-2 use, Jarrett et al. [2], in 2009, reported a 6.2%

Table 2
Retrograde ejaculation events

	rhBMP-2	Control	p Value*
L5/S1 (single level)	3 of 45 (6.7%, 90% CI: 0.55, 12.79)	0 of 110 (0%, 90% CI: <2.4)	.0233
L4/L5 and L5/S1	2 of 24 (8.3%, 90% CI: −0.95, 17.61)	1 of 64 (1.6%, 90% CI: −0.9%, 4.1%)	.179
Total	5 of 69 (7.3%, 90% CI: 2.11, 12.39)	1 of 174 (0.6%, 90% CI: −0.37, 1.51)	.0025

CI, confidence interval.
* Fisher exact test.

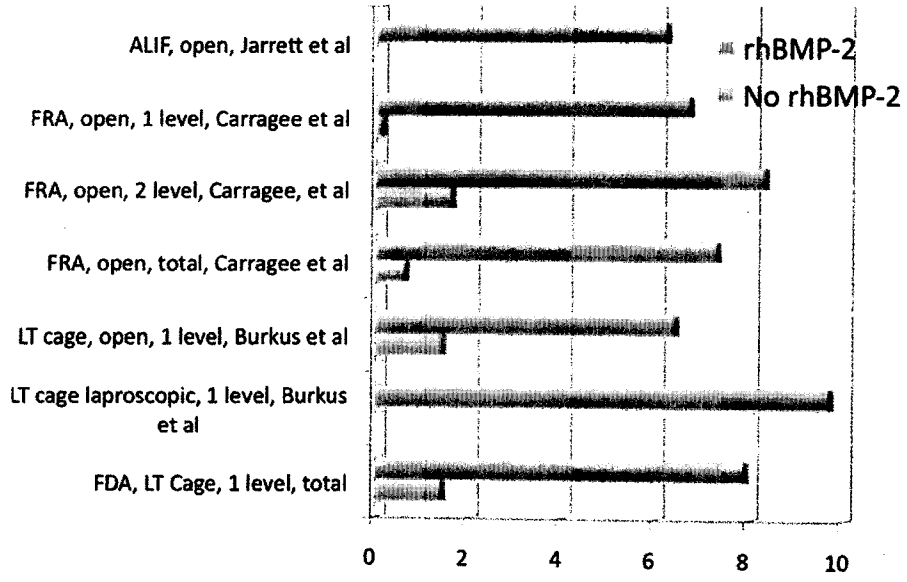


Figure. Comparison of retrograde ejaculation rates in male patients after anterior lumbar interobdy fusion (ALIF) from three studies: ALIF with recombinant bone morphogenic protein 2 (rhBMP-2) by Jarrett; femoral ring allographft (FRA)/rhBMP-2 vs. control group (single level and two levels) by Carragee et al.; LT cage/rhBMP-2 vs. control (open) group, LT cage/rhBMP-2 (laparaoscopic) group by Burkus et al.; and FDA data LT cage vs. control, total cases [2,5,17,23,24].

rate of RE. This is nearly identical to the rate reported by the FDA and Burkus et al. (6.4%). The rate in our review for patients receiving rhBMP-2 at a single level was also 6.7%. Our rate of RE in ALIF patients without rhBMP-2 was 0% and 1.6% for one- and two-level ALIF, respectively. Again this was very similar to the non-rhBMP-2 group in the FDA trial of FDA study (1.4%), but both were higher than reported by Kang et al. [4] (Figure).

The present study design has several inherent limitations and potential biases. The case review and analysis were retrospective with a database that did not allow primary chart review (perhaps biasing to lower rates of RE recognized). However, the surveillance for RE was the same for both rhBMP-2 cases and controls at the time of data collection and entry. Second, because a bilateral injury to the superior hypogastric plexus is more likely when dissecting between the bifurcation of the aorta [30], RE may be more common with ALIF involving the L5/S1 disc compared with a unilateral approach to L3/L4 or L4/L5. In our study design, all cases included an L5/S1 ALIF by case definition. It is likely, therefore, that the selection of ALIF cases that all involved at least the lumbosacral junction increased the incidence compared with a series that included fusion at higher levels without dissection to the lumbosacral junction. Finally, the placement of an FRA spacer may be less invasive, requiring less dissection than the placement of two threaded cages. Still, the reporting of RE rates from three separate series of 6% to 7% is much higher than both the FDA data (1.4%), the large series by Kang et al. (0%) and our previous and continuing experience of the senior author for ALIF without rhBMP-2 (0.5–1.5%).

Although uncommon, the risk of RE is an important potential complication for many male patients and their families. In a study at our institution of ALIF for isthmic spondylolisthesis, 8% of men refused anterior surgery because of the risk of RE, when the risk of RE was explained to them to be 1% or less (our previous experience) [29]. With the serious possibility that RE is associated with rhBMP-2 use in the lower lumbar spine, it is important that men be counseled about this risk and advised that avoiding rhBMP-2 in favor of alternative grafting methods may minimize the risk.

It is our practice to limit the use of rhBMP-2 with ALIF surgery to patients in whom the benefit is much clearer than appears to exist in the healthy patients undergoing single-level fusion in the rhBMP-2 industry-sponsored trials. Patients with a metabolic bone disease (eg, osteomalacia or osteoporosis), adverse exposure (eg, tobacco, radiation), or specific anatomic risks for nonunion may have a benefit to risk ratio favoring rhBMP-2 use. However, appropriate and specific discussion in male patients regarding the increased risks of sterility may be appropriate.

Conclusion

This study supports multiple lines of evidence that strongly suggest rhBMP-2 use with an anterior interbody fusion at the lumbosacral junction is associated with an increased risk of RE.

References

[1] Kaiser MG, Haid RW, Subach BR, et al. Comparison of the mini-open versus laparoscopic approach for anterior lumbar interbody fusion: a retrospective review. Neurosurgery 2002;51:97–103; discussion 103–5.

[2] Jarrett CD, Heller JG, Tsai L. Anterior exposure of the lumbar spine with and without an "access surgeon": morbidity analysis of 265 consecutive cases. J Spinal Disord Tech 2009;22:559–64.

[3] Fenton JJ, Mirza SK, Lahad A, et al. Variation in reported safety of lumbar interbody fusion. Spine 2007;32:471–80.

[4] Kang B, Choi W, Lee S, et al. An analysis of general surgery-related complications in a series of 412 minilaparotomic anterior lumbosacral procedures. J Neurosurg Spine 2009;10:60–5.

[5] Burkus JK, Heim SE, Gornet MF, Zdeblick TA. Is INFUSE bone graft superior to autograft bone? An integrated analysis of clinical trials using the LT-CAGE lumbar tapered fusion device. J Spinal Disord Tech 2003;16:113–22.

[6] Carragee EJ, Bono CM, Scuderi GJ. Pseudomorbidity in iliac crest bone graft harvesting: the rise of rhBMP-2 in short-segment posterior lumbar fusion. Spine J 2009;9:873–9.

[7] Center for Devices and Radiological Health. Public Health Notifications (Medical Devices)—FDA Public Health Notification: life-threatening complications associated with recombinant human bone morphogenetic protein in cervical spine fusion. Available at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062000.htm. Accessed January 18, 2011.

[8] Food and Drug Administration. Public Meeting Orthopedic and Rehabilitation Devices Advisory Panel. Proceedings January 10, 2002.

[9] Helgeson MD, Lehman RA, Patzkowski JC, et al. Adjacent vertebral body osteolysis with bone morphogenetic protein use in transforaminal lumbar interbody fusion. Spine J 2011;11:507–10.

[10] Klimo P Jr, Peelle MW. Use of polyetheretherketone spacer and recombinant human bone morphogenetic protein-2 in the cervical spine: a radiographic analysis. Spine J 2009;9:959–66.

[11] Knox JB, Dai JM, Orchowski J. Osteolysis in transforaminal lumbar interbody fusion with bone morphogenetic protein-2. Spine 2011;36:672–6.

[12] Mannion RJ, Nowitzke AM, Wood MJ. Promoting fusion in minimally invasive lumbar interbody stabilization with low-dose bone morphogenic protein-2—but what is the cost? Spine J 2011;11:527–33.

[13] Mroz TE, Wang JC, Hashimoto R, Norvell DC. Complications related to osteobiologics use in spine surgery: a systematic review. Spine 2010;35(9 Suppl):S86–S104.

[14] Perri B, Cooper M, Lauryssen C, Anand N. Adverse swelling associated with use of rh-BMP-2 in anterior cervical discectomy and fusion: a case study. Spine J 2007;7:235–9.

[15] Rihn JA, Patel R, Makda J, et al. Complications associated with single-level transforaminal lumbar interbody fusion. Spine J 2009;9:623–9.

[16] Smoljanovic T, Pecina M. Re: Burkus JK, Sandhu HS, Gornet MF. Influence of rhBMP-2 on the healing patterns associated with allograft interbody constructs in comparison with autograft. Spine 2006;31:775–81. Spine 2008;33:226.

[17] Smoljanovic T, Siric F, Bojanic I. Six-year outcomes of anterior lumbar interbody arthrodesis with use of interbody fusion cages and recombinant human bone morphogenetic protein-2. J Bone Joint Surg Am 2010;92:2614–5. Author reply 2615–6.

[18] Smucker JD, Rhee JM, Singh K, et al. Increased swelling complications associated with off-label usage of rhBMP-2 in the anterior cervical spine. Spine 2006;31:2813–9.

[19] Tumialán LM, Rodts GE. Adverse swelling associated with use of rh-BMP-2 in anterior cervical discectomy and fusion. Spine J 2007;7:509–10.

[20] Vaidya R, Weir R, Sethi A, et al. Interbody fusion with allograft and rhBMP-2 leads to consistent fusion but early subsidence. J Bone Joint Surg Br 2007;89:342–5.

[21] Williams BJ, Smith JS, Fu K, et al. Complications associated with BMP use in 11,933 cases of spinal fusion. Spine J 2010;10(9 Suppl 1):S98–9.

[22] Wong DA, Kumar A, Jatana S, et al. Neurologic impairment from ectopic bone in the lumbar canal: a potential complication of off-label PLIF/TLIF use of bone morphogenetic protein-2 (BMP-2). Spine J 2008;8:1011–8.

[23] United States Food and Drug Administration. Department of Health and Human Services, Center for Devices and Radiological Health. INFUSE bone Graft/LT-CAGE? Lumbar tapered fusion devices—P000058. 2002. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num5P000058. Accessed January 20, 2011.

[24] Smoljanovic T, Bojanic I, Rakovac M. Re: Sasso RC, Burkus JK, LeHuec JC. Retrograde ejaculation after anterior lumbar interbody fusion: transperitoneal versus retroperitoneal exposure. Spine (Phila Pa 1976) 2003;28:1023–6. Spine 2010;35:E622. Author reply E623.

[25] Smoljanovic T, Rakovac M, Bojanic I. Could chronic host inflammatory response be responsible for delayed onset of retrograde ejaculation after the labeled use of recombinant human bone morphogenetic protein-2? Spine J 2011;11:167–8.

[26] Carragee E, Wildstein M. A controlled trial of BMP and unilateral transpedicular instrumentation in circumferential single or double level lumbar fusion. Spine J 2007;7:8S–9S.

[27] Carragee EJ, Kim DH. A prospective analysis of magnetic resonance imaging findings in patients with sciatica and lumbar disc herniation. Correlation of outcomes with disc fragment and canal morphology. Spine 1997;22:1650–60.

[28] Carragee EJ, Han MY, Suen PW, Kim D. Clinical outcomes after lumbar discectomy for sciatica: the effects of fragment type and anular competence. J Bone Joint Surg Am 2003;85:102–8.

[29] Swan J, Hurwitz E, Malek F, et al. Surgical treatment for unstable low-grade isthmic spondylolisthesis in adults: a prospective controlled study of posterior instrumented fusion compared with combined anterior-posterior fusion. Spine J 2006;6:606–14.

[30] Lu S, Xu Y, Chang S, et al. Clinical anatomy study of autonomic nerve with respective to the anterior approach lumbar surgery. Surg Radiol Anat 2009;31:425–30.

SUN CITY WEST AMBULATORY SURGERY CENTER
14416 WEST MEEKER BLVD, #103
SUN CITY WEST, AZ 85375

Line 29
L Injection

POST PROCEDURE INSTRUCTIONS

☐ No driving today. Go home and rest. Do not bathe for 24 hours. Leave the band-aid on for 12 hours. You should be able to return to work the day after the procedure. Many procedures can take several days to be effective.

☐ You can resume all your regular medications/supplements after the procedure without restrictions except anticoagulants.

☐ Anticoagulants: Follow up with your primary care physician for instructions on when to resume.

☐ Symptoms commonly experienced: soreness/tenderness at the injection site, increased stiffness or muscle spasm, increased pain for 1-3 days as the anesthetic wears off and before the steroid begins to take effect.

☐ For discomfort: Ice pack 20-30 minutes every 2 hours and rest. You may use Tylenol, or your pain medication. Be patient and try these treatments before considering additional measures.

☐ If you received a steroid injection, a small percentage of patients may experience additional temporary side effects: sweating, flushing or redness of the face/chest, increased heart rate, moodswings, increased appetite, restlessness, slight increased blood pressure, difficulty sleeping, anxiety, hiccups, headache, extra energy, minor swelling, upset stomach, menstrual changes, frequency of urination; increased blood sugar; and slight fever (Temperature 99-100) with flu-like symptoms.

