THE STATE OF SOUTH CAROLINA
In The Court Of Appeals

APPEAL FROM THE ADMINISTRATIVE LAW COURT

HONORABLE SHIRLEY C. ROBINSON, ADMINISTATIVE LAW JUDGE

CASE NO. 12-ALJ-17-0505-CC
APPELLANT CASE NO. 2014-001457

CareAlliance Health Services d/b/a Roper St. Francis Healthcare,.....Respondent,

v.

South Carolina Department of Revenue,.....Appellant.

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VOLUME I

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FILED
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SC ADMIN. LAW COURT

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a, Roper St. Francis Medical Healthcare, Inc., Petitioner, v. South Carolina Department of Revenue, Respondent.	Docket No.: 12-ALJ-17-0405-CC **ORDER**

APPEARANCES: Petitioner: Raymond Carpenter, Esquire, John von Lehe, Jr., Esquire, and Bryson M. Geer, Esquire
Respondent: Adam N. Marinelli, Esquire, and Lauren Acquaviva, Esquire

STATEMENT OF THE CASE

This matter is before the South Carolina Administrative Law Court ("ALC" or "the Court") pursuant to a Request for Contested Case Hearing filed by CareAlliance Health Services d/b/a Roper St. Francis Medical Healthcare, Inc. ("Petitioner") challenging the final determination of the South Carolina Department of Revenue ("the Department") denying a refund request for sales and use taxes paid on the purchase of orthopedic and cardiovascular prosthetics and blood derivatives between August 1, 2007, and November 30, 2010. Petitioner is a healthcare corporation consisting of Roper and St. Francis hospitals in Charleston. Petitioner submitted multiple ST-14 forms requesting refunds totaling $5,014,576.76. The Department refunded approximately $1.3 million of sales and use taxes. Of the remaining requested refunds, approximately $3.1 million was predicated on an exemption for "prosthetic devices sold by prescription" under section 12-36-2120(28)(a) of the South Carolina Code (Supp. 2010), and another $435,000 was based on a purported exemption for "blood derivatives" under section 44-43-10 of the South Carolina Code (Supp. 2010).[1] In a letter dated March 24, 2011, the Department denied Petitioner's claim for refunds for the prosthetics and the blood derivatives. Petitioner contested the Department's denial, and the Department's initial determination was

[1] The actual amount contested is not at issue; here, I merely address the legal issue of whether a refund for the contested items is required under law.

upheld in a Final Determination issued on August 16, 2012. Thereafter, discovery was completed, and both parties filed Cross Motions for Summary Judgment. A motions hearing was held on October 1, 2013, before this Court.

ISSUES

I. **Whether Petitioner's purchases of prescription prosthetic devices are exempt from sales and use taxes under South Carolina Law?**

II. **Whether Petitioner's purchases of certain purported blood derivatives are exempt from sales and use taxes under South Carolina law?**

CONCLUSIONS OF FACT

The following facts were undisputed between the parties. The Petitioner is a healthcare corporation comprised of Roper and St. Francis hospitals, both of which are located in Charleston, South Carolina. Petitioner submitted multiple ST-14 forms requesting refunds totaling $5,014,576.76 for sales and use taxes paid on purchases of medical devices, including bone and joint implants, pacemakers and implantable cardioverter-defibrillators, bone, tissue, blood products, plasma derivatives, and oncology medicines. The Department refunded approximately $1.3 million of the requested refund and, on March 24, 2011, denied approximately $3.5 million of the remaining portions of the requested refunds on legal grounds. Thereafter, Petitioner timely contested the Department's decision denying its refund request by letter dated June 20, 2011. Petitioner claims it is entitled to a refund on the contested items because it is exempt from paying sales or use taxes on three types of items: (1) prescription reconstructive musculoskeletal and trauma musculoskeletal prosthetic devices ("Prosthetics A"); (2) prescription cardiac prosthetic devices ("Prosthetics B"); and (3) blood derivatives. The Prosthetics A category includes the following items: reconstructive musculoskeletal devices (hips, knees, shoulders, mastectomy reconstruction implants, other skeletal, other bone, muscle and tissue implants) and trauma musculoskeletal devices (pins, screws, nails, plates, other trauma implants). The Prosthetics B category includes the following items: cardiovascular devices (pacemakers and implantable cardioverter-defibrillators ("ICDs")).

All prosthetic devices in question are FDA regulated class II and class III prescription prosthetic devices. See 21 U.S.C. § 360c(a)(1). The parties agree the Prosthetics A devices, including hips, knees, shoulders, and mastectomy reconstruction implants, replace a missing part of the body. The parties disagree as to whether the remaining Prosthetics A and B devices also replace a missing part of the body.

Additionally, the parties agree Petitioner does not own any inventory of orthopedic or cardiac devices; however, Petitioner purchases and maintains a limited inventory of trauma devices for use on patients treated in the hospital. The parties also agree the reconstructive musculoskeletal devices and cardio devices are distributed to patients in the operating room by a certified physician who issues an oral order to the vendor for the orthopedic or cardiac prosthetic device. The device is immediately implanted into the patient after the physician orders the device.

Last, the parties agree the blood derivatives at issue include the following: Gamunex, Plasbumin, Albumin, Albutein, Buminate, Flexbumin, Octagam, Alburx and Albuminar.

CONCLUSIONS OF LAW

Based upon the submitted briefs, the oral arguments presented, and a thorough examination of the applicable statutes and jurisprudence, I conclude the following as a matter of law:

This Court has jurisdiction to hear this contested case pursuant to section 12-60-30 of the South Carolina Code (Supp. 2013). Generally, the party asserting the affirmative issue in an adjudicatory administrative proceeding has the burden of proof. See Leventis v. S.C. Dep't of Health & Envtl. Control, 340 S.C. 118, 133, 530 S.E.2d 643, 651 (Ct. App. 2000) (citing 2 Am.Jur.2d *Administrative Law* § 360 (1994)). Here, Petitioner requested a contested case hearing and, therefore, has the burden of proof to show by a preponderance of the evidence that the Department's tax assessment was incorrect. See id.; Anonymous (M-156-90) v. State Bd. of Med. Examiners, 329 S.C. 371, 375, 496 S.E.2d 17, 19 (1998) (holding the standard of proof in "administrative hearings is generally a preponderance of the evidence").

This Court's Rules of Procedure provide "[t]he South Carolina Rules of Civil Procedure . . . may, in the discretion of the presiding administrative law judge, be applied to resolve questions not addressed by these rules." ALC Rule 68. Rule 56(c) of the South Carolina Rules of Civil Procedure provides that summary judgment is properly granted when the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that any party is entitled to a judgment as a matter of law." See Bovain v. Canal Ins., 383 S.C. 100, 105, 678 S.E.2d 422, 424 (2009). In determining whether summary judgment is proper, this Court must construe all ambiguities, conclusions, and inferences arising from the evidence against the

moving party. Byers v. Westinghouse Elec. Corp., 310 S.C. 5, 7, 425 S.E.2d 23, 24 (1992). Although the evidence and inferences drawn therefrom generally must be construed against the moving party, "the nonmoving party may not rest upon the mere allegations or denials of the pleadings, but a response by affidavit or otherwise . . . must set forth specific facts creating a genuine issue for trial." Rule 56(e), SCRCP.

"If a statute's language is plain, unambiguous, and conveys a clear meaning 'the rules of statutory interpretation are not needed and the court has no right to impose another meaning.'" Buist v. Huggins, 367 S.C. 268, 276, 625 S.E.2d 636, 640 (2006) (quoting Hodges v. Rainey, 341 S.C. 79, 85, 533 S.E.2d 578, 581 (2000)). "The words of the statute must be given their plain and ordinary meaning without resorting to subtle or forced construction to limit or expand the statute's operation." Id. "The cardinal rule of statutory construction is to ascertain and effectuate the intent of the legislature." Id.

DISCUSSION

I. Whether Petitioner's purchases of prescription prosthetic devices are exempt from sales and use taxes under the South Carolina Code?

Under section 12-36-910(A) of the South Carolina Code (Supp. 2012), "[a] sales tax, equal to five percent of the gross proceeds of sales, is imposed upon every person engaged or continuing within this State in the business of selling tangible personal property at retail." Retail sales of tangible personal property includes, among other things:

> (i) sales of drugs, *prosthetic devices*,[2] and other supplies to hospitals, infirmaries, sanitariums, nursing homes, and similar institutions, medical doctors, dentists, optometrists, and veterinarians, if furnished to their patients as a part of the service rendered. These institutions, companies, and professionals are deemed to be the users or consumers of the property.

S.C. Code Ann. § 12-36-110(1)(i) (Supp. 2012) (emphasis added). Pursuant to this code section, the Department promulgated Regulation 117-308 to explain when tangible personal property constitutes taxable retail sales and when tangible personal property is considered part of the services rendered, which are generally not taxable. Regulation 117-308 initially states: "The receipts from services, when the services are the true object of the transaction, are not subject to the sales and use tax, unless the sales and use tax is specifically imposed by statute on such services (i.e. accommodation services, communication services)." The regulation then explains

[2] A "prosthetic device" is defined as "an artificial device to replace a missing part of the body." S.C. Code Regs. Ann. 117-332.

how it is applied to specific categories of professional and other services. Regarding hospital services, subsection 117-308.8 provides:

> Hospitals . . . are not liable for the sales tax with respect to their gross proceeds or receipts from meals, bandages, dressings, drugs, x-ray photographs and other tangible personal property where such property is used in the rendering of the primary medical service to patients.
>
> ****
>
> Where drugs, prosthetic devices and other supplies are furnished to their patients as part of the medical service rendered, such hospitals . . . are deemed to be users or consumers of such drugs, prosthetic devices and other supplies.

Therefore, sales of prosthetics to hospitals are generally taxable sales of tangible personal property.

However, section 12-36-2120 of the South Carolina Code (Supp. 2012) exempts certain retail sales of tangible personal property from sales tax, including "medicine and prosthetic devices *sold by prescription.*" § 12-36-2120(28)(a) (emphasis added). In Home Medical Systems, Inc. v. South Carolina Department of Revenue, the South Carolina Supreme Court determined whether, for tax exemption purposes under section 12-36-2120(28), certain devices were prosthetics and certain products constituted medicines sold by prescription. 382 S.C. 556, 563-64, 677 S.E.2d 582, 586-87 (2009). Although the alleged prescription prosthetic devices and prescription medicines in Home Medical are not the same as the prescription prosthetics at issue here, the supreme court's analysis of section 12-36-2120(28) is instructive. Id. In Home Medical, the supreme court adopted the Department's three-part test for determining when the section 12-36-2120(28) exemption applies. Id. The test provides "[1] the sale must require a prescription and [2] the device must actually be sold by prescription and [3] the device must replace a missing part of the body." Id. (quoting S.C. Rev. Rul. # 03–02 (2003)). Additionally, our case law provides that a tax exemption "must be strictly construed against the claimed exemption." Home Medical, 382 S.C. at 564, 677 S.E.2d at 587; see also Southeastern–Kusan, Inc. v. S.C. Tax Comm'n, 276 S.C. 487, 489, 280 S.E.2d 57, 58 (1981) ("As a general rule, tax exemption statutes are strictly construed against the taxpayer."). In this instance, the parties agree the devices are prescription devices, but disagree as to whether the prosthetics were sold by prescription and whether they replace missing body parts. I first address whether the prosthetics at issue were "sold by prescription."