☐ Today you received (circle): methylprednisolone kenalog celestone other none

☐ _____

☐ If you experience the following symptoms you need to notify Dr. Puttlitz at **(623)972-3800.** If you cannot wait for a return call or you are unable to contact a physician, then proceed to the nearest emergency room. SYMPTOMS INCLUDE THE FOLLOWING:
Progressively worsening weakness, bleeding at the injection site that is not stopped within 20 minutes of pressure, seizures, difficulty breathing or speaking, high fevers (>101), loss of bowel or bladder control, inability to urinate.

☐ Follow up with Dr. Puttlitz for an office visit in **ANY TIME AFTER** 2 weeks.

Call 6-12-12
Injection

☐ Call Dr. Puttlitz's office after 2 weeks from today and schedule your next injection.

_____
Patient/Responsible Person

_____ _____
Discharging Physician Date/Time

_____
Witness

JONES. KATHRYN Sex: F (480) 650-8263
Acct: 555432 DOB: [redacted]950
PO Box 72107, Phoenix, AZ 85050
6/29/12 1:15 pm CS: 99
Amsurg SCW O.R. Room C
Aetna Us Healthcare
AS:100% Insurance
UPIN: N/A

JONES. KATHRYN Sex: F (480) 650-8263
Acct: 555432 DOB: [redacted]950
PO Box 72107, Phoenix, AZ 85050
6/29/12 1:15 pm CS: 99
Amsurg SCW O.R. Room C
Aetna Us Healthcare
AS:100% Insurance
UPIN: N/A

scwasc Pain Packet (Dr. ____

TKT:2775598

ARIZONA NEUROLOGICAL INSTITUTE
Phone: 623-972-3800
PROCEDURE INSTRUCTIONS

PATIENT NAME: _____
PROCEDURE: _____
PROCEDURE DATE: _____
ARRIVAL TIME: _____ SCHEDULED TIME: _____

PLEASE READ THE FOLLOWING INSTRUCTIONS
(SIGN ON THE NEXT PAGE AFTER COMPLETION)

BEFORE PROCEDURE:

LOCATION AND GENERAL INFORMATION: The procedure is to be performed at Lumbar sympathetic block (hypogastric plexus block

For your comfort, the procedure may be performed with intravenous (IV) conscious sedation (to help with relaxation and pain) under x-ray (fluoroscopic) guidance for accurate needle placement. **Failure to adhere to the following instructions may result in cancellation of the procedure. If you have any questions, please call our office at 623-972-3800** Jennifer / Pain Division – Injection schedule hypogastric plexus block

SCHEDULING. Allow 60-90 minutes for procedures (two hours for discograms). You will be observed after the procedure. You must allow time for us to complete paperwork and get you prepped for the procedure; consequently, your arrival time listed above is earlier than your scheduled procedure time. You will be kept in the facility under supervision after the procedure, until we are sure that you are fully awake, alert, and have recovered from the procedure.

FOOD. If you have a morning procedure, do not eat or drink anything after midnight. If your procedure is scheduled in the afternoon, you may have a CLEAR liquid breakfast before 7 AM. Do not eat or drink 6 hours prior to the procedure if you are to be sedated.

MEDICATIONS (PART I). The following medications promote bleeding and must (or may have to) be discontinued prior to your injection. You cannot discontinue these medications without first seeing and obtaining written permission from your prescribing / treating physician:

Coumadin (warfarin)
Heparin: stop
Lovenox (Enoxaparin)
Fragmin (Dalteparin)
Persantine (Dipyridamole): stop 7 days prior
Plavix (clopidogrel)
Ticlid (ticlopidine)

Patient Signature_____ **Date**_____

SEE OTHER SIDE

YOUR NEXT APPOINTMENT WITH
KIRK PUTTLITZ, M.D. IS
Friday June 29 12:15

LAKES I - 10474 W. Thunderbird Blvd. | Suite 200 | Sun City, AZ 85351
WEST VALLEY - 10240 W. Indian School Rd. | Bldg. 1 | Suite 115 | Phoenix, AZ 85037
GLENDALE - 11851 N. 51st Ave. | Bldg. E | Suite 130 | Glendale, AZ 85304
LAKES II - 10494 W. Thunderbird Blvd. | Suite 108 | Sun City, AZ 85351
SUN CITY WEST - 14418 W. Meeker Blvd. | Suite 210 | Sun City West, AZ 85375
SCOTTSDALE - 7304 E. Deer Valley Rd. | Suite E100 | Scottsdale, AZ 85255

MEDICATIONS (PART II). The following medications promote bleeding and need to be stopped 5-7 days prior to your injection. Please notify the prescribing physician before discontinuing these medications; *DO NOT STOP TAKING YOUR OTHER REGULAR MEDICATIONS (FOR BLOOD PRESSURE, DIABETES, ETC):*

aspirin (Ecotrin; Ascriptin, Empirin, Bayer)
bromfenac (Duract)
diflunisal (Dolobid)
etodolac (Lodine)
flurbiprofen (Ansaid)
indomethacin (Indocin)
Excedrin
ketoprofen (Orudis, Actron)
ketorolac (Toradol)
meclofenamate (Meclomen)
mefenamic acid (Ponstel)
oxaprozin (Daypro),
piroxicam (Feldene)
salsalate (Disalcid; Salflex)
sulindac (Clinoril)
tolmetin (Tolectin)
Trilisate (salicylate combination)
diclofenac (Cataflam, Voltaren)
naproxen (Naprosyn; Aleve; Anaprox)
ibuprofen (Motrin, Advil, Nuprin, Rufen)
Relafen (nabumetone)
Vicoprofen (hydrocodone/ibuprofen)

Note: *soma compound* (carisoprodol *and aspirin*) must be discontinued 5-7 days prior to the procedure, but soma (carisoprodol *without aspirin*) does not need to be stopped.

Please inform the physician performing the procedure of all known medication allergies.

Discontinue the following herbs, as they may cause bleeding: feverfew, garlic, ginger, ginkgo biloba., Vitamin E.

SMOKING. Do not smoke the day of the procedure.

TRANSPORTATION. You should have a driver accompany you. You will not be allowed to drive yourself home.

ILLNESS. Any recent fever, colds, nausea, vomiting or infections MUST be brought to the attention of our office staff as soon as possible (e.g., prior to the day of the procedure). If you have an infection, please cancel your procedure by calling our office as soon as possible at 623-972-3800, as the injected steroid can worsen an infection.

BLOOD SUGAR. If you are diabetic and you are injected with steroid (Depomedrol, Kenalog, Celestone, etc.), your blood sugars may increase. We advise that during the weeks following the procedure that you frequently monitor your blood sugar and report these results to your primary care or treating physician.

CANCELLATION. Please call at least 48 hours in advance if you must cancel your procedure to avoid a $100.00 late cancellation fee.

ADDITIONAL INSTRUCTIONS. We will provide more detailed post-procedure instructions just prior to discharge.

I have read the above. All my questions have been answered and I have been given a copy of these instructions.

PATIENT: _____ DATE: _____

From: Sandra Chavez [mailto:SChavez@dallasneuro.com]
Sent: Monday, August 20, 2012 6:27 AM
To: A W Jones
Subject: RE: Post-surgery Bone Growth

Mrs. Jones,

Dr. Denning is currently out of town til mid next week, I will make sure he gets your email when he gets back

sc

From: A W Jones [mailto:[redacted]]
Sent: Saturday, August 18, 2012 1:54 PM
To: Sandra Chavez
Subject: Post-surgery Bone Growth

Hi Sandra –

Could you please forward this e-mail to Dr. Denning. Thanks.

Dr. Denning –

Recently, I have experienced significant bone growth in my spine. I can feel it when I put my hands on my back. And my spine is less fatigued, and more able to support itself.

But, I am also experiencing bone growth in other areas of my body. Within the last week, there has appeared a large mass of bone adjacent to, and on the toe side, of my left ankle. There is no pain at that site. There also appears to be a smaller bony spot growing next to my left knee. Smaller joints also seem to be affected. Are these bone growths related to my spinal surgeries?

Another complication of my surgeries appears to be a loss of hair. I have seen several doctors in the past few months, and may finally have an answer. I have an iron deficiency, which combined with the bone growth and Gentamicin shots, is probably responsible for the loss of more than half of the hair on my head. Other body areas are also affected. I have started iron supplements.

Your letter of May 24, 2012 stated that I should not hesitate to write if I have questions, or to contact Sandra. Also that you promised to be more prompt in the future. Please address the issue of the bone growths promptly. I did not receive an answer to my letter of July 6, 2012 at all.

Kathryn Marie Jones

Chavez
ct: Post-surgery Complications

Hi Sandra --

Please forward this email to Dr. Denning. Thank you.

Dr. Denning

I did not receive a response to my email sent on Saturday. Why not? I am very disappointed at your lack of response. I did not expect that from you.

I am scheduled for a bladder procedure next week, in which I will have an antibiotic "cocktail" infused directly into my bladder. The doctor has not yet determined which antibiotics she will be using. I feel that I need this procedure, even though the injections of Gentamicin that I have already received may have contributed to my extensive hair loss. So I am hoping these next medications will not have the same effect.

But I recently learned that Medtronics bone graft devices can cause urinary problems. So, I need to know if I have Medtronic infUSE bone graft implants. I need to make an informed decision. I may not need the bladder procedure. Or perhaps the chosen antibiotics need to reflect that the bone graft devices may be causing, or contributing to, my bladder problem. I cannot make an informed decision without knowing what implant devices were inserted in my spine.

Why was this information not provided to me when I had my surgeries? When I recently had eye surgery, the doctor provided me with a card stating the name of the device and its serial number, before I left the facility. Surely the information on my spinal implants is at least as important as info on a lens implant.

I need this information now. Please email it to me today.

Kathryn Marie Jones

From: A W Jones [mailto:a[redacted]
Sent: Saturday, September 22, 2012 1:39 PM
To: 'Sandra Chavez'
Subject: RE: Post-surgery Bone Growth
Importance: High

Hi Sandra --

Please forward this email to Dr. Denning.

Dr. Denning --

I did not receive a response to my email of 9-21-12, nor to the certified mail sent to (which you received on 9-7-12). Therefore, it is quite clear that you have terminated me as your patient.

Please respond to the following questions by email immediately. What are the specific names and identifying numbers for the Medtronics implants that you inserted in my back? Do I have Medtronic infUSE Bone Grafts? If so, how many?

Also, send me copies of all of my medical records. Include the surgical report, office visit records, hospital visit records, records related to Medtronics, records and correspondence related to Aetna, records and correspondence related to any and all other medical providers (such as Dr. Kirby, etc.), and copies of all communications with me and/or my husband. Send these to me, at no cost, as soon as possible.

Thank you in advance for a prompt response.

Kathryn Marie Jones

From: A W Jones [redacted]
Sent: Saturday, September 22, 2012 1:55 PM
To: 'Hagan, Paula'
Subject: RE: Medical Devices

Importance: High

Tracking:

Recipient	Read
'Hagan, Paula'	Read: 9/22/2012 4:56 PM

Ms. Hagan –

As you will recall, I underwent back surgery at Texas Health Presbyterian Hospital Dallas on October 26 and October 27, 2010. I am experiencing complications, and would like the hospital to provide me with the following information immediately.

Please email answers to the following questions immediately. What are the names and serial numbers for the Medtronics implants that were inserted in my back? How many bone graft spacers were implanted? Do I have Medtronics inFUSE bone graft devices? If not, please provide information and proof of the spacers that were used.

Also, could you please send me all of my medical records as soon as possible. Include the surgical report, nursing reports, ICU records, Intermediate care records, and Rehabilitation records. Be sure to include all records and correspondence with Aetna, and authorizations regarding the surgeries and implant devices, etc. – as well as the same for Medtronics. Include copies of all correspondence between the hospital (and hospital personnel) and my doctors, me, and/or my husband.

Thank you in advance for your timely response.

Kathryn Marie Jones

From: Hagan, Paula [mailto:PaulaHagan@texashealth.org]
Sent: Tuesday, October 12, 2010 4:57 PM
To: 'a[redacted]
Subject: RE: Medical Devices

Dear Ms. Jones,

This is a follow up to my email from yesterday and our previous conversation. It is my understanding your surgeon, Dr. Denning, is planning to implant an interbody fusion device manufactured by Medtronic during your spinal fusion surgery scheduled for October 26.

I spoke again today with the manager of the hospital's Materiels Management Department responsible for ordering products and supplies for the Operating Room. He checked on your inquiry of whether Medtronic provides a manufacturer's warranty for spinal fusion devices and determined that Medtronic does not provide a warranty for any implantable medical devices. He was informed this is industry standard and not applicable solely to Medtronic.

Our manager described the following process to me regarding devices purchased by Texas Health Presbyterian Hospital Dallas and provided to patients:

All medical devices and supplies purchased by the hospital and furnished to our patients are newly manufactured. Medical devices to be used in surgery are typically delivered to the hospital several days before the patient's surgery unless it is a standard device that is already in the hospital's inventory. Devices are selected by the patient's physician. Then prior to surgery, the devices are wrapped and sterilized by the hospital's sterile supply department and then brought into the surgical suite at the time of surgery.

I hope this information is helpful and alleviates your concern about the "as is" wording in our universal consent form. If you have any further questions, please let me know. I also hope you have a safe trip from Phoenix to Dallas.

Sincerely,
Paula Hagan
Vice President & Assistant General Counsel,
Texas Health Resources
(214) 345-7788

From: A W Jones [mailto[redacted]]
Sent: Monday, October 11, 2010 4:37 PM
To: Hagan, Paula
Subject: Medical Devices

Dear Ms. Hagan –

I spoke with you several weeks ago about the medical devices that will be used in my surgeries with Dr. Denning scheduled for October 26 and 27. As you will recall, my concern was with the wording in the "Universal Consent For Treatment" form that Presbyterian Hospital will require me to sign upon admission. That form states that all medical devices are supplied on an "AS IS" basis. It also states that I may request manufacturer's warranty information.

As you know, I am not very comfortable with the clause about devices implanted in my back being provided in an "as is" condition. You told me that you would provide me with information about the hospital procedures concerning the handling of such devices; and I said that would give me a higher level of confidence. But I have not received that information.

Also, prior to speaking with you, I spoke with your assistant; and she said she would try to obtain warranty information for me. I have not received that either.

Could you please let me know the status of these endeavors. I will be leaving home in about a week to travel to Dallas. Thank you.

Kathryn Marie Jones

A W Jones

From: Hagan, Paula [PaulaHagan@texashealth.org]
Sent: Tuesday, September 25, 2012 12:07 PM
To: [redacted]
Cc: Goodwill, Amanda
Subject: Authorization forms
Attachments: Katherine Marie Jones.pdf

Ms. Jones, attached, is the authorization form marked up for our HIM Department to email you the pages from your record that contain information regarding your spinal infusion device. You will need to fill in your phone number and SSN and then sign.

I spoke with Amanda, and she said it would be helpful to the HIM Department if you would sign the attached form for the pages to be emailed to you and then sign a second form for the copy of the record to be mailed.

I'm going to refer you to Amanda regarding the copy to be mailed. I'll cc her on this as she has a question to ask you about sending the copy of the complete record in paper form or copied on to a CD for you. She also has a suggestion that you may want to consider.

If you have any questions about the form I've attached, feel free to call me at 682.236.7147.

Paula Hagan

A W Jones

From: Hagan, Paula [PaulaHagan@texashealth.org]
Sent: Tuesday, September 25, 2012 12:07 PM
To: [redacted]
Cc: Goodwill, Amanda
Subject: Authorization forms
Attachments: Katherine Marie Jones.pdf

Ms. Jones, attached, is the authorization form marked up for our HIM Department to email you the pages from your record that contain information regarding your spinal infusion device. You will need to fill in your phone number and SSN and then sign.

I spoke with Amanda, and she said it would be helpful to the HIM Department if you would sign the attached form for the pages to be emailed to you and then sign a second form for the copy of the record to be mailed.

I'm going to refer you to Amanda regarding the copy to be mailed. I'll cc her on this as she has a question to ask you about sending the copy of the complete record in paper form or copied on to a CD for you. She also has a suggestion that you may want to consider.

If you have any questions about the form I've attached, feel free to call me at 682.236.7147.

Paula Hagan

Texas Health Resources

AUTHORIZATION FOR RELEASE OF PATIENT INFORMATION

Name of Patient: Katherine Marie Jones Phone Number: _____

Other Names Used: _____ Date of Birth: [redacted]50 Social Security Number: XXX -- _____ - _____

I, the undersigned, authorize the release of or request access to the information specified below from the medical record (s) of the above-named patient.

PATIENT INFORMATION IS NEEDED FOR: PLEASE SELECT ONE OPTION

☑ Continuing Medical Care ☐ Military ☐ Personal Use School ☐ Insurance
☐ Legal Purposes ☐ Social Security/Disability OTHER: _____

DATE (s) OF TREATMENT: _____

INFORMATION TO BE RELEASED OR ACCESSED:

☐ History & Physical ☐ Discharge/Death Summary ☐ Consultation Report Operative Reports
Emergency Room Record ☐ Face Sheet Lab Reports Pathology Reports
Radiology Reports ☐ Radiology Images ☑ OTHER Spinal infusion device sticker pages

FORMAT REQUESTED FOR INFORMATION TO BE PROVIDED:

Paper ☑ Electronic media ~~(requires 2 business days~~; only applies to data stored electronically) ~~a fee applies~~

METHOD OF DELIVERY:

☐ Pick Up (You will be notified via a telephone call when records are ready for pick up)
☐ Mail to Address listed below
☑ Via email

TEXAS HEALTH PRESBYTERIAN HOSPITAL DALLAS May release the above information to:
(Hospital Name)

Kathryn Marie Jones
(Name)

[redacted]
Address (Street, State, Zip Code) Phone Number

I understand that my records are confidential and cannot be disclosed without my written authorization, except when otherwise permitted by law. Information used or disclosed pursuant to this authorization may be subject to re-disclosure by the recipient and no longer protected. I ~~understand that the specified information to be released may include, but is not limited to~~ history, diagnoses, and/or treatment of ~~drug or alcohol abuse, mental illness, or communicable disease, including Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS)~~.

I understand that treatment or payment cannot be conditioned on my signing this authorization, except in certain circumstances such as for participation in research programs, or authorization of the release of testing results for pre-employment purposes. I understand that I may revoke this authorization in writing at any time except to the extent that action has been taken in reliance upon the authorization. I understand I may be charged a retrieval/processing fee and for copies of my medical records according to Texas Hospital Licensing law.

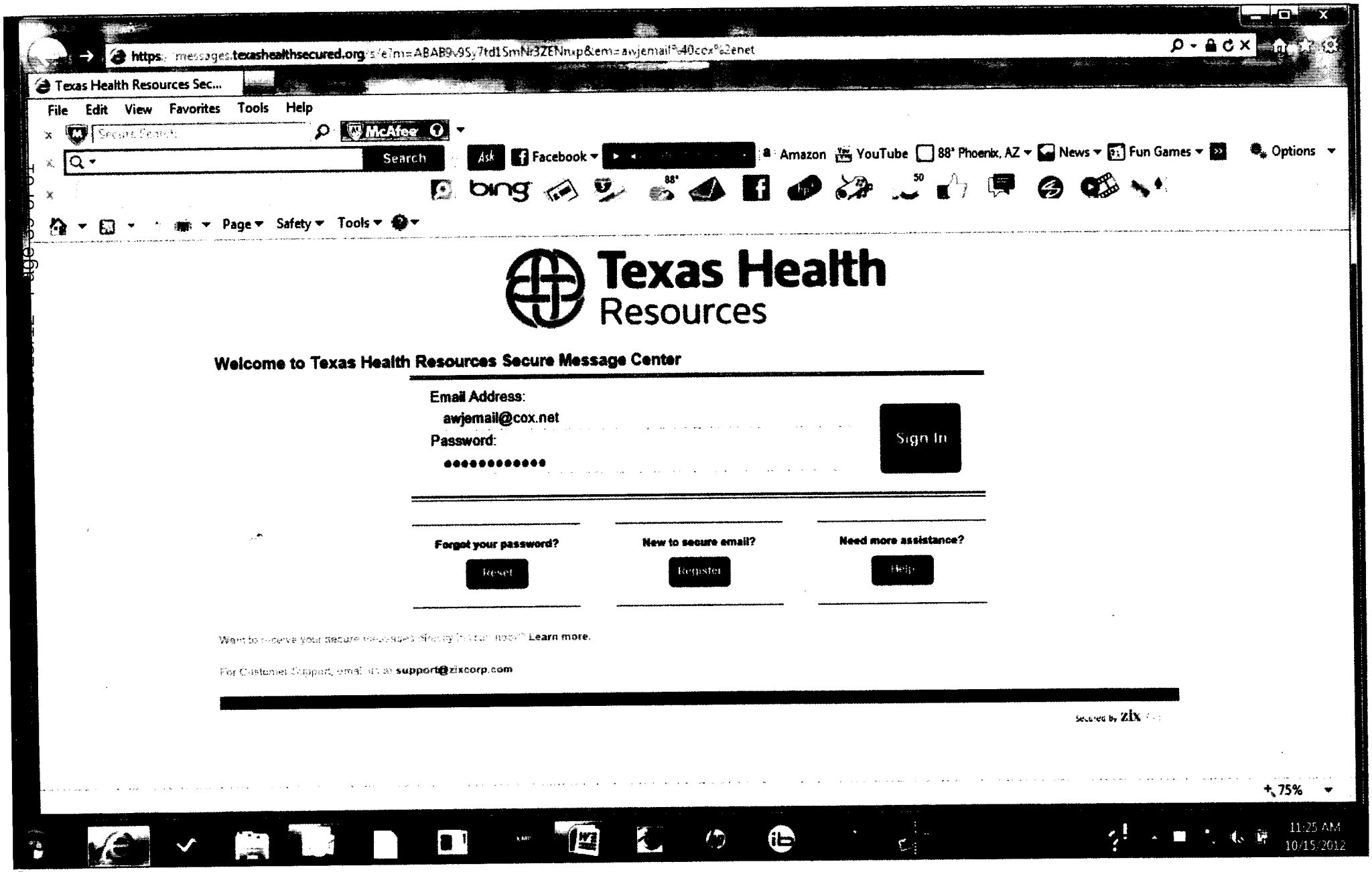
This authorization will expire One Hundred Eighty (180) days from the date of my signature unless I revoke the authorization prior to that time or unless otherwise specified by date, event, or condition as follows: _____.

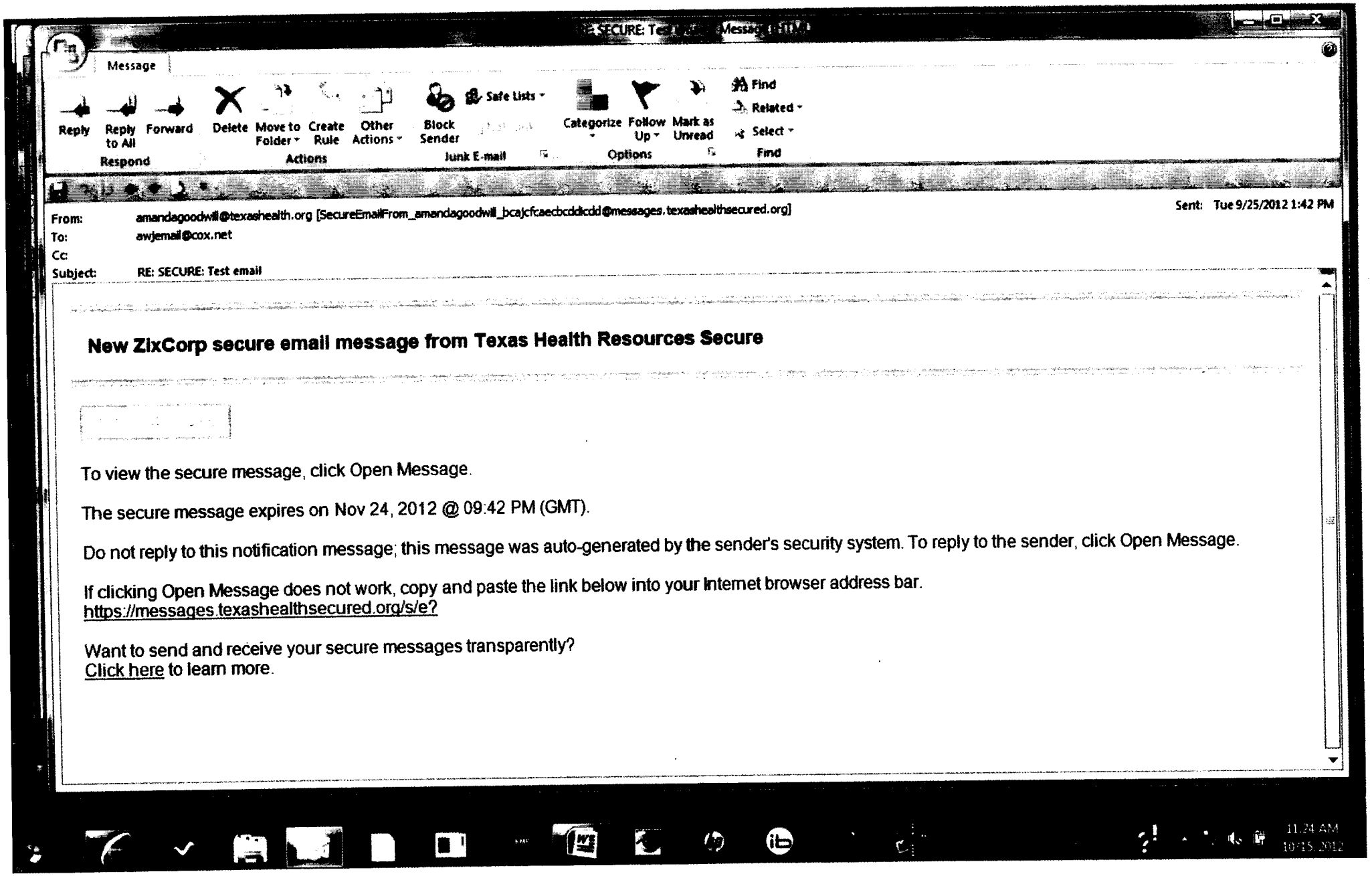
Date: _____ Signature: _____
Patient or Legally Authorized Representative