A. Sold by Prescription

Petitioner contends that because the prosthetic devices at issue are class II and class III federal prescription prosthetics, it would be a violation of federal law if the sale of these prosthetics to the hospital was not a "sale by prescription." Petitioner specifically points to section 801.109 of Title 21 of the Code of Federal Regulations to argue prescription devices cannot be sold except by prescription. Section 801.109 exempts prescription devices from certain labeling requirements under various specific circumstances,[3] including when the device "[i]s to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice." 21 C.F.R. §801.109(a)(2). Therefore, under this labeling regulation, a class II or class III prescription prosthetic can be sold directly to a physician, on the order of the physician, or on prescription of a physician without certain labeling requirements. The regulation suggests a sale *by prescription* is analogous to a sale *to a physician* or *by physician's order* for the purpose of protecting consumers with labeling requirements because, under all these circumstances, the devices pass through the physician gatekeeper before reaching the consumer.[4]

Thus, I find Petitioner's argument that any sale of a federal prescription prosthetic is a sale by prescription is incorrect because it is too narrow a reading of section 801.109(a)(2) and dismisses the plain language of the regulation, which presumably incorporates the conjunction "or" for a reason. Therefore, a sale to a hospital is not *de facto* a "sale by prescription." Because federal law does not require a strict "sale by prescription," we come to the linchpin of the issue: how does South Carolina define "sale by prescription" for the purposes of tax exemptions? Specifically, does a physician's verbal order qualify as a "sale by prescription?" Unfortunately, our code does not define prescription in this context. Nor is it appropriate, as the Department urges, for this Court to adopt the definition of prescription in the South Carolina Pharmacy

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[3] The purpose of the federal classification system is to regulate devices for which "general control by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device" or for which "insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C.A. § 360c(a)(1)(B) & (C). Accordingly, to ensure proper use and safety, prescription devices are subject to certain labeling requirements.

[4] This interpretation is supported by the affidavit of Mary K. Pendergast, former Deputy Commissioner and Senior Advisor to the Commissioner of the Federal Food and Drug Administration (FDA), who stated federal law requires prescription prosthetics be sold on a physician's "prescription *or other order*." (emphasis added). Affidavit of Mary Pendergast at 2.

Practice Act.[5] See Home Med. Sys., Inc., 382 S.C. at 566 n.7, 677 S.E.2d at 588 n.7 (holding the ALC erred in relying on the definition of medicine for pharmacists found in section 40–43–30(16) of the South Carolina Pharmacy Practice Act to determine whether certain alleged medicines were subject to sales tax). Accordingly, this Court must rely on what guidance is available in case law, the rules of statutory construction, and public policy to determine whether the prescription prosthetics at issue were "sold by prescription."

1. Definition of Sale by Prescription in South Carolina

The South Carolina Supreme Court's decision in Home Medical demonstrates the phrases "prescription prosthetic device" and "sold by prescription" are two separate requirements that must be met to apply the exemption under section 12-36-2120(28). 382 S.C. at 563-64, 677 S.E.2d at 586-87. Thus, the supreme court's holding implies prescription devices can be sold without a prescription under some circumstances, but the supreme court does not describe the circumstances under which a "sale by prescription" occurs.

In the absence of statutory or case law defining a "sale by prescription," this Court turns to the Department's interpretation of "sale by prescription" in Revenue Ruling #03-2. This Department ruling addresses whether section 12-36-2120(28)(a) exempts the sale of prescription prosthetic devices to hospitals from sales tax. In its ruling, the Department advised that while certain devices are classified as prescription devices, this does not mean the devices are *sold by prescription*. (citing in support Assoc. Med. Spec., P.A. V. S.C. Tax Comm'n & S.C. Dep't of Rev., No. 97-UP-447 (S.C. Ct. App. 1997)). The Department further advised that sales of prescription prosthetics to "a hospital, nursing home, or a similar institution or doctor" are retail sales and "are not exempt since such sales do not require a prescription." Although the Department determined sales of prescription prosthetics to hospitals or doctors are not sales by prescription, the Department did not define, or attempt to define, "sale by prescription" in its ruling.

While this Court generally gives deference to an agency's interpretation of an applicable statute or its own regulation, this Court is not bound to follow the Department's interpretation. Brown v. Bi-Lo, Inc., 354 S.C. 436, 440, 581 S.E.2d 836, 838 (2003); Buist, 367 S.C. at 276, 625 S.E.2d at 640 ("The construction of a statute by the agency charged with its administration

[5] S.C. Code Ann. §§ 40-43-10 et seq.

will be accorded the most respectful consideration and will not be overruled absent compelling reasons."). Here, I decline to follow the Department's interpretation of section 12-36-2120(28)(a)'s application to prescription prosthetics sold to hospitals. I find the Department's failure to define or attempt to define the circumstance under which a prosthetic is "sold by prescription" underscores the fact that the Department's interpretation is conclusory and without support, particularly because the plain and ordinary meaning of prescription is not clear in the context of the statute. Therefore, it is necessary to engage in statutory construction. See Buist, 367 S.C. at 276, 625 S.E.2d at 640 ("If a statute's language is plain, unambiguous, and conveys a clear meaning 'the rules of statutory interpretation are not needed and the court has no right to impose another meaning.'" (quoting Hodges, 341 S.C. at 85, 533 S.E.2d at 581)).

In Webster's dictionary, "prescription" is defined as "a written direction for the preparation, compounding, and administration of a medicine." Webster's Third New International Dictionary 1792 (1993). In the verb form, "to prescribe," as a physician would, means "to direct, designate, or order the use of as a remedy." Id. Therefore, generally, a prescription refers to a written direction or order from a physician. Although South Carolina has not addressed the definition of prescription in the context of sales tax exemptions, several other jurisdictions have addressed the matter. And while this Court is not bound to follow the decisions of other jurisdictions, these decisions do provide some guidance on the topic. See Nolan v. Daley, 222 S.C. 407, 412, 73 S.E.2d 449, 451 (1952) ("While this [c]ourt is in no sense bound by the construction of similar [a]cts by the courts of another state, we may well be moved to adopt the construction placed upon such [a]cts by such courts when we are impressed with the logic and reasonableness of their conclusions, especially when, as here, this [c]ourt has not construed same.").

In Northern Virginia Doctors Hospital Corporation v. Department of Taxation, the Supreme Court of Virginia addressed whether certain medicines and drugs were "sales to the Hospital and thereby subject to a sales tax . . . or whether they are medicines and drugs 'dispensed by or sold on prescriptions or work order of licensed physician,' and thereby exempt from the sales tax."[6] 193 S.E.2d 684, 685 (1973). The facts of this case were as follows:

[6] Virginia's statute exempts "[m]edicines, drugs, crutches, braces, artificial eyes, contact lenses, eyeglasses, hearing aids, prosthetic devices and orthopedic appliances dispensed by or sold on prescriptions or work orders of licensed physicians." Va. Code Ann. § 58-441.5 (Supp. 1973).

A physician prescribed a drug for a specific patient on a doctor's order sheet. Id. A nurse then transferred the order to a pharmacy requisition form, which was stamped with the patient's plate (including the patient's name, room number, and the prescribing physician's name). Id. The requisition form was then given to the pharmacy, the pharmacy filled the prescription, and the drug was returned to the nursing station for administration to the patient as directed by the physician. Id.

In analyzing this set of facts, the Virginia Supreme Court turned to the definition of "prescription" in Webster's Third New International Dictionary for guidance because the Virginia Code did not include a definition for prescription in the context of tax exemptions. Id. at 688. Applying the dictionary definition to the specific facts of the case, the Virginia Supreme Court found the prescription drugs were exempt from sales tax under Virginia's tax code. Id. The court stated:

> We think the General Assembly, in enacting [the sales tax exemption for remedies "dispensed by or sold on prescription or work orders of licensed physicians"], intended to exempt drugs and medicines that are prescribed by a physician to be administered to a patient and which are prepared and compounded by a pharmacist from a written prescription or order."

Id. Furthermore, the court concluded the "order of the physician, whether it takes the form of a prescription or a work order, is the salient feature of the transaction, for without it the pharmacist takes no action." Id.

Similarly, in Syncor International Corporation v. Palmer, the Supreme Court of Appeals of West Virginia determined certain prescription radiopharmaceutical drugs were "dispensed upon prescription," and therefore exempt from sales tax under West Virginia law.[7] 542 S.E.2d 479, 481 (2001). In this case, Syncor sold prescription radiopharmaceuticals to hospitals, doctors, and other similar health care providers. Id. Some of its sales constituted unit doses of radiopharmaceuticals prepared for a particular patient pursuant to the prescription of the patient's physician.[8] Id. Specifically, a patient's physician would issue a verbal, facsimile, or electronic prescription to Syncor requesting a particular radiopharmaceutical. Id. at 482. Syncor then

[7] West Virginia's code exempted from sales tax "sales of drugs dispensed upon prescription." W. Va. Code § 11-15-9(a)(11) (1997). Like Virginia's Code, West Virginia's Code did not define "prescription" in the context of the sales tax exemptions.

[8] Other sales constituted bulk sales of radiopharmaceuticals to health care providers for subsequent use in preparing unit doses for individual patients. The bulk sales were not contested and deemed subject to sales tax.

produced a prescription label to be attached to the unit dose of the drug. Id. Syncor billed the hospital or clinic for the unit radiopharmaceuticals, and the bills did not always include the patient's name or other patient identifying information. Id. Palmer, West Virginia's tax commissioner, argued the unit sales should be taxed because the sales exemption only applied "when the patient directly buys and self-administers" a drug. Id. The tax commissioner further argued the units were sold to the hospital and not the individual patients. Id. Essentially, the tax commissioner claimed the definition of prescription required the drug to be sold to the patient and self-administered by the patient.

The court rejected the tax commissioner's arguments, and instead found that the issue turned on whether the drugs were "dispensed pursuant to prescriptions". In this instance, the pertinent regulations did not define a "prescription-type sale;" rather, the regulations emphasized the distinction between individual sales pursuant to prescription and bulk sales to medical service providers without prescriptions. Id. at 483-84 n.9. The court concluded:

> the sale of a radiopharmaceutical to a medical service provider is exempt from the consumer sales tax under the provisions of West Virginia [law] where the radiopharmaceutical is purchased and dispensed pursuant to a physician's prescription that was prepared for a particular individual patient.

Id. at 483-84.