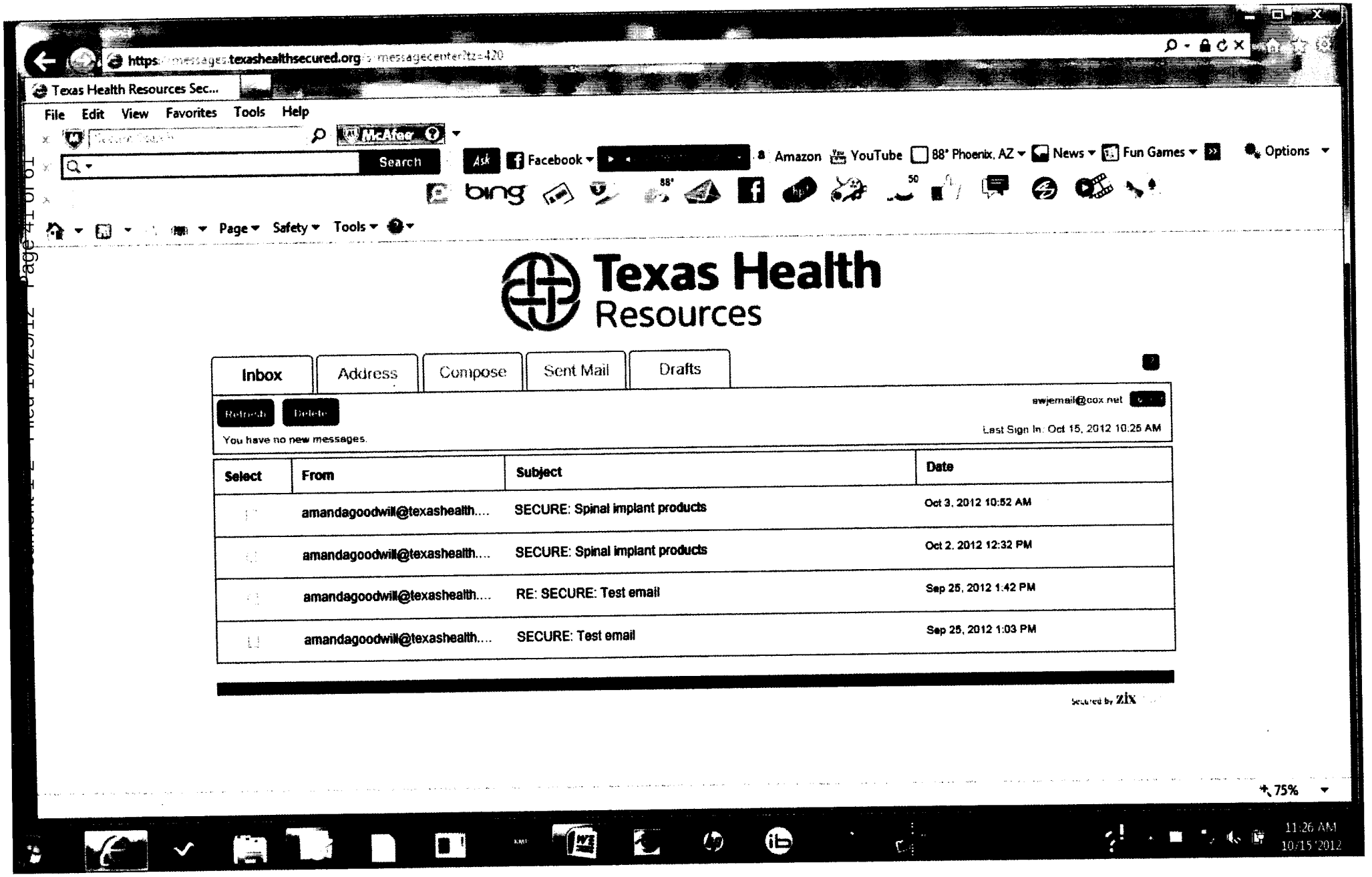
_____
Printed Name of Patient or Legally Authorized Representative

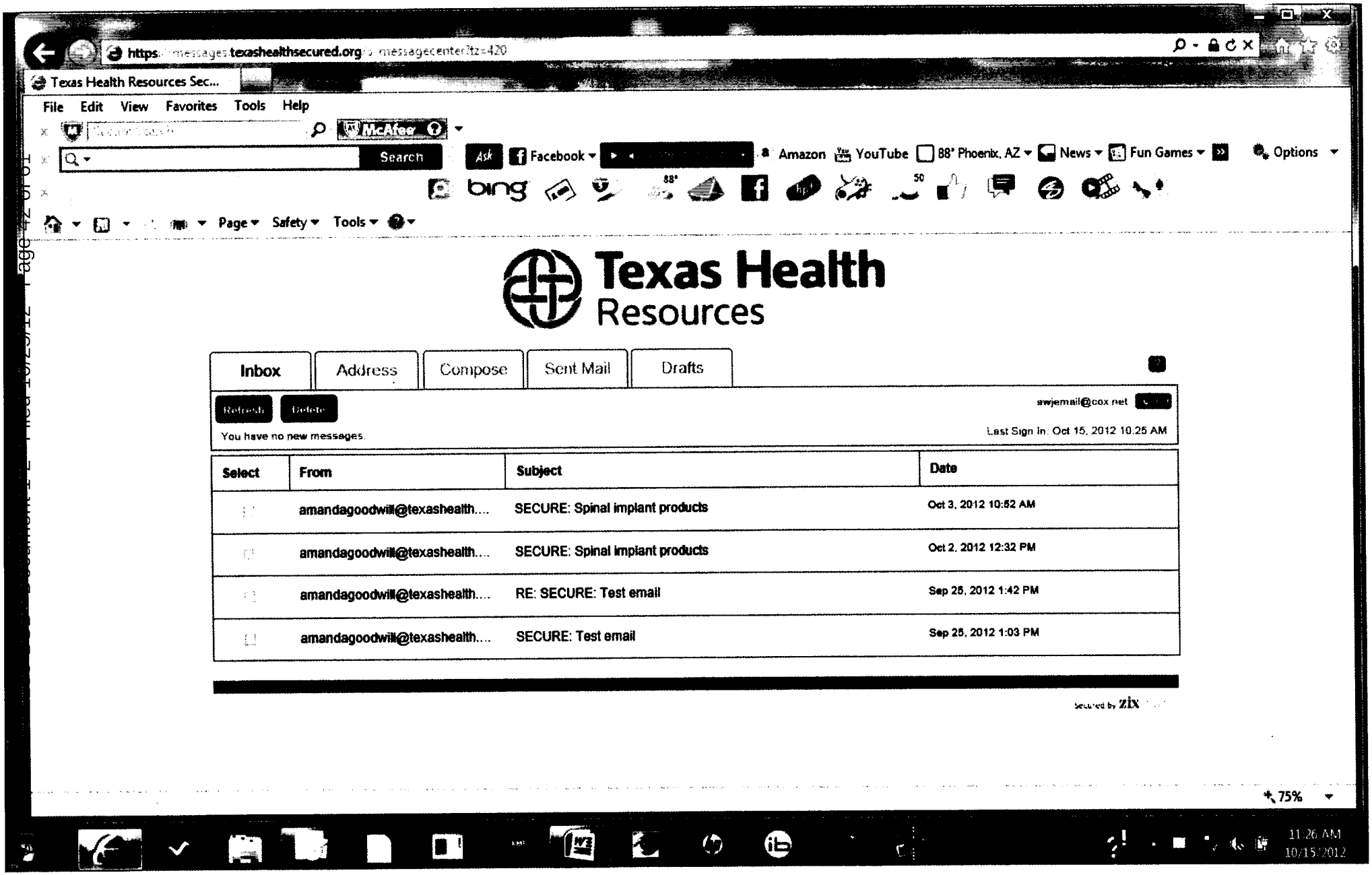
_____ _____
For Department use: MRN/Acct # Relationship to Patient

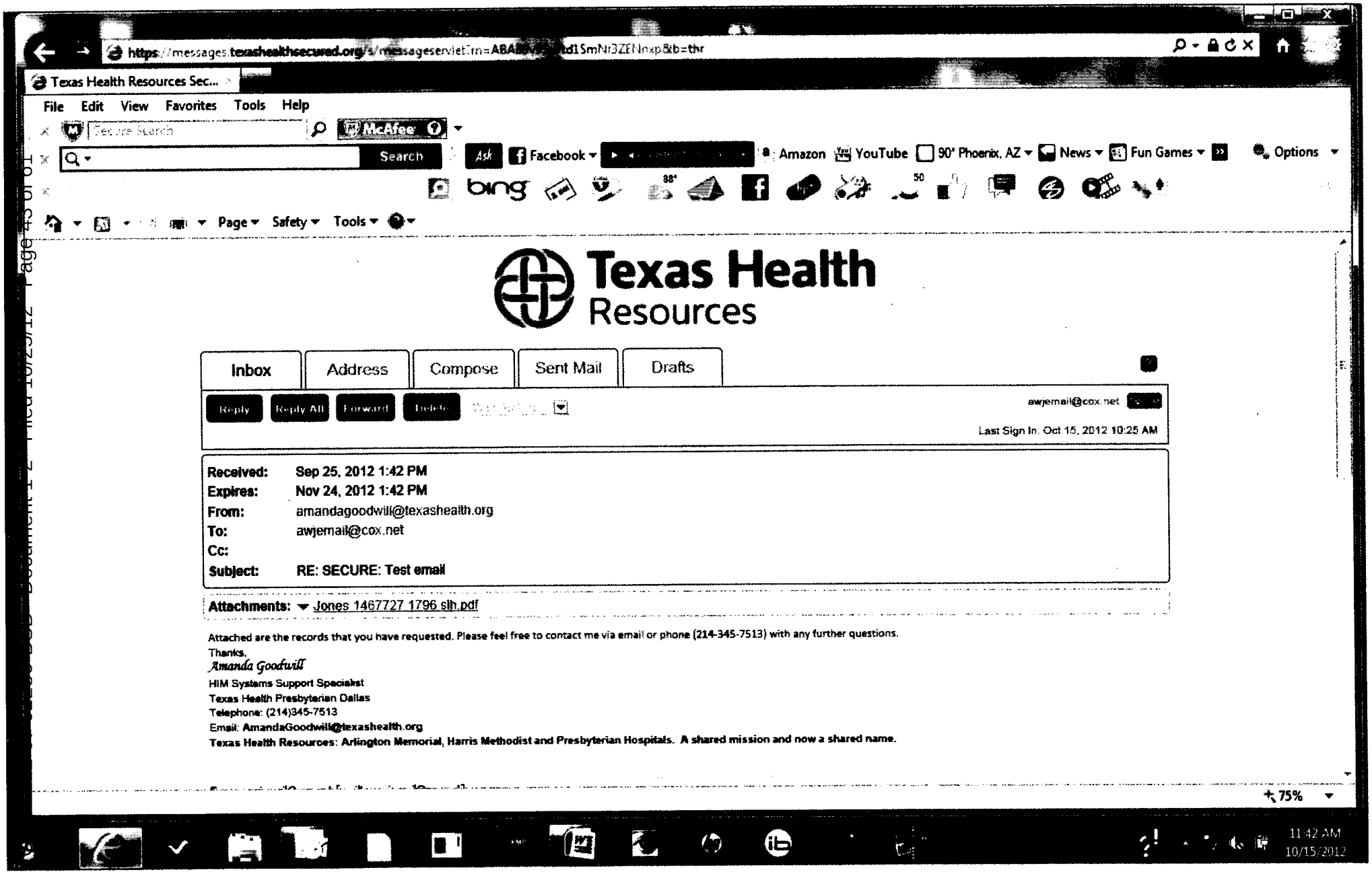
☐ Texas Health Allen X Texas Health Dallas Texas Health Kaufman
☐ Texas Health Arlington ☐ Texas Health Denton Texas Health Plano
☐ Texas Health Azle ☐ Texas Health Fort Worth Texas Health Southwest
☐ Texas Health Cleburne ☐ Texas Health HEB ☐ Texas Health Stephenville

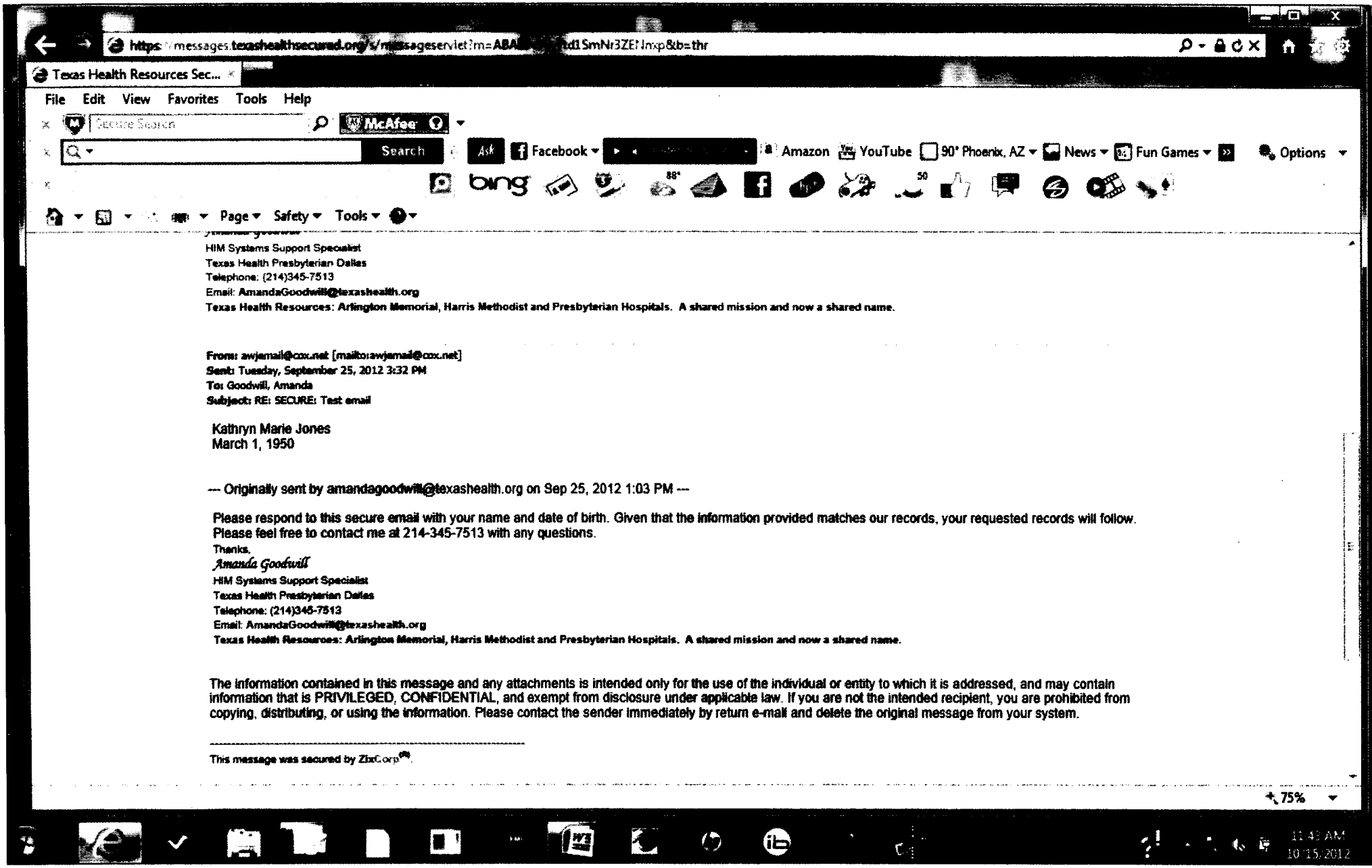

https://messages.texashealthsecured.org/s/e?m=ABAB9v95y7td15mNr3ZENnxp&em=awjemail%40cox%2enet
Texas Health Resources Sec...
File Edit View Favorites Tools Help
Search
Facebook
Amazon
YouTube
88° Phoenix, AZ
News
Fun Games
Options
Page
Safety
Tools
Texas Health Resources
Welcome to Texas Health Resources Secure Message Center
Email Address:
awjemail@cox.net
Password:
Sign In
Forgot your password?
Reset
New to secure email?
Register
Need more assistance?
Help
Learn more.
For Customer Support, email us at support@zixcorp.com
Secured by zix
75%
11:25 AM
10/15/2012

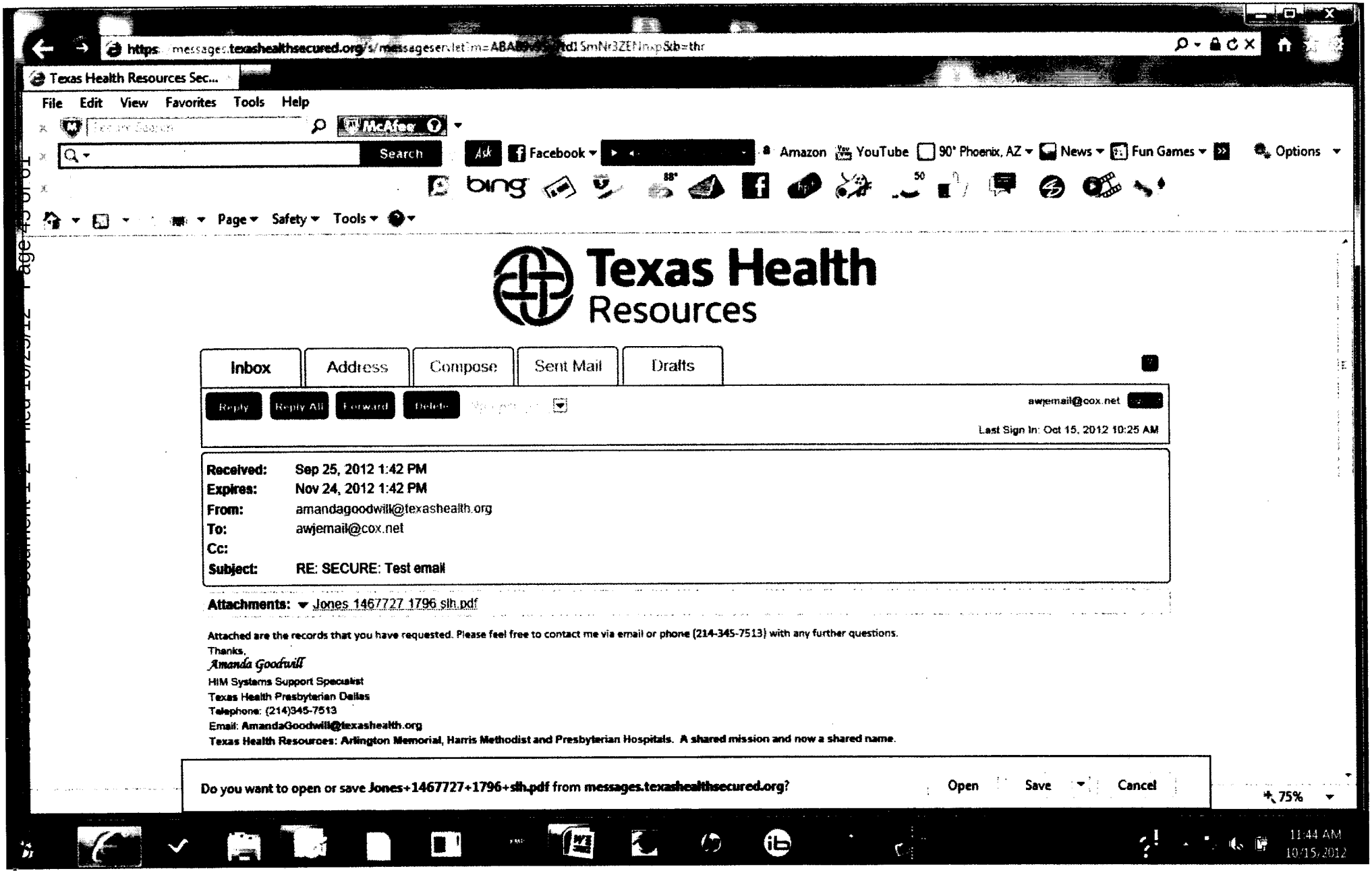

RE: SECURE: Test email - Message (HTML)
Message
Reply
Reply to All
Forward
Respond
Delete
Move to Folder
Create Rule
Other Actions
Actions
Block Sender
Safe Lists
Junk E-mail
Categorize
Follow Up
Mark as Unread
Options
Find
Related
Select
Find
From: amandagoodwill@texashealth.org [SecureEmailFrom_amandagoodwill_bcajcfcaecbcddlcdd@messages.texashealthsecured.org]
Sent: Tue 9/25/2012 1:42 PM
To: awjemail@cox.net
Cc:
Subject: RE: SECURE: Test email
New ZixCorp secure email message from Texas Health Resources Secure
To view the secure message, click Open Message.
The secure message expires on Nov 24, 2012 @ 09:42 PM (GMT).
Do not reply to this notification message; this message was auto-generated by the sender's security system. To reply to the sender, click Open Message.
If clicking Open Message does not work, copy and paste the link below into your Internet browser address bar.
https://messages.texashealthsecured.org/s/e?
Want to send and receive your secure messages transparently?
Click here to learn more.
11:24 AM
10/15/2012




https://messages.texashealthsecured.org/messagecenter?tz=420
Texas Health Resources Sec...
File Edit View Favorites Tools Help
McAfee
Search
Ask
Facebook
Amazon
YouTube
88° Phoenix, AZ
News
Fun Games
Options
bing
Page
Safety
Tools
Texas Health Resources
Inbox
Address
Compose
Sent Mail
Drafts
Refresh
Delete
swjemail@cox.net
You have no new messages.
Last Sign In: Oct 15, 2012 10:25 AM
Select
From
Subject
Date
amandagoodwill@texashealth.... SECURE: Spinal implant products Oct 3, 2012 10:52 AM
amandagoodwill@texashealth.... SECURE: Spinal implant products Oct 2, 2012 12:32 PM
amandagoodwill@texashealth.... RE: SECURE: Test email Sep 25, 2012 1:42 PM
amandagoodwill@texashealth.... SECURE: Test email Sep 25, 2012 1:03 PM
Secured by ZIX
75%
11:26 AM
10/15/2012







Jones+1467727+1

File Edit View Window Help

1 / 3 53.7% Tools Sign Comment

MRN: 1467727 Visit 46830175 DocType:PROGRESS NOTES

Physician's Progress Record

Physician's Progress Record PLIF T12-S1

Date Time

Implants

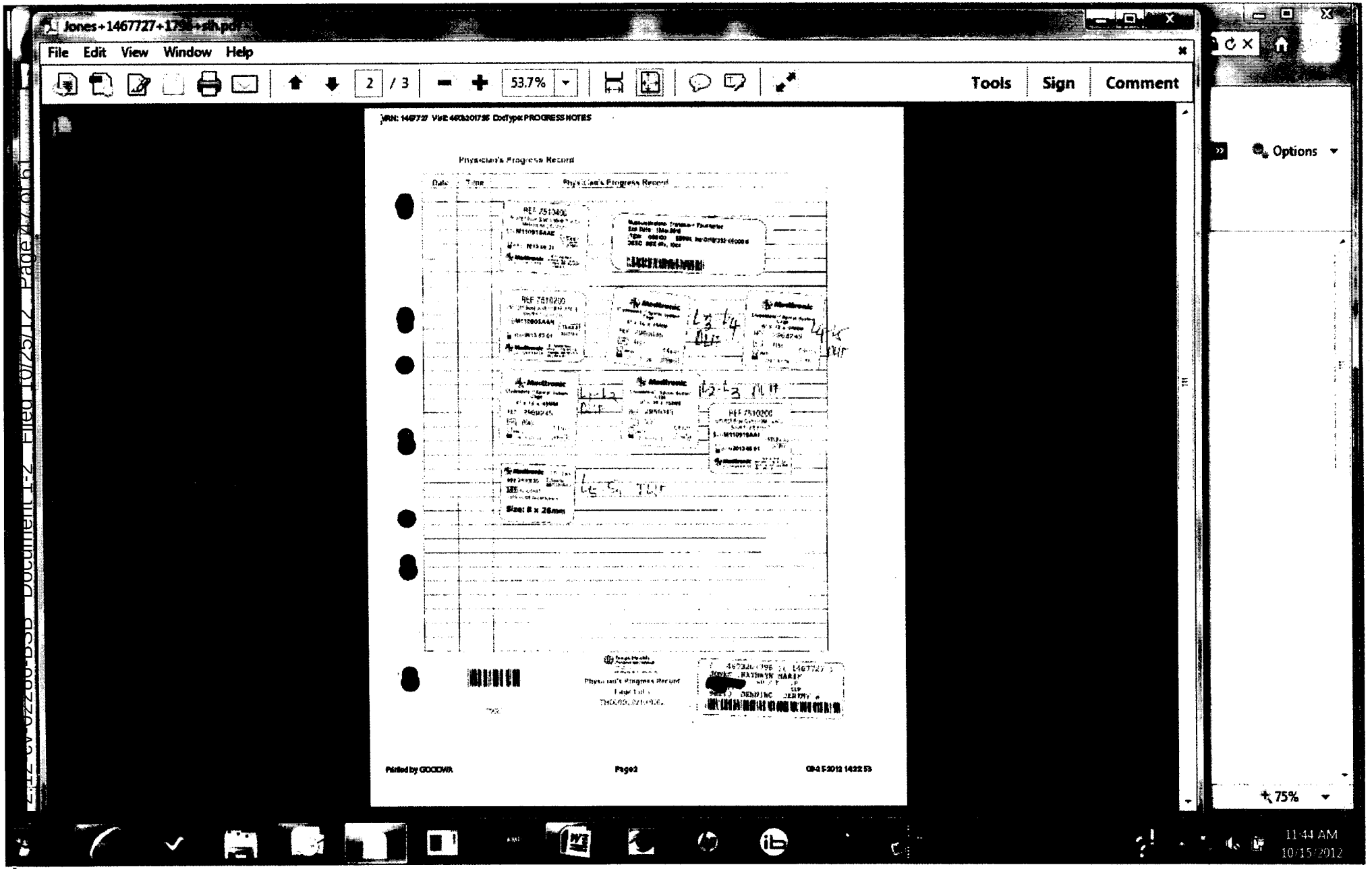
Qty	Part #	Description
2	7575540	5.5 x 40 Cannulated Screw
3	7575545	5.5 x 45 Cannulated Screw
4	7576545	6.5 x 45 Cannulated Screw
2	7576540	6.5 x 40 Cannulated Screw
1	7571220	220mm Rod
1	7571190	190mm Rod
11	7570955	Longitude Set Screw