Further, in Deaconess Medical Center v. Department of Revenue, the Court of Appeals of Washington addressed whether prescription heart-lung machines purchased for a hospital were exempt from sales tax.[9] 795 P.2d 146 (1990). The court ultimately determined the heart-lung machines were not exempt, primarily because the machines were sold to the hospital, not to individual patients. Id. at 149. In its ruling, the court described the machines as becoming

> part of the hospital's surgical equipment, used routinely in all surgical procedures involving the heart and lungs. The machines are not sold to a hospital because they have been prescribed for an individual, and they are not sold to patients at all. Indeed, their use is not "prescribed" in the common medical meaning of the word, let alone prescribed for or dispensed to an individual by any of the practitioners identified.

Id. (citing Webster's Third New International Dictionary 1792 (Merriam 1966)).

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[9] Washington's code provides prosthetic devices are exempt from sales tax when they are "prescribed for an individual" by a licensed physician. Wash. Rev. Code § 82.08.0283 (Supp. 1990).

Irrespective of the final outcome, the commonality between these cases is a recognition that in order to qualify as a sale by prescription for tax exemption purposes, the prescription must be a *written order* prescribing a certain medicine or prosthetic for *a particular patient*. I find this definition of prescription to be reasonable and adopt it for the purposes of this case.

2. Application of the Definition of Prescription to This Case

Applying this definition of prescription to the facts of the case, I conclude the prescription prosthetics at issue were "sold by prescription." Here, Petitioner's Director of Material Services, Charles Prescott Ferguson, described in his deposition how the prosthetics are sold to Petitioner. He stated Petitioner's treating physician contacts the prosthetics vendor a few weeks before the prosthetic will be implanted to let the vendor know what type of product he needs. Ferguson Deposition at 11-15. The day of the operation, the vendor is present in the operating room. Ferguson Deposition at 11-12; Deposition of Melanie Hutcherson at 9-10. During the procedure, the physician orally communicates the patient's exact needs to the vendor, the vendor selects the appropriate prosthetic, the prosthetic is immediately implanted, and the purchase is made.[10] Id. The transaction is memorialized on a requisition sheet, which contains patient-specific information, and, from the requisition sheet a purchase order and invoice are created for accounting purposes. Ferguson Deposition at 33-36; Hutcherson Deposition at 10-11. Thus, it is on the physician's oral order, memorialized in writing on a requisition sheet, that the prosthetic is purchased by the hospital for a specific patient.[11]

Under these facts, a physician's oral order for a specific patient is memorialized in writing and used to purchase the prosthetic from the vendor, which this Court finds constitutes a "sale by prescription." Furthermore, this Court does not find it determinative that the hospital, and not the patient, pays the bill for the prescription prosthetic; presumably this cost is ultimately passed on to the recipient of the prosthetic, the individual patient.[12]

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[10] Additionally, Petitioner's physician affiants asserted they considered their oral orders to be prescriptions. Affidavit of John McCrosson, M.D. at 1; Affidavit of Brett M. Baker, M.D. at 1.

[11] In his affidavit, the Director of Material Services repeatedly stated Petitioner only acquires prescription devices "upon the prescription or order of a physician."

[12] The exemptions from sales tax under S.C. Code Ann. § 12-36-2120, including the exemption for prosthetic prescription devices, were promulgated pursuant to 1990 Act No. 612, Part II, § 74A. The Act provides no guidance as to the legislative intent for the sales tax exemption for prescription devices.

However, I also find public policy favors the sale of some prescription items in bulk without a prescription. For example, in his affidavit, Steven Silverman, the Director of Compliance of the Center for Devices and Radiological Health at the United States Food and Drug Association, states it would be against public policy to deny hospitals the ability to purchase an inventory of prescription devices when emergency care necessitates utilizing the devices with a quickness that would be defeated by waiting for the manufacturer to fill a prescription. Accordingly, Silverman asserted hospitals may purchase an inventory of prosthetic devices as long as the device is ultimately dispensed to a patient on the prescription or other order of a licensed physician.

Here, although the parties agree Petitioner does not actively keep an inventory of all the prosthetic devices at issue, Petitioner concedes it purchases a small inventory of prescription trauma prosthetics, such as screws, plates, rods, and heart valves, for emergency situations. Petitioner asserts all sales of inventory are made upon the order of a physician even if the orders fail to prescribe the trauma devices for particular persons. Ferguson Affidavit at 2. Under these circumstances, I find it logical to distinguish between a sale related to a particular individual and a bulk sale to a medical provider. Accordingly, bulk sales of prescription devices to medical providers are not "sales by prescription" and are subject to sales tax. See Deaconess Medical Center, 795 P.2d at 149 (holding certain heart-lung machines were not subject to the sales tax exemption for prescription prosthetic devices because they were sold to the hospital and were not prescribed for, or sold to, a particular patient). 382 S.C. at 563-64, 677 S.E.2d at 586-87.

Because I conclude the non-inventory prosthetic devices at issue were sold "by prescription," I must now address whether the prosthetic devices at issue "replace a missing part of the body."

B. Replace a Missing Body Part

Home Medical provides that in order for the sales tax exemption to be applicable, the prescription prosthetic "must replace a missing part of the body." 382 S.C. at 564, 677 S.E.2d at 587. Further, a "device that merely replaces a missing function is not exempt." Id. In its decision in Home Medical, the supreme court made it clear that although some more modern definitions of prosthetic include the replacement of a missing function, the exemption in section 12-36-2120(28)(a) is limited to prosthetics that replace a missing body part. Id. at 564-65, 677 S.E.2d at 587.

The parties agree that hip, knee, shoulder, and mastectomy reconstructive implants replace a missing part of the body. However, the Department contests whether implanted cardiac devices, some orthopedic devices (other bone, muscle, and tissue implants), and trauma devices (pins, screws, nails, plates) replace a missing part of the body. The Court will address each type of device in turn.

First, the parties dispute whether prescription cardiac implants replace a missing part of the body. Petitioner submitted the deposition of Brett M. Baker, M.D., who regularly implants the pacemakers and ICDs at issue here. Dr. Baker has worked for Petitioner previously. Baker Deposition at 6. Dr. Baker indicated prescription cardiac devices are necessary when cells in the heart die, causing the heart to function abnormally. Id. at 9, 12-13, 17. Essentially, prescription cardiac devices do not replace a part of the heart; rather, they replace the function of the dead cells to restore normal heart function.[13] Id. at 17. Accordingly, this Court concludes prescription cardiac devices enhance or correct the functioning of the heart, but do not replace a missing body part. Therefore, prescription cardiac devices are not prosthetics as defined in regulation 117-332 of the South Carolina Code of Regulations, and, therefore, are not subject to the sales tax exemption under the test in Home Medical. 382 S.C. at 564, 677 S.E.2d at 587 (providing that in order for the sales tax exemption to be applicable, the prescription prosthetic "must replace a missing part of the body").

Second, this Court finds other bone, muscle, and tissue implants replace missing parts of the body just like a man-made hip replacement replaces a human hip that is removed from a patient. The Court finds no reason to distinguish "other bone" from a hip bone or a rib bone, etc. In all these cases, a part of the body is removed and replaced with a prosthetic.

Third, the Court has already determined trauma devices that are purchased in bulk or kept in inventory at the hospital are subject to sales tax because they are not sold by prescription. However, this Court further finds that these devices do not replace a body part, but rather enhance existing body parts.

In sum, this Court finds hip, knee, shoulder, mastectomy reconstructive implants, other bone, muscle, and tissue implants replace missing parts of the body. In contrast, prescription

[13] Dr. Baker indicated he removes and replaces heart tissue in approximately 1-10% of his patients. Baker Deposition at 16-17. This amount is too small to impact this Court's determination that cardiac devices do not replace a missing part of the body.

cardiac devices and prescription trauma devices do not replace missing parts of the body and are not prosthetics as defined in section 117-332 of the South Carolina Code of Regulations. S.C. Code Regs. Ann. 117-332 (defining a "prosthetic device" as "an artificial device to replace a missing part of the body"). Because prescription cardiac devices and prescription trauma devices do not replace a missing part of the body, they are not exempt from the sales tax under section 12-36-2120(28)(a). See Home Medical, 382 S.C. at 563-64, 677 S.E.2d at 586-87 (holding that to qualify for a section 12-36-2120(28) exemption "[1] the sale must require a prescription and [2] the device must actually be sold by prescription and [3] the device must replace a missing part of the body" (quoting S.C. Rev. Rul. # 03–02 (2003)).

C. Conclusion

The issue presented is a novel issue, which primarily concerns the application of law. Under the facts presented, I conclude the prescription reconstructive musculoskeletal devices are exempt from sales and use taxes whereas prescription trauma musculoskeletal prosthetic devices and prescription cardiac prosthetic devices are subject to sales and use taxes.[14] I believe my decision is consistent with our case law, which generally requires a tax exemption to be strictly construed against the claimed exemption. Southeastern–Kusan, Inc. v. S.C. Tax Comm'n, 276 S.C. 487, 489, 280 S.E.2d 57, 58 (1981) ("As a general rule, tax exemption statutes are strictly construed against the taxpayer."). Further, because this was a legal issue, and Respondent has failed to demonstrate a genuine issue as to any material fact to prevent Petitioner from being entitled to judgment as a matter of law regarding the application of the exemption to prescription reconstructive musculoskeletal prosthetic devices, I therefore grant Petitioner's motion for summary judgment and deny Respondent's motion for summary judgment as to this issue. See Rule 56(c), SCRCP. Similarly, because Petitioner has failed to demonstrate a genuine issue as to any material fact to prevent Respondent from being entitled to judgment as a matter of law regarding the application of the exemption to prescription cardiac devices, I grant Respondent's motion for summary judgment and deny Petitioner's motion for summary judgment as to this issue. See id.

II. Whether Petitioner's purchases of certain purported blood derivatives are exempt from sales and use taxes under South Carolina law?

[14] Because the devices are not exempt from the sales tax, they are also subject to the use tax. See S.C. Code Ann. §12-36-1310.

South Carolina adopted the Revised Uniform Anatomical Gift Act, otherwise known as the "blood shield law." See S.C. Code Ann. § 44-43-10 (Supp. 2012). This law provides:

> The implied warranties of merchantability and fitness are not applicable to a contract for the sale, procurement, processing, distribution, or use of human tissues including, but not limited to, corneas, bones or organs, whole blood, plasma, blood products, or *blood derivatives*. Human tissue, whole blood, plasma, blood products, and *blood derivatives* must not be considered commodities subject to sale or barter, and the transplanting, injection, transfusion, or other transfer of these substances into the human body are considered a medical service.

Id. (emphasis added). In Samson v. Greenville Hospital System, 297 S.C. 409, 411, 377 S.E.2d 311, 312 (1989), the South Carolina Supreme Court stated the language of the statute "clearly indicates that the Legislature did not intend for blood to be classified as a product." Moreover, the supreme court further commented that the underlying purpose of the blood shield statute is to "facilitate a readily available supply of blood by limiting liability to defects resulting from negligence." Id.