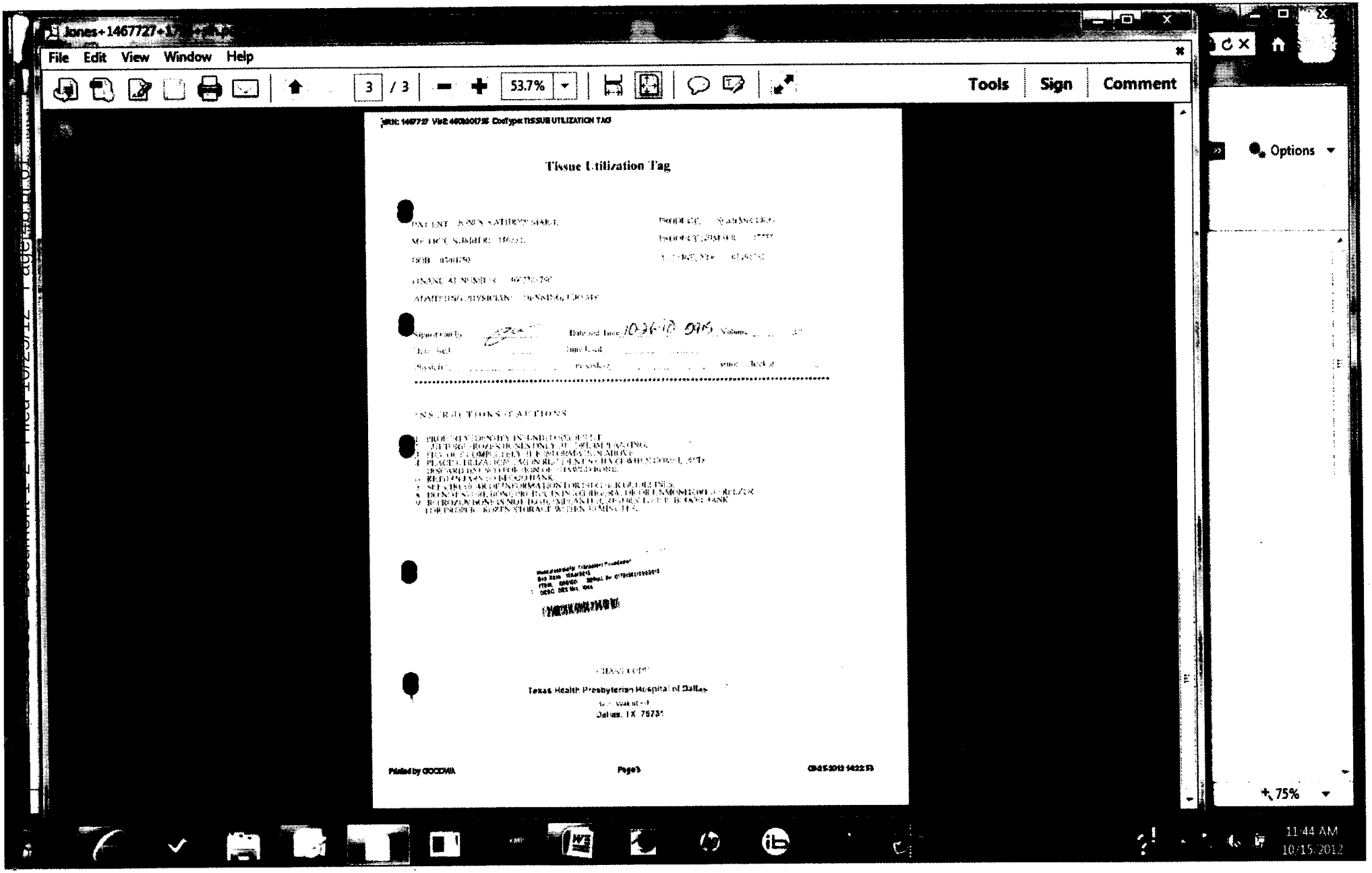
Printed by GOODWIN Page 1 08/15/2012 1422:44

Options

75%

11:44 AM
10/15/2012


Jones+1467727+1798+ch.pdf
File Edit View Window Help
2 / 3
53.7%
Tools Sign Comment
MRN: 1467727 Visit:460320736 EncType:PROGRESS NOTES
Physician's Progress Record
Date Time Physician's Progress Record
L3-L4
L4-L5
L2-L3
L5 S1
Size: 8 x 26mm
Physician's Progress Record
Printed by GOODWIN
Page2
Options
75%
11:44 AM
10/15/2012


Jones+1467727+1
File Edit View Window Help
3 / 3
53.7%
Tools
Sign
Comment
MRN: 1467727 Visit: 460360736 DocType: TISSUE UTILIZATION TAG
Tissue Utilization Tag
Signed on by
Dated/Time 10-26-12 0915
INSTRUCTIONS/CAUTIONS
Texas Health Presbyterian Hospital of Dallas
Dallas, TX 75231
Printed by GOODWIN
Page 5
Options
75%
11:44 AM
10/15/2012

A W Jones

From: Sandra Chavez [SChavez@dallasneuro.com]
Sent: Wednesday, September 26, 2012 11:50 AM
To: awj
Subject: RE: Post-surgery Complications

Mrs. Jones,

Dr. Denning dictated his response to me, and yes he did use INFUSE in your spine surgeries. As you have requested a letter will be mailed to you with Dr. Denning signature
please allow 2-3 days for all records to arrive.

Thanks,
SC

From: awj [mailto:[redacted]]
Sent: Wednesday, September 26, 2012 10:31 AM
To: Sandra Chavez
Subject: RE: Post-surgery Complications

Hi Sandra –

Thanks for the reply. I am somewhat confused. Did Dr. Denning himself dictate the response? It does not quite sound like him, and appears to be a general statement, not specifically about me. Is the response confirmation that Dr. Denning used INFUSE in my spine surgeries?

Please ask Dr. Denning to sign and mail a copy of his response to me. Thanks.

Kathryn Marie Jones

From: Sandra Chavez [mailto:SChavez@dallasneuro.com]
Sent: Wednesday, September 26, 2012 8:04 AM
To: A W Jones
Subject: RE: Post-surgery Complications

Mrs. Jones,

See below for Dr. Denning's response.

We have use INFUSE in all of our fusions for 6 years and continue to use this technology if insurance carriers cover it, because it has worked and studies have proven its effectiveness.
We place it only inside cages or spacers, where it is contained and never in the anterior cervical area. It is not exposed to nerves in any of our surgeries, We have never seen any serious complications from its use. specifically no bladder/urinary complications.
The alternative to INFUSE is to take bone from the hip, which we haven't done for years because of the chronic pain it can cause afterward and because the studies that were done showed INFUSE to be as effective. The other option is to use donor or cadaver bone which does not heal as well and can be rejected by the body.

SC

From: A W Jones [mailto:[redacted]]
Sent: Tuesday, September 25, 2012 12:34 PM

Dallas Neurosurgical & Spine

September 26, 2012

Kathryn Marie Jones
P.O Box 72107
Phoenix, Arizona 85050

PATIENT: Jones, Kathryn

Dear Mrs. Jones:

In response to your recent e-mail on September 26, 2012 regarding the use of Infuse in your minimally invasive spinal surgery for scoliosis correction in October of 2010, it did involve the use of Infuse bone growth product.

The alternative to the use of this product would be harvesting a large chunk of bone from your hip, which was performed routinely in the past but notoriously associated with chronic pain and often a debilitating morbidity of the surgery itself. The other option is the use of allograft or cadaveric donor bone, which typically did not heal as well or as quickly and if contaminated can be passed on to the patient. Infuse has been used for years in spinal surgery as well as other procedures where bone healing is essential such as dental, cranial and facial reconstructive surgeries. I have personally used Infuse in my spinal surgeries without any complications for over 7-years including my fellowship at NYU in New York. To this day, I continue to use the product because of its effectiveness in bone healing after surgery.

Sincerely,

Jeremy W Denning, MD

Dallas
8230 Walnut Hill Lane
Prof. Bldg. III, Suite 220
Dallas, Texas 75231
214.750.3646
214.739.6815

Allen / McKinney
1105 N. Central Expwy
Suite 2310
Allen, Texas 75013
972.747.6393
214.363.2351

Denton
3537 S. I-35E
Suite 220-B
Denton, Texas 76210
940.484.8800
940.384.4770

Plano
4708 Alliance Blvd
Suite 620
Plano, Texas 75093
972.665.4810
972.665.4815

Rockwall / Rowlett
7801 Lakeview Parkway
Suite 130
Rowlett, Texas 75088
972.475.2150
214.987.4865

10-1-12

MRI's. Even after Kathryn suffered a very bad fall, Dr. Denning did not order any investigational studies.

119. In its approval for INFUSE, the FDA instructed Medtronic to develop a test to determine if a patient was having an autoimmune response to INFUSE. But, once again, when Kathryn asked Dr. Denning if her extensive hair loss was related to her fusion surgeries – Dr. Denning said "no". And he chose not to investigate. Dr. Denning has ordered three x-rays of Kathryn's lumbar spine post-surgery. That is all. Nothing else. There was no "meticulous assessment".

120. Clearly, Dr. Denning and Dr. Jackson experimented on Kathryn. How else to explain their complete disregard of the Medtronic warning to doctors, regarding use of INFUSE. How else to explain the presence of Medtronic representatives in the operating room. And, how else to explain the lies and deception to Kathryn and me. But why? Dr. Denning and Dr. Jackson did no post-surgery "investigations". There was no "evaluation of outcome". Or was there? Did Dr. Denning and Dr. Jackson conduct an experiment - a trial - that was only concerned with the surgeries themselves, not with the patient outcome? Did the Medtronic representatives actively participate in the experiment, the trial? But a trial of what?

ELSEVIER

The Spine Journal 11 (2011) 469–470

THE SPINE JOURNAL

Editorial

Physican-directed (off-label) use of recombinant bone morphogenic protein-2: let us do it well!

Charles L. Branch, Jr., MD*

Department of Neurosurgery, Wake Forest Baptist Medical Center, Medical Center Blvd, Winston-Salem, NC 27157-1029, USA

Received 4 April 2011; accepted 5 April 2011

As the entire health-care delivery system in this country comes under increasing pressure to control and reduce costs, the "off-label" applications of technology and pharmaceuticals have come under intense scrutiny. This targeting derives from the fact that newly introduced products are more expensive, and there is often a widespread physician-directed use outside of the original Food and Drug Administration (FDA)-approved indication. This wide net of physician-directed use has resulted in significant patient benefit for conditions outside of the original FDA approval. Examples I would cite include the use of lateral mass screw rod fixation for posterior cervical spine fusion and the use of gabapentin for subacute or chronic neuropathic pain syndromes. This wide net of physician-directed use has exposed patients to unrecognized or unpredicted issues or even complications that are undoubtedly drivers of health-care costs as well.

In recent years, recombinant bone morphogenic protein-2 (rhBMP-2) appears to have been assigned the role of the poster child for all that is wrong with "off-label" or physician-directed use of a novel beneficial technology. After receiving initial FDA approval for marketing as a specific product and technique that used rhBMP-2 on an absorbable collagen sponge embedded in a titanium-threaded fusion cage for use in anterior lumbar interbody fusion, INFUSE rhBMP-2 (Medtronic, Inc., Minneapolis, MN, USA) was widely used successfully in a host of fusion-related applications. The physician-directed or "off-label" use of this product to enhance fusion throughout the spine soon far outdistanced the approved use. This increased up-front cost along with a virtual monopoly of this product by Medtronic placed this company, its marketing and educational programs, the product, and those who developed it under increased scrutiny and public media sensationalism. The result has been the socioeconomic politicization of a beneficial novel health-care technology.

Adding fuel to this fire was the recognition of adverse events associated with this physician-directed use of INFUSE in the cervical spine. Problematic, even life-threatening swelling with the use of INFUSE in anterior cervical fusions led to FDA warnings [1] and alterations in usage patterns. Intense efforts to determine the cause of these sporadic adverse events have failed to pinpoint the exact cause, but excessive dose of rhBMP-2 appears to be the leading etiology. In the article by Helgeson et al. [2], another associated finding or observation with physician-directed use of INFUSE is reported. Adjacent vertebral osteolysis appears several months after implantation and may persist for years. The clinical significance of this observation is yet unknown as this finding does not appear to have an impact on fusion rate or clinical outcome. The nature or physiologic etiology of this observation is not discussed, but this is not a unique observation, and in other reports, dosage or containment of rHBMP-2 has been implicated.

Outside of this highly charged socioeconomic environment, these observations along with those of exuberant bone formation by Haid et al. [3] and Alexander and Branch [4] in the posterior-threaded fusion cage trial, or heterotopic bone by Branch et al. [5] in a bilateral impacted PLIF trial, would be hailed as significant contributions to the knowledge base driving the indications and ultimate benefit or concern associated with this new technology. Indeed, widespread careful physician-directed use of new technology, with meticulous observation of outcomes and imaging, is the major contributor to the knowledge base for any new technology. Current FDA approval pathways are restrictive and will become increasingly so. Ascertaining the true impact of a new technology or pharmaceutical has been accomplished in the realm of "off-label" or

FDA device/drug status: Indicated for some use and not for others (Infuse).

Author disclosures: ***CLB:*** Royalties: Medtronic (G); Consulting: Medtronic (D); Board of Directors: American Board of Neurological Surgery (B), Board of Regents of Pepperdine University (nonfinancial), Board of the Childress Institute for Pediatric Trauma (nonfinancial), Board of Directors of Eastern European Missions (nonfinancial).

The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

* Corresponding author. Professor and Chair, Department of Neurosurgery, Wake Forest Baptist Medical Center, Medical Center Blvd, Winston-Salem, NC 27157-1029, USA. Tel.: (336) 716-4083; fax: (336) 716-3065.

E-mail address: cbranch@wfubmc.edu (C.L. Branch).

1529-9430/$ - see front matter
doi:10.1016/j.spinee.2011.04.005

physician-directed use in the past, and this realm of research will have an increasing role in the future.

Physician-directed or "off-label" use of novel technology must be accompanied by careful meticulous physician-directed observation and assessment of patient outcomes. The Achilles Heel of contemporary health-care evidence is the inconsistent or highly variable methodologies of outcome assessment and reporting. Even in the highly controlled military health-care system from which Helgeson et al. reported their observations of osteolysis, only 30% had sufficient follow-up and imaging to be included in this observational report. Although this does not diminish the quality of their observation, little else may be derived from this report. They are building evidence along with others that this is an observation with rhBMP-2 and transforaminal lumbar interbody fusion. Frequency, clinical impact, or etiology cannot be determined from their or others reports.

Industry-sponsored FDA approval pathway studies have been the most meticulous or complete for outcome assessment. Yet, these are limited in scope and now held under suspicion as a consequence of their industry sponsorship. The knowledge base for new technology must be established with prospective, well-designed and executed, and widely implemented studies with imaging and technology intensive outcome assessment and interpretation. Physician-directed use of novel technology should not be prohibited or severely restricted but should be encouraged in the setting of quality outcomes assessment.