Petitioner contends the blood shield statute prohibits the Department from taxing blood derivatives because blood derivatives are considered a service and not tangible personal property subject to the retail sales tax under section 12-36-910(A) of the South Carolina Code. Conversely, the Department contends the blood shield law was not legislated with the intention that it would be applied to tax situations. The Department argues that in absence of the blood shield statute, blood derivatives are taxable tangible personal property.

This Court agrees with the Department. The Court recognizes the Department has inconsistently exempted other human products, like rib cartilage,[15] from sales tax in deference to the blood shield statute; however, since 1992 the Department appears to have adopted the unofficial policy that blood and its derivatives are tangible personal property. See Deposition of John P. McCormack at 41-52. More specifically, the Department seems to have consistently taxed blood derivatives in practice, even if it does not have an official policy governing the taxation of blood derivatives. See id. at 59-64. See Brown, 354 S.C. at 440, 581 S.E.2d at 838 (holding the ALC generally gives deference to an agency's interpretation of an applicable statute or its own regulation unless the plain language of the statute in contrary to the agency's interpretation).

[15] See Affidavit of Christine Buddin.

The blood shield statute, while providing that blood derivatives "must not be considered commodities subject to sale or barter," but must rather be considered "medical services," cannot be taken out of context of tort liability and applied to a tax situation. Cf. Liberty Mut. Ins. Co. v. S.C. Second Injury Fund, 363 S.C. 612, 621, 611 S.E.2d 297, 301 (Ct. App. 2005) ("All rules of statutory construction are subservient to the one that legislative intent must prevail if it can be reasonably discovered in the language used, and that language must be construed *in the light of the intended purpose of the statute.*" (emphasis added)). If the legislature had intended blood derivatives to be exempt from the sales tax, it would have specifically enumerated an exemption for blood derivatives or, at the very least, incorporated the blood shield statute by reference. In the absence of an exemption in the tax code, this Court finds the blood derivatives at issue are retail sales of taxable personal property.[16] Because this Court finds blood derivatives are subject to sales and use taxes as a matter of law,[17] and Petitioner has failed to demonstrate a genuine issue as to any material fact to prevent Respondent from being entitled to judgment as a matter of law. Therefore, I grant Respondent's motion for summary judgment and deny Petitioner motion for summary judgment as to this issue. See Rule 56(c), SCRCP.

CONCLUSION

The Department properly denied the portion of Petitioner's sales tax refund claim related to the purchase of prescription cardiac devices and blood derivatives. However, the Department erred in denying the portion of Petitioner's sales tax refund claim related to the purchase of prescription reconstructive musculoskeletal prosthetic devices.

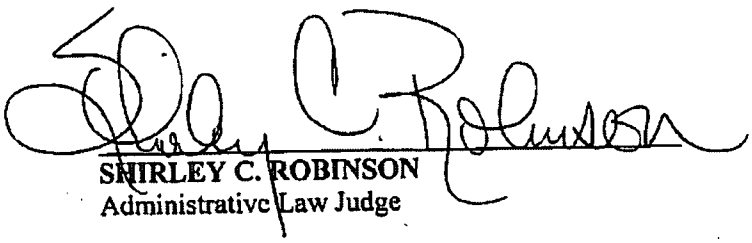
THEREFORE, IT IS HEREBY ORDERED that the Department's Motion for Summary Judgment **IS GRANTED IN PART** and **DENIED IN PART**, and Petitioner's Motion for Summary Judgment is **GRANTED IN PART** and **DENIED IN PART.**

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[16] Because this Court finds blood derivatives are subject to tax as a matter of law, I do not address whether the blood derivatives at issue are manufactured.

[17] Because the devices are not exempt from the sales tax, they are also subject to the use tax. See S.C. Code Ann. § 12-36-1310.

AND IT IS SO ORDERED.



SHIRLEY C. ROBINSON
Administrative Law Judge

May 20, 2014
Columbia, South Carolina

CERTIFICATE OF SERVICE
This is to certify that the undersigned has this date served this order in the above entitled action upon all parties to this cause by depositing a copy hereof in the United States mail, postage paid, or in the interagency Mail Service addressed to the party(ies) or their attorney(s).

This 20 day of May 2014

By: Jackie Henderson
Judicial Law Clerk

FILED
JUN 27 2014
SC ADMIN. LAW COURT

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a Roper St. Francis Healthcare, Petitioner, v. South Carolina Department of Revenue, Respondent.	Docket No. 12-ALJ-17-0405-AP **ORDER GRANTING IN PART AND DENYING IN PART MOTIONS FOR RECONSIDERATION**

This matter is before the South Carolina Administrative Law Court ("the ALC" or "the Court") pursuant to CareAlliance Health Services d/b/a Roper St. Francis Healthcare's ("Petitioner's") Contested Case Filing concerning a final decision of the South Carolina Department of Revenue ("the Department"). The Department's final decision denied Petitioner's request for a refund of sales and use taxes paid on the purchase of orthopedic and cardiovascular prosthetics and blood derivatives between August 1, 2007, and November 30, 2010. Petitioner and the Department filed cross motions for summary judgment. On May 20, 2014, this Court issued an Order granting in part and denying in part each party's summary judgment motion.

Subsequently, on May 30, 2014, Petitioner and the Department filed motions requesting the Court to reconsider its decision. Petitioner asks this Court to reconsider its determinations that (1) the prescription cardiac devices at issue do not replace a missing part of the body, and (2) the blood derivatives at issue are subject to sales and use taxes. Petitioner argues there is a factual dispute as to whether prescription cardiac devices replace a missing part of the body, and, therefore, this issue was inappropriate for summary judgment. Regarding the blood derivatives, Petitioner argues the "true object" of the sale was to provide services and, as such, the transaction was not subject to sales and use taxes. Moreover, Petitioner claims there is no reason to distinguish between the blood derivatives at issue and other forms of blood, such as whole blood and plasma, which are not taxed.

In contrast, the Department asks this Court to reconsider its determinations that (1) the sale of prescription prosthetics at issue was a sale by prescription as defined by this Court, and (2) "other bone, muscle and tissue implants" replace a missing part of the body. The Department

contends a sale is not a "sale by prescription" unless the purchaser is required to use a prescription in order to obtain the device. Further, the Department maintains this Court erred in its adoption of a definition of "prescription." Regarding the "other bone, muscle and tissue implants," the Department asserts there were no facts in the record to support this Court's decision.

Initially, I grant Petitioner's request for a hearing on whether the prescription cardiac devices at issue replace a missing part of the body. Furthermore, upon review, I grant a hearing on whether the blood derivatives at issue are subject to sales tax.

Regarding the Department's argument that this Court erred in finding the sale of prescription prosthetics was a sale by prescription, after considering the facts of this case and Petitioner's and the Department's Motions for Reconsideration, the Court finds its Order granting Petitioner's motion for summary judgment on this issue must stand. The Department argues this Court failed to address or misapprehended the first prong of the Home Medical test; specifically, whether a prescription is required for the sale of the prosthetics at issue. See 382 S.C. 556, 677 S.E.2d 582 (2009). This is a novel issue and, upon review, the Court finds it necessary to amend and clarify its finding in this regard.

The first two prongs of Home Medical overlap in that they both intimate the same requirement: the sale of the device must require and be made with a prescription for the tax exemption to apply. 382 S.C. at 563-64, 677 S.E.2d at 586-87. However, the word "actually" in the second prong implies the two prongs are distinct. The second prong implies there are situations in which a prescription is required for sale, but the sale is not actually accomplished by prescription. Having distinguished between the two prongs, I return to the application of the first prong in this case: did the sale of the prosthetic devices at issue require a prescription?

As the Department duly notes, this Court determined a "prescription" is not strictly necessary for all sales under section 801.109 of Title 21 of the Code of Federal Regulations, because this regulation allows devices to be sold to *or* on the prescription *or* other order of a physician for use in the course of his or her professional practice. 21 C.F.R. § 801.109(a)(2) (emphasis added). However, this Court also noted that the over-arching purpose of the regulation is to require a gate-keeper to protect consumers from purchasing potentially dangerous products. I find too strict a reading of the federal regulation, specifically parsing out the language, defeats the statute's purpose, especially as applied to Home Medical. Specifically, if a

distinction is made between "prescription" and "order" in the federal regulation, then no device would ever *require* a prescription for sale – an order could always suffice. Consequently, the first prong of Home Medical would never be satisfied and no devices would ever be tax exempt. Presumably, our legislature did not craft the exemption with the intent it would never apply. Therefore, I interpret the federal regulation broadly to find "order" and "prescription" are synonymous in the context of the purpose of the federal regulation. Accordingly, I find the prosthetic prescription devices at issue require a prescription to be sold, and they satisfy the first prong of Home Medical.[1]

Next, whether the devices at issue were *actually* sold by prescription and satisfy the second prong of Home Medical depends on the definition of "prescription." As previously discussed in this Court's order, "prescription" is not defined for the purposes of our tax code. Accordingly, this Court must look outside the tax code for guidance. In defining prescription in its order, this Court did not examine the South Carolina Pharmacy Code for guidance. The Department argues this Court misapprehended the Supreme Court's admonishment in Home Medical not to look to the South Carolina Pharmacy Practice Act ("Pharmacy Act") for a definition of a term in the context of a tax case. Upon review, the Court agrees with the Department that the admonishment only applied because "medicine," unlike "prescription," was already defined in the tax code. 382 S.C. at 566 n.7, 677 S.E.2d at 588 n.7. Therefore, I now review the definition of "prescription" in the Pharmacy Act for guidance.

The Pharmacy Act defines "prescription drug order" as "a lawful order from a practitioner for a drug or device for a specific patient, issued for a legitimate medical purpose within the prescriber's course of legitimate practice and including orders derived from collaborative pharmacy practice." S.C. Code Ann. § 40-43-30(47). I now adopt this definition, which does not affect my overall finding that the devices at issue were actually sold by prescription.

The Department contends the devices were not sold by prescription, but were sold by "chart order," which is separately defined as:

> a lawful order from a practitioner for a drug or device for patients of a hospital or extended care facility, or such an order prepared by another person and signed by

[1] The Court realizes that under the broad interpretation it has adopted, prescription prosthetics will always require a prescription to be sold and, therefore, the first prong of Home Medical will always be satisfied. The Court finds this to be a less absurd result than the alternative interpretation.

> a practitioner either immediately or at another time, issued for a legitimate medical purpose within the practitioner's course of legitimate practice and including orders derived on behalf of a practitioner from a practitioner approved drug therapy management.

S.C. Code Ann. § 40-43-30(5).