It is encouraging to acknowledge that professional societies that shape spine care in this country are collaborating in outcome registry development efforts. A conference in July 2010 organized by Dan Resnick and the Coalition Task Force for Lumbar Fusion [6] brought all of the major participants in this arena together. The FDA, Centers for Medicare and Medicaid Services, United Healthcare, Blue Cross Blue Shield, and spine representatives engaged in a vigorous deliberating on the development of outcome assessment tools and metrics. Human and economic resources are being directed at outcome development from all fronts.

Osteolysis, exuberant and heterotopic bone formation, and cervical soft-tissue swelling represent only a sample of the potential observations associated with the novel rhBMP-2 technology. These observations were made and disseminated by physicians using this technology in an "off-label" or physician-directed indication. The knowledge gained has been invaluable and more is yet to be learned. But the best knowledge or evidence comes from thoughtful, careful, hypothesis-directed investigations with meticulous assessment, and evaluation of outcome. This must be the environment in which we all practice our profession of spine care, especially as we use novel technology and pharmacology for physician-directed indications.

References

[1] FDA public health notification: life-threatening complications associated with recombinant human bone morphogenetic protein in cervical spine fusion. Available at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062000.htm. Accessed July 1, 2008

[2] Helgeson MD, Lehman RA Jr, Patzkowski JC, et al. Adjacent vertebral body osteolysis with bone morphogenetic protein use in transforaminal lumbar interbody fusion. Spine J 2011;11:507–10.

[3] Haid RW, Branch CL Jr, Alexander JT, Burkus JK. Posterior lumbar interbody fusion using recombinant human bone morphogenetic protein type 2 with cylindrical interbody cages. Spine J 2004;4:527–38.

[4] Alexander JT, Branch CL Jr. Recombinant human bone morphogenic protein-2 in a posterior lumbar interbody fusion construct: 2-year clinical and radiologic outcomes. Spine J 2002;2(5 Suppl):48S.

[5] Branch CL Jr, Eickman J, Geibel P, et al. Posterior lumbar interbody fusion using recombinant human bone morphogenetic protein type 2 with polyetheretherketone cages. Spine J 2009;9(10 Suppl):186S–7S.

[6] Resnick D, Glassman S. Comparative efficacy of treatments for the lumbar spine. Proceedings from the Professional Society Coalition on Lumbar Fusion Outcomes Meeting, July 11–13, 2010, Madison, WI: SpineLine; September to October 2010.

Dallas Neurosurgical & Spine

dallasneurosurgical.com

Jeremy W. Denning, MD
J. Michael Dykstra, MD
Richard H. Jackson, MD
Jan A. Krumerman, MD
Richard L. Weiner, MD, FACS
Gary C. Hutchison, MD, FACS

September 23, 2010
ESTABLISHED/ FOLLOW UP PATIENT VISIT

PATIENT: **Jones, Katherine**

Ms. Jones did contact our office several times wanting to proceed with surgery. This surgery would be to correct her lumbar spinal deformity and to prevent any further worsening of her spinal alignment as well as correcting her nerve compression at L5-S1. The patient understood that this would involve a direct lateral approach as well as a posterior approach and that if we were going to do this percutaneously I would recommend doing it in two days due to the increased time from the fluoroscopy. The patient understood there was a risk of the need for a blood transfusion, and she has elected to auto donate units of her own blood, which will be transported to Dallas prior to her surgery. The patient also understood that we will be using spinal instrumentation and that there are risks of nerve injury due to the direct lateral approach. The patient will likely have some hip flexor weakness that most of the time is temporary due to the muscle inflammation through the psoas muscle. There is also the risk of dysesthetic pain from a direct lateral approach, but this would be a less invasive approach for her. This will also involve a posterior approach where we will place percutaneous screws and instrumentation as well as an L5-S1 TLIF to address her nerve compression. This will mean for the patient probably at least a week stay in the hospital and likely a stay in the rehabilitation unit in the Jackson Building prior to going home.

The patient has had a bad reaction to multiple pain medications and it may be difficult for us to completely manage all of her pain postoperatively, but we will try to do our best to avoid medications that she has had bad reactions to and at the same time controlling her pain. The patient will need a preoperative medical clearance. Again, we will have this set up for sometime in October.

Jeremy W. Denning, M.D.

JWD/KR
D: 9/23/2010 @ 5:42 PM
T: 9/27/2010 @ 1:49 PM
J: 4149175

Rocking in New Lumbar DLIF L5-S1 TLIF
10/26/10

(4603201796)(1467727)
JONES ,KATHRYN MARIE
[redacted]950 60 / F IP
10/26/10 SUR
96210 DENNING JEREMY W

Dallas
8230 Walnut Hill Lane
Prof. Bldg III, Suite 320
Dallas, Texas 75231
t 214.750.9646
f 214.739.6815

Allen/McKinney
1005 N Central Expwy
Suite 2310
Allen, Texas 75013
t 972.747.6493
f 214.363.2351

Denton
3535 S. I-35E
Suite 220-B
Denton, Texas 76210
t 940.484.8800
f 940.384.3740

Plano
4708 Alliance Blvd
Suite 620
Plano, Texas 75093
t 972.665.4810
f 972.665.4815

Rockwall/Rowlett
7801 Lakeview Parkway
Suite 150
Rowlett, Texas 75088
t 972.475.2150
f 214.987.4865

Dallas Neurosurgical & Sp

dallasneurosurgical.com

Jeremy W. Denning, MD
Michael Donahue, MD
Richard H. Jackson, MD
Ian A. Kramerman, MD
Richard L. Wence, MD, FACS
Gary C. Hutchison, MD, FACS

September 23, 2010
ESTABLISHED/ FOLLOW UP PATIENT VISIT

PATIENT: Jones, Katherine

Mrs. Jones comes back to the office today. We had a long discussion. The patient did see Dr. O'Brien and did have her thoracolumbar myelogram with weightbearing images as well. This did reveal good information with regard to her back. This revealed a moderate dextroscoliosis of the lumbar spine with a mild compensatory upper thoracic scoliosis and a lower lumbar levoscoliosis. The patient has a grade I to II spondylolisthesis at L5-S1 that increases in severity with flexion and weightbearing and decreases with non-weightbearing and extension. This is from bilateral pars defects. There is a disk protrusion into and lateral to the right neural foramen causing severe, right foraminal stenosis and mild left foraminal stenosis. The patient has a retrolisthesis of L1-2 and L2-3 and some narrowing of the left L2-3 and L1 lateral recesses and foramen.

We had a long discussion with regard to her findings and options for treatment. I did explain to her that she originally came here to see Dr. O'Brien, and she stated understood this but wanted me to perform her surgery. As such, we had a long discussion regarding her options. One includes managing this with pain management versus a minimally invasive L5-S1 TLIF versus correcting her lumbar deformity. I explained to the patient that she would recover more quickly if we did her L5-S1 TLIF, but to correct her whole deformity would require a much longer recovery time. I told the patient that she and her husband needed to think about this before they made any decisions and they could certainly get another opinion back in Arizona. The patient will contact us if she decides to have any surgery, but she and her husband are going to think about her options. Again, I did recommend to her and she is going to see a surgeon closer to home for a second opinion. All of her questions were answered to her satisfaction. The patient will call us as needed.

Jeremy W. Denning, M.D.

JWD/KR
D: 9/23/2010 @ 5:39 PM
T: 9/27/2010 @ 1:56 PM
J: 4149173

Dallas	Allen/McKinney	Denton	Plano	Rockwall/Rowlett
8230 Walnut Hill Lane	1105 N. Central Expwy	3537 S. I-35E	4508 Alliance Blvd	7801 Lakeview Parkway
Prof. Bldg. III, Suite 220	Suite 2310	Suite 220-E	Suite 620	Suite 150
Dallas, Texas 75231	Allen, Texas 75013	Denton, Texas 76210	Plano, Texas 75093	Rowlett, Texas 75088
t 214.750.5646	t 972.747.6193	t 940.484.8500	t 972.665.4800	t 972.475.2150
f 214.739.6815	f 214.363.2351	f 940.384.4550	f 972.665.4815	f 214.987.4865

Kathryn Jones

(4603201796)(1467727)
JONES ,KATHRYN MARIE
[redacted] 950 60 / F IP
10/26/10 SUR
96210 DENNING JEREMY W

Presbyterian Hospital of Dallas
A Member of Presbyterian Healthcare System

SCLOSURE AND CONSENT
EDICAL AND SURGICAL PROCEDURES

TO THE PATIENT: You have the right , as a patient, to be informed about your condition and the recommended surgical, medical or diagnostic procedure to be used so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so you may give or withhold your consent to the procedure.

I (we) voluntarily request Dr. _Jeremy Denning__ as my physician , and such associates, technical assistants and other health care providers as they may deem necessary, to treat my condition which has been explained to me as:

_____**Scoliosis/Spondylolisthesis** _____

I (we) understand that the following surgical, medical, and/or diagnostic procedures are planned for me and I (we) voluntarily consent and authorize these procedures:

_____**Xtreme Lumbar Interbody Fusion L1-L5; Posterior T12-S1 Fusion with Translumbar Interbody Fusion** _____

I (we) understand that my physician may discover other or different conditions which require additional or different procedures than those planned. I (we) authorize my physician, and such associates, technical assistants and other health care providers to perform such other procedures which are advisable in their professional judgment.

I (we) do KMJ X do not ___ consent to the use of blood and blood products as deemed necessary. I (we) also realize that the following risks and hazards may occur in the connection with this particular procedure: fever, transfusion reaction which may [redacted] kidney failure or anemia, heart failure, hepatitis, A.I.D.S. (acquired immune deficiency syndrome), other infections.

I (we) understand that no warranty or guarantee has been made to me as a result of care.

Just as there are may be risks and hazards in continuing my present condition without treatment, there are also risks and hazards related to the performance of surgical, medical, and/or diagnostic procedures planned for me. I (we) realize that common to surgical, medical and/or diagnostic procedures is the potential for infection, blood clots in veins and lungs, hemorrhage, allergic reactions and even death. I (we) also realize that the following risks and hazards may occur in connection with this particular procedure:
1. Pain, numbness, or clumsiness 2. impaired muscle function 3. incontinence or impotence 4. unstable spine 5. recurrence or continuation of the condition that required the operation 6. injury to major blood vessels 7. Cerebral spinal fluid leakage requiring repair

For [redacted]aroscopically assisted procedures, the additional risks include: damage to intra-abdominal structures (e.g. bowel, bladder, blo[redacted]vessels, or nerves); intra-abdominal abscess and infectious complications; trocar site complications (e.g. hematoma/bleeding, leakage of fluid, or hernia formation); conversion of the procedure to an open procedure; cardiac dysfunction.

I (we) understand that anesthesia involves additional risks and hazards but I (we) request the use of anesthetics for the relief and protection from pain during the planned and additional procedures. I (we) realize the anesthesia may have to be changed possibly without explanation to me (us).

I (we) understand that certain complications may result from the use of any anesthetic, including respiratory problems, drug reactions, paralysis, brain damage or even death. Other risks and hazards which may result from the use of general anesthetics ra[redacted]rom minor discomfort to injury to vocal cords, teeth or eyes. I (we) understand that other risks and hazards resulting from sp[redacted]r epidural anesthetics include headache and chronic pain. Other risks may include:

I [redacted]ave been given the opportunity to ask questions about my condition, alternative forms of anesthesia and treatment, risks of [redacted]reatment, the procedures to be used, and the risks and hazards involved, and I (we) believe that I (we) have sufficient information to give this informed consent.

I (we) certify this form has been fully explained to me, that I (we) have read it or have had it read to me, that the blank spaces have been filled in and that I (we) understand its contents.

DATE: 10/26/10 TIME: 0630

Kathryn Marie Jones

PATIENT/OR OTHER LEGALLY RESPONSIBLE PERSON SIGN

W[redacted]s Name: Debbie Sims RN

Address: THD

(Street or P.O. Box) (City, State, Zip code)

The risks, benefits, and alternatives have been explained and the patient/family understand(s) and agree(s) to the procedure.

Physician signature: _____ Date: 10/26/10

The risks, benefits, and alternatives have been explained and the patient/family understand(s) and agree(s) to the procedure

Physician signature: _____ Date: 10/26/10

DNA(4/09)

[redacted]

[redacted]

[redacted]

(4603201796)(1467727)
JONES ,KATHRYN MARIE
[redacted]950 60 / F IP
SUR
10/26/10
96210 DENNING JEREMY W

D/C Summaries (continued)

ranitidine (ZANTAC 75) 75 mg Tab Take 75 mg by mouth at bedtime as needed.								
acetaminophen (TYLENOL) 325 mg tablet Take 2 Tabs by mouth every six(6) hours as needed.								
docusate sodium (COLACE) 100 mg capsule Take 1 Cap by mouth two(2) times daily.								
lactulose (CEPHULAC) 10 gram/15 mL solution Take 15 mL by mouth every day.								
mupirocin (BACTROBAN) 2 % ointment Apply 1 application to affected area three(3) times daily.								
prochlorperazine (COMPAZINE) 5 mg tablet Take 1 Tab by mouth three(3) times daily.								
psyllium (METAMUCIL) packet Take 1 Packet by mouth as needed only as directed by physician. bowel program								
temazepam (RESTORIL) 15 mg capsule Take 1 Cap by mouth at bedtime as needed.								
triamterene-hydrochlorothiazide (DYAZIDE) 37.5-25 mg capsule Take 1 Cap by mouth every evening.								
diphenhydrAMINE (BENADRYL) 25 mg capsule Take 1 Cap by mouth every six(6) hours as needed.								

Follow-up:
1. Spine surgery: Dr. Jeremy Denning
2. PCP in Arizona

Alberto I Lin, MD 11/10/2010 1:16 PM

H&P

H&P signed by Lin, Alberto I., MD at 11/03/10 1429

Author:	Lin, Alberto I., MD	Specialty:	Physical Medicine & Rehabilitation.	Author Type:	Physician
Filed:	11/03/10 1429	Note Time:	11/03/10 1412		

Inpatient Rehabilitation
Admission History and Physical Note

Name: Kathryn Marie Jones
MR#: 1467727
Room #:
Admit Date: 11/3/2010

Date: 11/3/2010
DOB: 3/1/1950
Age/Sex: 60 y.o. female
Admitting: Alberto I. Lin, MD

H&P (continued)

Chief Complaint: Mobility and ADL deficits s/p right L5-S1 far lateral discectomy and hemilaminectomy with posterior fusion and L1-L5 osteotomy and fusion

Referring physician: Dr. Jeremy Denning

History of present illness: Kathryn Marie Jones is a pleasant 60 y.o. female with a history of hypertension, gastroesophageal reflux disease, Meniere's disease and scoliosis who was initially admitted to Texas Health Resources - Dallas on 10/26/10 for surgical management of back pain. Per patient, she has had low back pain for over 40 years and was diagnosed with scoliosis in 1995 in Arizona, where she resides. She states that for the past few months, she has had increasing painful paresthesias and cramping down the right hip, buttock and thigh. This is associated with intermittent buckling of the right leg with a few falls. More recently, she also began to experience bilateral leg cramping. She was evaluated by neurosurgery and noted to have significant scoliosis as well as grade 2 L5-S1 spondylolisthesis and right greater than left L5-S1 foraminal stenosis. There was no evidence of significant central canal stenosis. Several management options were discussed with patient. Due to increasing debility, pain and suffering, she opted for surgical decompression and correction of scoliosis. After pre-operative risk stratification by internal medicine, patient underwent a right L5-S1 far lateral discectomy and hemilaminectomy with posterior fusion and L1-L5 osteotomy and fusion on 10/26/10 by Dr. Jeremy Denning with assistance by Dr. Randall Kirby for exposure. Post-operatively, pain was initially controlled via percutaneous analgesia with eventual transition to oral medications. Patient was placed on sequential compression devices for deep vein thrombosis prophylaxis. Internal medicine continued to follow patient for close medical management. When appropriate, patient was restarted on usual medications for her medical co-morbidities. She was noted to be hypokalemic, which resolved with supplementation and adjustment of her medications. Once hemodynamically stable, Kathryn Marie Jones was evaluated by rehabilitation services and noted to have functional deficits in gait, transfers and activities of daily living that would preclude a safe discharge home. Patient demonstrated motivation to improve and potential to tolerate and benefit from intensive rehabilitation. As such, Kathryn Marie Jones is now being admitted for acute inpatient rehabilitation at Texas Health Resources - Dallas for functional upgrading with close nursing supervision and physiatric management.

Functionally, Kathryn Marie Jones has been debilitated by the long-standing low back pain. She is disabled, as is her husband. She has required the use of a straight cane for stability with mobility. Patient lives in Arizona in a single story home. Plans are for patient to remain in Dallas in the Park Hyatt hotel for home health rehabilitation until follow-up with neurosurgery.

Previous Functional Status prior to Lumbar Sx	Current Functional Status on admit:
Mobility: ind ADL: ind Speech: Clear and Appropriate	Mobility: min A 25' RW ADL: min A T's, ADI's Speech: Clear and Appropriate

Past Medical History	
Diagnosis	Date
• Spondylolisthesis	
• Pernicious anemia	
• Meniere disease	
• Scoliosis	
• Urinary urgency	
• Gastritis	2007
• Esophagitis	2007
• Atrial arrhythmia *nuclear stress test 9-2010*	
• Asthma *symptoms happen if eats peanuts*	
• Stress headaches	
• Concussion *walked into openkitchen cabinet*	2-2010

Past Surgical History	
Procedure	Date
• Appendectomy	1991
• Hysterectomy *partial, states still has ovaries*	1991
• Other *D&C*	1970
• Other *tubal ligation*	1972
• Other *left fractured elbow with hardware, since been removed*	2000
• Other *nasal fracture repaired*	child
• Other *Lower Left Lobectomy secondary to Valley Fever*	2007

A W Jones

From: awj [redacted]
Sent: Friday, October 12, 2012 11:58 AM
To: 'Hagan, Paula'
Subject: Implant Devices

Importance: High

Directory
Clinical Trials
Research
Education and Training
Institutional Review Board
Texas Health Minimally Invasive Technology Center
Partnering with Texas Health Research & Education
Grants and Contracts Support

Texas Health Research & Education Institute

Advancing Health

Texas Health Research & Education Institute advances health through research and education.

As an independent, not-for-profit organization within Texas Health Resources, Texas Health Research & Education:

- Conducts research that contributes to the prevention, diagnosis and treatment of disease.
- Offers continuing medical education to physicians and other health care professionals.

TEXAS HEALTH RESEARCH & EDUCATION INSTITUTE

Quick Facts

- **200 research studies conducted across the Texas Health system**
- **All research studies approved by system Institutional Review Board**
- **53,000 CME credit hours awarded annually to health care professionals**
- **800 CME activities annually**
- **More than 10,000 physicians have trained at Texas Health Minimally Invasive Technology Center**

Research Coordination
Texas Health Research & Education facilitates and conducts clinical and pre-clinical research throughout Texas Health Resources. We advance patient care through translational research, including research and clinical trials in varied specialties, product evaluation, proof of concept testing and product development.

Continuing Medical Education
We help keep physicians and other health care professionals current with medical knowledge through accredited continuing medical education (CME) programs. Along with traditional classroom learning, physicians and nurses take courses online and through satellite broadcasts.

Texas Health Research & Education Institute Minimally Invasive Technology Center
The Texas Health Minimally Invasive Technology Center, operated by Texas Health Research & Education, provides research and training capabilities for both Texas Health-affiliated physicians, as well as physicians affiliated with other institutions.

CME THE ALLIANCE

2010 Recipient

Online Tools

Pre-register for Service
MyCare Patient Portal
Pay Hospital Bill
Donate to Foundations
Request Medical Records
Email a Patient
Send Flowers or Gifts
Oh Baby! eNewsletter
Send Flowers or Gifts
eLearning Childbirth

Locations

Texas Health Allen
Texas Health Alliance
Texas Health Arlington Memorial
Texas Health Azle
Texas Health Burleson
Texas Health Cleburne
Texas Health Craig Ranch
Texas Health Dallas
Texas Health Denton
Texas Health Flower Mound
Texas Health Fort Worth
Texas Health Heart & Vascular
Texas Health HEB
Texas Health Kaufman
Texas Health Plano
Texas Health Diag. & Surgery Plano
Texas Health Rockwall
Texas Health Southlake
Texas Health Southwest Fort Worth
Texas Health Specialty Hospital
Texas Health Stephenville
Texas Health WNJ Sherman

Helpful Info

Classes and Events
Foundations
Patients and Visitors
Community Commitment
Newborn Baby Photos
Volunteer Opportunities
Faith and Spirituality
Living Will
Support Groups
Research, Education and Training
Texas Health Magazine

Links

Clinical Trials
Careers
Physician Opportunities
Texas Health Nurse
Texas Health Heart
Texas Health Moms
Texas Health Ben Hogan
Facebook
Twitter
YouTube
Employee Portals
Vendor Compliance

Texas Health Research & Education Institute | 612 E. Lamar Blvd., Suite 1212 | Arlington, TX 76011 | 682-236-6734

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Alan W. Jones and Kathryn Marie Jones, Plaintiffs, Vs. **Dallas Neurosurgical and Spine Associates, P.A.; Dr. Jeremy Denning; Dr. Richard Jackson;** **Texas Health Presbyterian Hospital of Dallas;** **Medtronic Corporation; James Sherman; Josh Tsokanas; Nora (Lora) Jean Enty;** **DOE DEFENDANTS 1-10,** Defendants.	CIVIL NO. _____ **NOTICE OF LAWSUIT AND REQUEST FOR WAIVER OF SERVICE OF SUMMONS**

TO: _____

as _____ of _____

A lawsuit has been commenced against you (or the entity on whose behalf you are addressed). A copy of the complaint is attached to this notice. It has been filed in the United States District Court for the State of Arizona and has been assigned docket number _____.

This is not a formal summons or notification from the court, but rather my request that you sign and return the enclosed waiver of service in order to save the cost of serving you with a judicial summons and an additional copy of the complaint. The cost of service will be avoided if I receive a signed copy of the waiver within 30

days after the date designated below as the date on which this Notice and Request is sent. I enclose a stamped and addressed envelope (or other means of cost-free return) for your use. An extra copy of the waiver is also attached for your records.

If you comply with this request and return the signed waiver, it will be filed with the court and no summons will be served on you. The action will then proceed as if you had been served on the date the waiver is filed, except that you will not be obligated to answer the complaint before 60 days from the date designated below as the date on which this notice is sent (or before 90 days from that date if your address is not in any judicial district of the United States).

If you do not return the signed waiver within the time indicated, I will take appropriate steps to effect formal service in a manner authorized by the federal Rules of Civil Procedure and will then, to the extent authorized by those Rules, ask the court to require you (or the party on whose behalf you are addressed) to pay the full costs of such service. In that connection, please read the statement concerning the duty of parties to waive the service of the summons, which is set forth on the reverse side (or at the foot) of the waiver form.

I affirm that this request is being sent to you on behalf of the plaintiff, this _____ day of _____, _____.

_____

Alan W. Jones
P. O. Box 25722, Scottsdale, AZ

To be printed on reverse side of the waiver form or set forth at the foot of the form:

Duty to Avoid Unnecessary Costs of Service of Summons

Rule 4 of the Federal Rules of Civil Procedure requires certain parties to cooperate in saving unnecessary costs of service of the summons and complaint. A defendant located in the United States who, after being notified of an action and asked by a plaintiff located in the United States to waive service of a summons, fails to do so will be required to bear the cost of such service unless good cause be shown for its failure to sign and return the waiver.

It is not good cause for a failure to waive service that a party believes that the complaint is unfounded, or that the action has been brought in an improper place or in a court that lacks jurisdiction over the subject matter of the action or over its person or property. A party who waives service of the summons retains all defenses and objections (except any relating to the summons or to the service of the summons), and may later object to the jurisdiction of the court or to the place where the action has been brought.

A defendant who waives service must within the time specified on the waiver form serve on the plaintiff's attorney (or unrepresented plaintiff) a response to the complaint and must also file a signed copy of the response with the court. If the answer or motion is not served within this time, a default judgment may be taken against that defendant. By waiving service, a defendant is allowed more time to answer than if the summons had been actually served when the request for waiver of service was received.

[Adopted April 22, 1993, effective December 1, 1993.]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Alan W. Jones and Kathryn Marie Jones, Plaintiffs, Vs. **Dallas Neurosurgical and Spine Associates, P.A.; Dr. Jeremy Denning; Dr. Richard Jackson;** **Texas Health Presbyterian Hospital of Dallas;** **Medtronic Corporation; James Sherman; Josh Tsokanas; Nora (Lora) Jean Enty;** **DOE DEFENDANTS 1-10,** Defendants.	CIVIL NO. _____ **WAIVER OF SERVICE OF SUMMONS**

TO: _____

I acknowledge receipt of your request that I waive service od a summons in the action of Jones vs. Dallas Neurosurgical and Spine Associates, P.A., et al., which is case number _____ in the United States District Court for the State of Arizona. I have also received a copy of the complaint in the action, two copies of this instrument, and a means by which I can return the signed waiver to you without cost to me.

I agree to save the cost of service of a summons and an additional copy of the complaint in this lawsuit by not requiring that I (or the entity on whose behalf I am acting) be served with judicial process in the manner provided by Rule 4.

I (or the entity on whose behalf I am acting) will retain all defenses or objections to the lawsuit or to the jurisdiction or venue of the court except for objections based on a defect in the summons or in the service of the summons.

I understand that a judgment may be entered against me (or the party on whose behalf I am acting) if an answer or motion under Rule 12 is not served upon you within 60 days after October 25 of 2012, or within 90 days after that date if the request was sent outside the United States.

_____ _____

Date Signature

_____

Printed/typed name

as _____

of _____

To be printed on reverse side of the waiver form or set forth at the foot of the form:

Duty to Avoid Unnecessary Costs of Service of Summons

Rule 4 of the Federal Rules of Civil Procedure requires certain parties to cooperate in saving unnecessary costs of service of the summons and complaint. A defendant located in the United States who, after being notified of an action and asked by a plaintiff located in the United States to waive service of a summons, fails to do so will be required to bear the cost of such service unless good cause be shown for its failure to sign and return the waiver.

It is not good cause for a failure to waive service that a party believes that the complaint is unfounded, or that the action has been brought in an improper place or in a court that lacks jurisdiction over the subject matter of the action or over its person or property. A party who waives service of the summons retains all defenses and objections (except any relating to the summons or to the service of the summons), and may later object to the jurisdiction of the court or to the place where the action has been brought.

A defendant who waives service must within the time specified on the waiver form serve on the plaintiff's attorney (or unrepresented plaintiff) a response to the complaint and must also file a signed copy of the response with the court. If the answer or motion is not served within this time, a default judgment may be taken against that defendant. By waiving service, a defendant is allowed more time to answer than if the summons had been actually served when the request for waiver of service was received.

[Adopted April 22, 1993, effective December 1, 1993.]