The Department contends the terms "prescription drug order" and "chart order" are mutually exclusive, which suggests lawful orders from physicians in a hospital setting are never prescriptions. I disagree. The important difference between the definition of "prescription drug order" and "chart order" is the word "specific" in the definition of "prescription drug order" and "hospital or extended care facility" in the definition of "chart order." I find that while the format of the sale is better represented by the definition of "chart order", a chart order can constitute a prescription as in this case.

Specifically, here, although the sales presented like a chart order because the physician signed off on the requisition sheet, it is important to note that at all times the device was procured for a specific patient. A physician initially contacted the vendor for a specific patient, the physician lawfully ordered the device for the specific patient in the operating room, patient-specific information followed the device on the requisition sheet, and the device was issued for a legitimate medical purpose. This process meets the definition of prescription. Accordingly, the hospital purchased the prosthetic devices by prescription.[2]

Finally, I deny the Department's motion concerning the "other bone, muscle, and tissue implants." This was presented to the Court as a "catch-all" category of devices, and the Court declines to now address the items individually.

THEREFORE, IT IS HEREBY ORDERED that Petitioner's Motion for Reconsideration and Respondent's Motion for Reconsideration are **GRANTED IN PART** and **DENIED IN PART.**

AND IT IS SO ORDERED.

SHIRLEY C. ROBINSON
Administrative Law Judge

June 27, 2014
Columbia, South Carolina

[2] This is consistent with my finding that the bulk sales of trauma devices were subject to sales and use taxes because they were not actually sold by prescription. This finding likewise stands.

27 June 2014
Received Jurisdiction

FILED
JUL 29 2014
SC ADMIN. LAW COURT

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a Roper St. Francis Healthcare, Petitioner, v. South Carolina Department of Revenue, Respondent.	Docket No. 12-ALJ-17-0405-AP **ORDER DENYING MOTION TO PROCEED**

This matter is before the South Carolina Administrative Law Court ("the ALC" or "the Court") pursuant to CareAlliance Health Services d/b/a Roper St. Francis Healthcare's ("Petitioner's") Contested Case Filing concerning a final decision of the South Carolina Department of Revenue ("the Department"). The Department's final decision denied Petitioner's request for a refund of sales and use taxes paid on the purchase of orthopedic and cardiovascular prosthetics and blood derivatives between August 1, 2007, and November 30, 2010. Petitioner and the Department filed cross motions for summary judgment. On May 20, 2014, this Court issued an Order granting in part and denying in part each party's summary judgment motion.

Subsequently, on May 30, 2014, Petitioner and the Department filed motions requesting the Court to reconsider its decision. In an order dated June 27, 2014, this Court granted Petitioner's motion to reconsider and denied summary judgment as to whether (1) the prescription cardiac devices at issue do not replace a missing part of the body and (2) the blood derivatives at issue are subject to sales and use taxes. In so doing, this Court granted a hearing on these two issues. In the same order, this Court denied the Department's motion to reconsider whether (1) the sale of prescription prosthetics at issue was a sale by prescription as defined by this Court, and (2) "other bone, muscle and tissue implants" replaced a missing part of the body.

Thereafter, on July 3, 2014, this Court received a Notice of Appeal. The Notice of Appeal indicated the Department was appealing this Court's May 20, 2014 order and its June 27, 2014 order. The Notice of Appeal did not specify particular issues which the Department was appealing. Following the parties receipt of the Notice of Appeal, a status conference call was held with this Court on July 11, 2014. During the conference call, Petitioner requested the Court

proceed with a hearing to resolve the issues of whether cardiac devices replace a missing part of the body and whether the blood derivatives at issue are subject to sales and use taxes. The Department argued this Court does not have jurisdiction to proceed with the hearing at this time due to the appeal. At Petitioner's request, the Court granted Petitioner and the Department leave to file briefs addressing whether this Court could proceed with the cardiac and blood derivative issues. The Court received Petitioner's brief on July 18, 2014, which I treat as a motion to proceed.

In order to proceed with the case as Petitioner desires, this Court must determine whether it still has jurisdiction in light of the pending appeal. Rule 205 of the South Carolina Appellate Court Rules ("SCACR") explains the effect of an appeal and provides:

> Upon the service of the notice of appeal, the appellate court shall have *exclusive jurisdiction* over the appeal; the lower court or administrative tribunal shall have jurisdiction to entertain petitions for writs of supersedeas as provided by Rule 241. Nothing in these Rules shall prohibit the lower court, commission or tribunal from proceeding with matters *not affected* by the appeal.

(emphasis added). The Rule provides the appellate court will have *exclusive jurisdiction* over the matters appealed. In this case, the Department has appealed the two substantive orders issued by this Court in their entirety. Because the Department appealed the entirely of the orders and did not select particular issues for appeal, this Court no longer has jurisdiction to move forward with any issues covered by its prior orders.[1] Whether or not all the issues addressed by these orders are ripe for appeal is a separate issue for the Court of Appeals to determine at this stage in the litigation. Moreover, the issue of whether or not cardiac devices replace a missing part of the body will be rendered moot if the Court of Appeals reverses this Court's decision concerning prescription prosthetics. Therefore, the cardiac issue is affected by the appeal. See Rule 205, SCACR.

Even if this Court has jurisdiction, I find it is in the interest of judicial economy to stay a hearing on the issues of the cardiac devices and the blood derivatives until the Court of Appeals addresses the issue of the prescription prosthetics for two reasons. Cf. Midlands Util., Inc. v. S.C. Dep't of Health & Envtl. Control, 287 S.C. 483, 487, 339 S.E.2d 862, 864 (1986) ("The statute does not set forth the terms under which an appeal from the ruling of an administrative

[1] Petitioner argues the Department's statements during the conference call indicated the Department would not, at the very least, appeal the blood derivatives issue and therefore the Court should move forward with a hearing on this issue. However, in the absence of an official statement of the issues from the Department filed with the Court of Appeals, this Court will not rely on a conference call to determine its jurisdiction.

board may be stayed. In the absence of a stipulation on this point, we hold that the granting of a stay is within the discretion of the Circuit Judge . . . ."); City of Spartanburg v. Belk's Dep't Store of Clinton, 199 S.C. 458, 20 S.E.2d 157, 167 (1942) ("The granting of a motion for a stay of proceedings rests entirely within the discretion of the trial Judge."). First, as previously stated, the cardiac issue will be affected by the appeal. Second, to hold a hearing solely on the blood derivatives, an issue unlikely to be affected by the appeal, would create piecemeal litigation, which both parties expressed an interest in avoiding, as does this Court.

Thus, I deny the Petitioner's Motion to Proceed because this Court does not have jurisdiction to proceed with a hearing on the cardiac and blood derivative issues at this time. Moreover, even if the Court did have jurisdiction, I find it is in the interest of judicial economy to stay further proceedings until the Court of Appeals has resolved the prescription prosthetics issue.

THEREFORE, IT IS HEREBY ORDERED that Petitioner's Motion to Proceed is **DENIED.**

AND IT IS SO ORDERED.

SHIRLEY C. ROBINSON
Administrative Law Judge

July 24th, 2014
Columbia, South Carolina

29 July 2014
Received/Filed

DEPARTMENT DETERMINATION

Taxpayer:

Roper/St. Francis Medical Healthcare, Inc.
315 Calhoun Street
Charleston, SC 29401

Periods Involved:

August 1, 2007 through November 30, 2010

Matters in Dispute:

1. Do Roper/St. Francis Medical Healthcare, Inc.'s (taxpayer) purchases of prosthetic devices (classified by taxpayer as "Class A") that are furnished on site qualify as exempt from sales and use tax pursuant to S.C. Code Ann. § 12-36-2120(28) (Supp. 2011) as prosthetics sold by prescription?

2. Do the taxpayer's purchases of devices (classified by taxpayer as "Class B") that are furnished on site qualify as exempt from sales and use tax pursuant to § 12-36-2120(28) as prosthetics sold by prescription, and do they meet the requirements of 27 S.C. Code Ann. Regs. 117-332 (Supp. 2011) for the definition of "prosthetic device" in the first place?

3. Do the taxpayer's purchases of medicines manufactured from plasma derivatives qualify as exempt from sales and use tax pursuant to § 12-36-2120(28) as medicines sold by prescription?

4. Can the taxpayer toll the limitations period set forth by S.C. Code Ann. § 12-54-85 (Supp. 2011) by filing a claim for refund before attaining valid assignments of rights?

5. Is the taxpayer liable for use tax for consumption of tangible personal property even though it erroneously paid sales tax to an out-of-state vendor that is unregistered with the State of South Carolina?

Amounts In Dispute:

Refund Requests	
"Class A" Prosthetics	$ 1,502,408.29
"Class B" Devices	$ 1,553,408.41
Plasma Derivatives	$ 435,368.74
Invalid Assignments	$ 7,056.54
Total	$ 3,498,241.98

Tax	
Use Tax	$ 93,544.67
Interest	$ 12,608.49[1]
Total Amount At Issue	**$ 3,604,395.14**

Determinations:

1. The taxpayer's purchases of prosthetic devices (classified as "Class A") that are furnished on site do not qualify as exempt from sales tax pursuant to § 12-36-2120(28) as prosthetics sold by prescription.

2. The taxpayer's purchases of devices (classified as "Class B") that are furnished on site do not qualify as exempt from sales tax pursuant to § 12-36-2120(28) as prosthetics sold by prescription, and do not meet the requirements of Regulation 117-332 for the definition of "prosthetic device" in the first place.

3. The taxpayer's purchases of medicines manufactured from plasma derivatives do not qualify as exempt from sales tax pursuant to § 12-36-2120(28) as medicines sold by prescription.

4. The taxpayer cannot toll the limitations period set forth by § 12-54-85 by filing a claim for refund before attaining valid assignments of rights.

5. The taxpayer is liable for use tax for the consumption of tangible personal property even though it erroneously paid sales tax to an out-of-state vendor that is unregistered with the State of South Carolina.

Relevant Facts:

1. The taxpayer is a healthcare corporation comprised of Roper and St. Francis hospitals, which are located in Charleston, South Carolina.

2. The taxpayer submitted multiple ST-14 forms for refund requests, totaling $5,014,576.76[2] for sales and use tax on purchases of medical devices (largely bone and joint implants and pacemakers), bone, tissue, blood products, plasma derivatives, and oncology medicines.

3. A three year audit was conducted by the Department of Revenue (Department), resulting in an assessment of $284,756.08, of which the taxpayer paid $183,848.02. The remaining amount of $93,544.67 is attributed to use tax paid in

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[1]Interest has been calculated through July 31, 2012.

[2]The Department has deemed a large portion of the taxpayer's claim as valid, and has paid approximately 1.3 million in refunds of sales and use taxes to date.

error to an unregistered out-of-state company, and was protested by the taxpayer.

4. The Department denied the remaining portions of the refund requests on March 24, 2011.

5. The taxpayer timely protested by letter dated June 20, 2011.

Analysis:

1. The taxpayer's purchases of prosthetic devices (classified as "Class A") that are furnished on site do not qualify as exempt from sales tax pursuant to § 12-36-2120(28) as prosthetics sold by prescription.

The taxpayer's refund claim contains over three million dollars based upon purchases of medical devices. These items have been placed into two categories, "Class A," which are prosthetic devices that replace a missing body part, and "Class B," which are devices that replace a missing function. Both categories were denied by the Department on the basis that the hospital was deemed the end user of these retail purchases. Class B's second distinction and reason for denial is explained at length in Point Heading 2 below.

S.C. Code Ann. § 12-36-120 (2000) defines "wholesale sales" as sales of "tangible personal property to licensed retail merchants, jobbers, dealers, or wholesalers for resale, and **do not include sales to users or consumers** not for resale[.]" Id. (emphasis added). It is well settled law in this State that medical practitioners are regarded as the end users of prosthetics if such devices are furnished as part of the services rendered. S.C. Code Ann. § 12-36-110 (2000), in relevant part, clearly defines the terms "sale at retail" and "retail sale" to include:

> (i) sales of drugs, prosthetic devices, and other supplies to hospitals, infirmaries, sanitariums, nursing homes, and similar institutions, medical doctors, dentists, optometrists, and veterinarians, if furnished to their patients as a part of the service rendered. These institutions, companies, and professionals are deemed to be the users or consumers of the property[.]

27 S.C. Code Ann. Regs. 117-308.8 (Supp. 2011) states:

> Hospitals, infirmaries, sanitariums, nursing homes and like institutions are engaged primarily in the business of rendering services. They are not liable for the sales tax with respect to their gross proceeds or receipts from meals, bandages, dressings, drugs, x-ray photographs and other tangible personal property where such property is used in the rendering of the primary medical service to patients.

> This is true irrespective of whether or not such tangible items are billed separately to their patients. Hospitals, infirmaries, sanitariums, nursing homes and like institutions are deemed to be the users or consumers of such tangible personal property and the instate [sic] sellers of these items are required to report and remit the tax due on the sale of such property to the hospitals, infirmaries, sanitariums, nursing homes, and like institutions . . ..

Regulation 117-308.3 adds: "Doctors are the consumers of the supplies, medicines, office furniture and fixtures and special tools and equipment they use in the practice of their profession. Sales of such supplies and equipment to doctors are retail sales and subject to the sales tax."

Clearly, in the absence of an exemption, the sale of prosthetics to a medical institution that are furnished as part of the medical services rendered is a retail sale and subject to sales tax. The fact that the taxpayer purchases these devices on a patient specific basis or bills for them separately does not remove such purchases from the province of retail sales. These devices are furnished as part of the treatment provided, and in these regards, the taxpayer's purchases are subject to sales tax.

While there is an exemption from sales and use tax provided by § 12-36-2120(28)(a) for "medicine and prosthetic devices **sold by prescription**" the transactions at issue here do not qualify (emphasis added). The taxpayer contends that these devices are in fact purchased pursuant to doctors' purchase orders, and are required by the Federal Food and Drug Administration to be sold "only by or on the order of a physician" and therefore must be considered "sold by prescription." The taxpayer's argument is without merit. As a hospital, the taxpayer has the ability to purchase at will any of these devices as it sees fit. The FDA prohibits the sale of these devices to the ***general public*** by any person not licensed as a medical professional or without the authorization of a licensed medical provider. The decision to purchase these devices as each individual patient's need arises does not automatically create access to the prescription exemption. It is important to note that the taxable transaction is between the manufacturer and the hospital, not the patient and hospital. There is no restriction on the purchase of these devices from manufacturers by medical professionals.

S.C. Rev. Rul. #03-2 further explains the Department's long-standing interpretation of the prescription exemption's requirements. It states:

> In order for the exemption to be applicable, the medicine must be of a type that requires a prescription, **the sale must require a prescription**, and must actually be sold by prescription. As such, **sales of medicine to a hospital . . . or a similar institution or doctor are not exempt since such sales do not require a prescription.**

(emphasis added). This departmental interpretation was addressed and applied by the South Carolina Supreme Court in Home Medical Systems, Inc. v. South Carolina Dept. of Revenue, 382 S.C. 556, 566, 677 S.E.2d 582, 588 (2009), when it noted, "[i]n our opinion, however, the current statutory language – 'medicine . . . sold by prescription' – clearly evidences a legislative intent that the exemption be only for those medicines requiring a prescription." It logically follows, therefore, that the exemption applies only to sales transactions in which the purchaser is required to use a prescription in order to obtain the drug. As a medical hospital, the taxpayer here is not required to use prescriptions to purchase the devices from manufacturers. And, as the end user, sales and use tax applies to these retail transactions.

A similar situation was also addressed in Associated Medical v. S.C. Tax Comm'n, Unpub. Op. No. 97-UP-447 (August 26, 1997). In that case, the Court of Appeals decided that a professional medical association (like the taxpayer) was the user and consumer of the drugs it administered to patients as part of its professional services. The court further determined that the sale of such drugs to the doctors did not qualify for the exemption for "medicine . . . sold by prescription" because the purchases did not require a prescription. Rather, the court recognized that doctors have the ability to purchase medicines without a prescription, regardless of whether one is written.[3]

Because the sale of these devices to the taxpayer does not require a prescription, they are not exempt from sales and use tax under § 12-36-2120(28)(a) as "prosthetic devices sold by prescription." The statutory exemption applies only to sales transactions that require prescriptions; otherwise, if the Department were to accept the taxpayer's argument, doctors could start writing unnecessary prescriptions for all incidental items associated with health care provided to patients in order to avoid taxation. "The language of a tax exemption must be given its plain, ordinary meaning and must be strictly construed against the claimed exemption." Thayer v. S.C. Tax Comm'n, 307 S.C. 6, 14, 413 S.E.2d 810, 815 (1992). In this matter, the taxpayer has the unfettered ability to purchase the referenced devices without prescriptions as a licensed medical service provider. The choice to not keep an inventory of these devices, but rather, send patient specific

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[3]While it may appear curious that the exemption does not apply to Appellant in this case but would apply if Appellant's patients simply took a prescription to a pharmacist, purchased the . . . medicine, and returned to Appellant for administering of the drug, we believe the exemption's plain language, its legislative history, and Department's interpretation of the exemption clearly demonstrate the legislature's intent that the transaction be the focus of the tax.

Associated Medical, Op. No. 97-UP-447.

purchase orders to the manufacturer does not trigger the exemption from sales and use tax.

2. **The taxpayer's purchases of devices (classified as "Class B") that are furnished on site do not qualify as exempt from sales tax pursuant to § 12-36-2120(28) as prosthetics sold by prescription, and do not meet the requirements of Regulation 117-332 for the definition of "prosthetic device" in the first place.**

Similar to the "Class A" devices, the devices designated as "Class B" do not qualify for the prescription exemption for the same analysis outlined above. These devices, however, are also non-exempt on the grounds that they do not meet the definition of "prosthetic device" in the first place. The devices at issue in this category are largely pacemakers and similar artificial devices which **replace a function** of the body – not a missing part.

Regulation 117-332, adopted by the Legislature with the full force and effect of law, clearly defines "'Prosthetic Device'--an artificial device to replace a missing part of the body." In addition, in Home Medical Systems, Inc., 382 S.C. 556, the South Carolina Supreme Court upheld the Department's long-standing definition of a "prosthetic device," as set forth in Regulation 117-332, as "an artificial device to replace a missing part of the body." A device that merely replaces a missing function is not exempt.

The taxpayer contends that although a pacemaker initially replaces a function of the heart, eventually the sino-atrial valve atrophies and withers away, thereby causing an eventual "replacement" of the body part. This argument fails for two reasons. First, there is simply no way of verifying that such atrophy takes place. The speculative nature of such atrophy, and whether or not it takes place at all are entirely enough to determine that the artificial pacemaker has fully "replaced" the body part is simply too remote. The tax is applied at the time of the transaction, and at the time these devices are surgically implanted no body part is actually replaced. Secondly, and most important, the atrophy is a direct result of the device **replacing a function**, and therefore, by the very nature of the medical procedure it is outside the scope of the definition of a prosthetic device. Clearly, the Class B devices are not exempt from the imposition of sales tax.

3. **The taxpayer's purchases of medicines manufactured from plasma derivatives do not qualify as exempt from sales tax pursuant to § 12-36-2120(28) as medicines sold by prescription.**

In 1968, the South Carolina General Assembly enacted a statute known as the "blood shield" law. This law is now codified as S.C. Code Ann. § 44-43-10 (Supp. 2011) and reads:

> The implied warranties of merchantability and fitness are not applicable to a contract for the sale, procurement,

> processing, distribution, or use of human tissues including, but not limited to, corneas, bones or organs, whole blood, plasma, blood products, or blood derivatives. Human tissue, whole blood, plasma, blood products, and blood derivatives must not be considered commodities subject to sale or barter, and the transplanting, injection, transfusion, or other transfer of these substances into the human body are considered a medical service.

The intent of this law was to encourage a readily available supply of blood, bone, and tissue with protection from products liability claims. This statute, as is apparent from its plain language, simply does not contemplate tax applications.

On February 28, 1992, the South Carolina Tax Commission held in Commission Decision #92-26 that the provisions of § 44-43-10 were not controlling with respect to sales and use tax and that blood products were tangible personal property as defined under S.C. Code Ann. § 12-36-60 (2000). The Commissioners further held, in determining whether blood products were exempt from the sales and use tax, that the blood products of the taxpayer were used to treat diseases and injuries and were "medicines for purposes of § 12-28-2120(28)."

The Department has never taken a formal position, nor issued any official policy on whether or not human body parts, whole blood, and blood derivatives (red blood cells, white blood cells, plasma, and platelets) are wholly exempt from the sales and use tax. Sales of manufactured medicines made from plasma derivatives have been taxed unless the transaction qualifies under § 12-36-2120(28) as a "medicine sold by prescription." It is important to note that an express statutory tax exemption for human tissue, bone, and blood has never been enacted by the South Carolina General Assembly.

The medicines at issue in this case are manufactured from individual proteins that are isolated and derived from human plasma. These proteins include globulin, fibrinogen, and albumin. Pharmaceutical manufacturers take these proteins, immunize them from viruses, and then generally mix them with various solutions such as capyrlates (a salt or ester of caprylic acid) or glycine. Treatment involving these medicines typically involves intravenous injections, and is often mixed further onsite into a mixture of dextrose and water for buffering. One drug at issue here, which represents a majority of the purchases, is called "Gamunex©," which consists of only nine to eleven percent of the globulin protein.

The primary basis for sales and use tax to apply to sales of these medicines is the absence of any express statutory exemption. For the exact same reasoning that is applied to both classes of devices above, the sale of medicine to a hospital does not constitute a transaction that requires a prescription. As a hospital, the taxpayer has the ability to purchase these medicines from the manufacturers as it sees fit, regardless of whether the orders are placed individually or in bulk. The hospital is deemed the end user for these

injectable plasma derivatives, as they are furnished onsite as part of the services rendered. For this reason, the purchases of manufactured plasma derivatives by the taxpayer are not eligible for the exemption pursuant to § 12-36-2120(28).

The taxpayer argues that these manufactured plasma derivatives fall within the enumerated categories of human parts of § 44-43-10, and thus the Department is inconsistent by taxing these medicines in light of its failure to tax corneas, bones, or organs, whole blood, plasma, blood products, and blood derivatives. The taxpayer's argument is without merit. The Department has no authority to extend Title 44's blood shield law to sales and use tax. The language of § 44-43-10 contains no reference to sales and use taxes and there is no evidence the General Assembly intended to extend this statute to taxation. As stated earlier in Commission Decision #92-26, the Tax Commission exempted the blood products at issue therein as "medicines" under § 12-36-2120(28) and rejected any application of § 44-43-10.[4]

The proteins at issue here are derived from plasma and then manufactured into various medicines. Despite the lack of relevance of the "Blood Shield Law" to matters of taxation, the technological dilution for drugs such as Gamunex© is quite far removed from the blood derivatives contemplated in Title 44. Regardless of this distinction, plasma derivatives do not have an express statutory exemption, and thus they are subject to sales and use tax as medicine furnished as part of the medical services provided by the taxpayer.

4. The taxpayer cannot toll the limitations period set forth by § 12-54-85 by filing a claim for refund before attaining valid assignments of rights.

Section 12-54-85 sets forth time limits within which the Department must assess and collect taxes and within which taxpayers must file claims for refund. In some instances, the taxpayer may benefit where the Department does not act within the required time and in other instances, the taxpayer may be disadvantaged where he does not take action within the required time.

Although the statute of limitations is arbitrary and can cause hardships, its application is designed to be neutral. As noted by the Supreme Court in Rothensies v. Electric Storage Battery Co., 329 U.S. 296 (1946), the "statute of limitation is an almost indispensable element of fairness as well as of practical administration of income tax policy."

S.C. Code Ann. § 12-60-470 (Supp. 2011), in relevant part, states that:

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[4]To the extent that the Department or any of its employees has relied upon § 44-43-10 to exempt human tissue, blood, and related products from sales and use taxes – such action was erroneous. Audits of hospitals such as the taxpayer will need to examine whether prescriptions exist to support the purchase of human tissue, blood, and blood derivatives in order to exempt the same as "medicines sold by prescription."

(A) A taxpayer may seek a refund of a state tax by filing a written claim for refund with the department. A claim for refund is timely filed if filed within the period specified in Section 12-54-85 even though the time for filing a protest under Section 12-60-450 has expired and no protest was filed.

(B) The refund claim must specify:

(1) the name, address, and telephone number of the taxpayer;
(2) the appropriate taxpayer identification number or numbers;
(3) the tax period or date for which the tax was paid;
(4) the nature and kind of tax paid;
(5) the amount which the taxpayer claims was erroneously paid;
(6) a statement of facts supporting the taxpayer's position;
(7) a statement outlining the reasons for the claim, including law or other authority upon which the taxpayer relies; and
(8) other relevant information that the department may reasonably require.

The department will make forms available which taxpayers may use to file a claim for refund.

(C)(1) **Only the taxpayer legally liable for the tax may file a claim for refund or receive a refund**, except that:

(a) a person who acts as a collector and remitter of state taxes may claim a credit or refund of the tax collected, but only if the person establishes that he has paid the tax in question to the State; and
(i) repaid the tax to the person from whom he collected it; or
(ii) obtained the written consent of the person from whom he collected the tax to the allowance of the credit or refund;
(b) a purchaser who has paid sales tax to a retailer for a specific transaction may claim a refund if the retailer who paid the sales tax to the State has

> assigned, in writing, the right to a refund of that sales tax to the purchaser.

(Emphasis added). This code section sets forth unambiguously that only the legally liable taxpayer may file a claim for refund.[5] To that extent, before a refund can be considered proper and timely filed, it must meet all the requirements of subsection (B). Furthermore, subsection (C)(1)(b) clearly states that before a claim for refund can be filed by a **purchaser** who paid the sales tax to a retailer, an assignment of rights must first be attained. This is clearly indicated by the use of past tense of the word "assigned." Until that assignment of rights is obtained and provided to the Department, a purchaser does not have the legal authority to file a claim for refund of sales taxes paid to a retailer.

The taxpayer here filed refund claims for taxes paid to multiple pharmaceutical and medical supplies vendors without first attaining assignments of rights. While these initial refund claims fell within the time limitations of § 12-54-85, they were not valid claims. The taxpayer then allowed the statute of limitations to lapse before acquiring proper assignments for each of the vendors. Beyond the plain language of our refund statute, which clearly limits the **right to file** a claim for refund to legally liable taxpayers in subsection (C)(1), the common law surrounding the application of statutes of limitations does not allow an improper party to extend the limitations period by filing multiple invalid claims for refund while trying to secure the proper assignment of rights to do so. Without the Department having notice that a valid assignment had been issued, the refund claims cannot be legally treated as proper. See Yancey v. Stark, 132 S.C. 171, 129 S.E. 81, 82 (1925) (citing Harvin v. Galluchat, 28 S.C. 211, 217, 5 S.E. 359, 361 (13 Am. St. Rep. 671) ("It is elementary that such an assignment 'is subject to all the equities existing between the original parties, not only at the time of the assignment, but up to the time of notice to the debtor.'").

5. The taxpayer is liable for use tax on purchases paid in error to an out-of-state unregistered company.

A. Imposition of the use tax on out-of-state retail sales is proper.

S. C. Code Ann. § 12-36-1310(A) (2000) provides:

> A use tax is imposed on the storage, use, or other consumption in this State of tangible personal property purchased at retail for storage, use, or other consumption in this State, at the rate of five percent of the sales price of the

[5]In South Carolina the retailer is legally liable for the sales tax.

> property, regardless of whether the retailer is or is not engaged in business in this State.[6]

S.C. Code Ann. § 12-36-1330(A) (2000) discusses the responsibility for paying the use tax. Specifically, "[e]very person storing, using, or otherwise consuming in this State tangible personal property[7] purchased at retail, is liable for the use tax, until the tax is paid to the State."

B. The taxpayer's purchases are retail sales.

Out-of-state retail sales are subject to a use tax for the user or consumer of that tangible personal property. Section 12-36-110, in relevant part, defines the terms "sale at retail" and "retail sale" to include:

> (i) sales of drugs, prosthetic devices, and other supplies to hospitals, infirmaries, sanitariums, nursing homes, and similar institutions, medical doctors, dentists, optometrists, and veterinarians, if furnished to their patients as a part of the service rendered. These institutions, companies, and professionals are deemed to be the users or consumers of the property[.]

Regulation 117-308.8 states:

> Hospitals, infirmaries, sanitariums, nursing homes and like institutions are engaged primarily in the business of rendering services. They are not liable for the sales tax with respect to their gross proceeds or receipts from meals, bandages, dressings, drugs, x-ray photographs and other tangible personal property where such property is used in the rendering of the primary medical service to patients. This is true irrespective of whether or not such tangible items are billed separately to their patients. Hospitals, infirmaries, sanitariums, nursing homes and like institutions

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[6]"[T]he Act levies a use tax which is manifestly for the purpose of preventing evasion by purchases at retail from without the State or under other circumstances which might or would avoid application of the retail sales tax." State ex rel Roddey v. Byrnes, 219 S.C. 485, 66 S.E.2d 33, 46 (1951). More specifically, "[a] use tax complements a sales tax by ensuring that the local use of an item purchased outside the state is taxed in the same amount it would be if it were purchased locally." Thayer v. South Carolina Tax Commission, 307 S.C. 6, 413 S.E.2d 810, 813 (1992).

[7]Section 12-36-60 defines "tangible personal property" as ". . . personal property which may be seen, weighed, measured, felt, touched, or which is in any other manner perceptible to the senses." The taxpayer's purchases fall within this definition.

> are deemed to be the users or consumers of such tangible personal property and the instate sellers of these items are required to report and remit the tax due on the sale of such property to the hospitals, infirmaries, sanitariums, nursing homes, and like institutions **or in the case of out-of-state purchases, use tax shall be reported and remitted by the purchaser**.

(emphasis added).

C. The taxpayer is legally liable for the use tax.

Under South Carolina law, "[h]ospitals . . . and like institutions are deemed to be the users or consumers of [] tangible personal property and . . . in the case of out-of-state purchases, use tax shall be reported and remitted by the purchaser." Regulation 117-308.8 (emphasis added). The taxpayer's use tax liability is only relieved if a receipt showing the tax was paid to an out-of-state retailer who is required or authorized to collect the tax can be produced, or if the purchase was for resale. S.C. Rev. Rul. # 91-12. Furthermore, 27 S.C. Code Ann. Regs. 117-334.2(C) (Supp. 2011) states:

> When tangible personal property is purchased for use or consumption in this State and the property is shipped from a point outside this State directly to the purchaser or the purchaser's designee at a point in this State, there is a rebuttable presumption that the purchase is subject to the use tax. If the receipt from a seller does not separately state the South Carolina tax, the Department may assess either the purchaser or the seller (if licensed or nexus exists) for the use tax.

As a defense to the imposition of the use tax, the taxpayer argues that Drager Inc. – the out-of-state vendor – which collected tax on the purchases at issue and remitted it to North Carolina[8] – has sufficient ties to South Carolina thereby making it liable for sales tax liability with nexus pursuant to Regulation 117-308.8. Drager is a North Carolina company that may or may not have a sufficient nexus with this State for the Department to impose a sales tax liability upon it. However, the extent to which Drager may be liable does not preclude the Department from assessing the use tax upon the "purchaser or the seller," as noted above. See Regulation 117-334.2(C) (emphasis added). Furthermore, § 12-36-1330(A) imposes the tax upon the purchaser of tangible personal property "until the tax is paid to the state." The taxpayer has failed to provide any evidence to show that the tax due on these purchases was paid to South Carolina, nor has it offered any receipts that would relieve it of tax liability for the use and consumption of those items that are

[8]This fact, albeit immaterial to the legal liability for use tax, has not been verified by any evidence.

furnished as part of its services rendered. Therefore, the taxpayer remains liable for the use tax pursuant to § 12-36-1310(A).

Conclusion:

The Department properly denied portions of the taxpayer's refund claims for prosthetics used onsite, plasma derivative medicines furnished onsite, and improper refunds filed without valid assignments of rights. Furthermore, the taxpayer is legally liable for use tax on purchases from a North Carolina vendor, regardless of whether or not that vendor charged tax that was not remitted to South Carolina. The Department's denial of the taxpayer's remaining refund claim and assessment are upheld.

August 16, 2012

Transcript of the Testimony of
CARE HEALTH ALLIANCE V. SC DOR

Date: October 1, 2013

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STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT DIVISION
Docket No. 12-ALJ-17-0405-CC

Care Health Alliance Service d/b/a Roper St. Francis Medical Healthcare, Inc.,

Petitioner,

v.

South Carolina Department of Revenue,

Respondent.

ADMINISTRATIVE HEARING

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Tuesday, October 1, 2013
10:08 a.m. - 11:54 a.m.

The hearing before the Honorable Shirley Canty Robinson, was taken at the Edgar A. Brown Building, 1205 Pendleton Street, Suite 224, Columbia, South Carolina, on the 1st day of October, 2013 before M. Sean Cary, Court Reporter and Notary Public in and for the State of South Carolina.

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EXHIBITS

(There were no exhibits marked during this hearing.)

STIPULATIONS

It is stipulated and agreed that this hearing is being taken pursuant to the rules of the Administrative Law Judge Division and the South Carolina Rules of Civil Procedure.

THE COURT: If everyone is ready, we'll get started. We're here to hear arguments on Cross Motions for summary judgments that's been filed by the petitioner as well as the respondent. This is Care Alliance Health and Services doing business as Roper Saint Francis Healthcare versus the South Carolina Department of Revenue. It's Docket Number 12-ALJ-17-0405. I'll let the attorneys appearing introduce themselves for the record, beginning with petitioner.

OPENING STATEMENT BY MR. CARPENTER:

MR. CARPENTER: Good morning, Your Honor. I'm Raymond Carpenter. I'm here for Care Alliance doing business as Roper Saint Francis. With me at counsel's table is Bryson Geer and John von Lehe with Nelson Mullins Law Firm, and Mr. Britt Dobbins with the hospital.

THE COURT: Thank you Mr. Carpenter.

OPENING STATEMENT BY MR. MARINELLI:

MR. MARINELLI: Good morning, Your Honor. I'm Adam Marinelli with the Department of Revenue. With me is Lauren Acquaviva. If you need me to spell that I can.

THE COURT: I think we're familiar with Ms.

Acquaviva. Okay. Before we move to the arguments, are there any matters that we need to address beforehand?

MR. CARPENTER: Your Honor, we did file a motion to exclude the affidavit of the respondent's FDA witness, and because of the fact that it was late filed and because of the fact that we -- he had not named the witness beforehand, we did not have an opportunity to depose the witness. And basically we think the testimony that he would -- in the affidavit was highly prejudicial. It is a surprise to the petitioner, and we filed our motion in our previous support and would ask the court to rule on that so that we know how to proceed this morning.

THE COURT: Okay. Mr. Marinelli?

MR. MARINELLI: Your Honor, as we stated in our brief in opposition to their motion to exclude, the affidavit was filed a week prior to the hearing. We have until two days prior to file all our opposing affidavits. This affidavit was filed in opposition to their proposed expert's affidavit, simply that's how it's being used. They have no rights or we have no

duty to allow them an opportunity to depose a declarant in opposing affidavits. Furthermore, there is no prejudicial effect in the testimony other than the damage that it might do to the validity of their case, and so to that extent, we ask you to deny that motion.

THE COURT: Okay. I reviewed all the filings that were made by the parties and Mr. Carpenter, I am ruling in favor of admitting the affidavit that was submitted by the party. I didn't really -- from my review, I didn't see that it would really prejudice you to the extent that you seem to have advanced in your argument.

MR. CARPENTER: Thank you, Your Honor.

MR. MARINELLI: There is one other preliminary matter, Your Honor.

THE COURT: Yes.

MR. MARINELLI: In their reply to our response to their Motion for Summary Judgment, and you may recall the original objection that we had with their original motion, they also included some video deposition testimony attached to that reply. The same objection that we had stands for that. There isn't really a prejudicial effect in that the affidavit that had been

subsequently filed would say the same thing, but we simply wish that you would rule upon the objections that are within those video taped depositions prior to their being admitted to the record.

THE COURT: Okay. One second.

MR. MARINELLI: It's Exhibit C to their memorandum and opposition to our Motion for Summary judgment.

THE COURT: Thank you, Mr. Marinelli. I am denying your Motion to Exclude those excerpts from the record. I think anything that aids me in understanding the issue and making a ruling that is fair and supported by the law, I'm going to allow it.

MR. MARINELLI: Okay.

THE COURT: Thank you. Mr. Carpenter.

MR. CARPENTER: Your Honor, just back on the affidavit, just one thing. Mr. Marinelli did indicate that the affidavit was submitted in order -- opposition to our motion as opposed to being in support of theirs. So, I would ask the court if it considers that affidavit, only consider it as a -- an opposition to our Motion for Summary Judgment and not in support of

their motion.
THE COURT: Okay. Thank you. Okay. Any other preliminary matters.
MR. MARINELLI: The only other thing is there is some question as to who will go first. We filed first, but they're the petitioner, so we leave it up to you.
THE COURT: Right, I -- yeah, yeah. I'm going to allow the petitioner to go first with their argument. Thank you Mr. Marinelli.
STATEMENT BY MR. CARPENTER:
MR. CARPENTER: Thank you, Your Honor. I won't be long. Once again, I'm Raymond Carpenter representing Care Alliance Inc. doing business as Roper Saint Francis, and we're here this morning on a Motion for Summary Judgment, the petitioner's motion. We are the petitioner in the case. Your Honor, I express my appreciation to the court for allowing me to practice in your court pro hac vice. Thank you very much for much for that deference. The matter before you, Your Honor, arises when the petitioner in the case did some review of its tax filings and financial issues with regard to its tax obligations of the State. Over a three

year period, we determined that we had overpaid sales and use tax to the tune of almost $5 million -- more than $5 million in fact. We filed a Motion for Summary Judgment -- I'm sorry, we filed a refund claim. A large portion of that refund claim was in fact repaid to the petitioner. The two matters that are still at issue are vestiges of that claim, and that's why we're here today. Just very briefly, the two issues that we're going to be discussing today with the court involve first, whether or not the sale of specific orthopedic and orthopedic prosthetic -- I'm sorry. Whether or not the sale of specific orthopedic and cardiovascular prosthetic devices to a hospital upon the lawful order of a physician as required by federal law is a sale by prescription as that term is used in the sales and use tax exemption statute, 1236-21-20-28-A. The second issues that is still unresolved in this case involves products derived from whole blood. The legislature of the State of South Carolina has defined the sale of whole blood and products derived from whole blood as the sale of a medical service. Medical services

are not subject to the sales and use tax in South Carolina. Therefore, we believe that the services are excluded from the sales and use tax, not exempted, because the statute is not broad enough to cover those types of items. We recognize that we have the burden of carrying our load with regard to this item and we are fully prepared to do so. We believe that our briefs and affidavits that we have submitted to the court in support of our motion will show the court that the prosthetic devices at issue in the case are in fact prosthetic devices as that term is defined by South Carolina Department of Revenue -- Revenue rulings. Prosthetic devices at issue in this case are prosthetic devices which require for their sale a prescription before the hospital can in fact purchase it. And since the prosthetic devices at issue in this case can only be sold by prescription, they are in fact sold by prescription. Those are the requisites in order to prevail, and I think we have sufficient information in the record in order to carry that verdict. The Department of Revenue has issued Regulation 117-332. That

sets up a three part test to qualify for the exemption, and we believe the petitioner has shown and will show that we come under those three headings. That provision in 117-332 reads that in order for the exemption to be applicable, the sale must require a prescription, the device must actually be sold by a prescription and the device must be placed on the missing part of the body. That's the test that the statute sets up, that the regulations of the Department of Revenue set up, and that's the test that we believe we have met. The first question is do we have a prosthetic device, because if we don't have a prosthetic device the other two won't make any difference. The Department of Revenue has adopted a definition in the revenue code of what is a qualifying prosthetic device, and they basically said a prosthetic device is an artificial device that replaces a missing part of the body. Okay? Now, the parties have agreed that the prosthetic devices in question in this case are all FDA regulated type two and type three prosthetic devices. The parties have also stipulated that the prosthetic A

devices, and that is the hips, shoulders, knees and things of that sort, are qualifying prosthetic devices as that term is used in the revenue regulation. So, whether or not they're prosthetic, whether or not prosthetics-A or prosthetic devices is not a question. That's not an issue for -- we're there on that. There are a few items under prosthetic A which are bone pins, bone screws, bone nails and things of that sort, which are trauma devices. In other words, if a person is injured, comes to the hospital in an emergency situation, these are the kinds of the things that are inserted on an emergency basis. The State has not agreed that these items in fact replace the missing part of the body, but to the extent that these screws and bones and nails displace the bone into which they are inserted, we believe that it is a minor question. We believe it's without question that they do in fact replace a missing part of the body. So, the musculoskeletal section -- the trauma musculoskeletal prosthetic devices which were also a part of prosthetics-A, we think also are qualifying prosthetic devices. Now, we also

had a prosthetic B just for clarification, and those were the pacemakers and the implantable cardioverter defibrillators or the ICDs. These are devices that are inserted into the heart by a cardiologist for the purpose of keeping the heart rhythm going. And we believe and we'll show that these devices also replace a missing part of the body and are qualifying prosthetic devices, okay. Now, back to Regulation 117-332, it defines again a prosthetic device as an artificial device which replaces a missing part of the body. Now, we don't know what part of the body must be replaced. We don't know when the part of the body must be replaced, what would be missing. We don't know how much of the body must be missing in order to qualify. We don't know where, in relation to the device, the missing part of the body has to be. The only thing the regulation says is that the device must replace a missing part of the body. So, with regard to the prosthetic A, about which there is not question, there's no question because when you put an artificial knee in someone, it's because of the fact that the cartilage in the knee is no longer there

and the device replaces the cartilages and relieves the pain and discomfort that the individual may be suffering. So, once again, the State has agreed that these devices are qualifying prosthetic devices because they replace a missing part of the body. In a similar manner, Your Honor, the cardio devices, Dr. Brett Butler -- Baker, I'm sorry. Dr. Brett Baker, a board certified cardiologist testified in his affidavit that the cardio tissue in and around the heart -- when you're 20 years old, you've got all kinds of cardio tissue in your heart, and that cardio tissue conducts the electrical stimulants that keep the heard in rhythm. By the time you get to your mid 50's, a lot of that cardio tissue, Dr. Baker said, had died off or degenerated or had worn away, in his words. In other words, it's missing. Therefore, Dr. Baker said he inserts a pacemaker or an ICD and that replaces -- what that does is, conducts that signal that the tissue used to conduct when there was tissue there. So based upon what Dr. Baker says, the ICDs and the pacemakers replace the missing cardio tissue and therefore they replace a

missing part of the body and they would qualify as a -- for a -- as a prosthetic device under the Department of Revenue's definition of that term. The testimony of Dr. Baker is uncontroverted (sic). As a result, Your Honor, we believe that all of the prosthetic devices that are at issue in the case, the prosthetics-A, including the musculoskeletal bones and screws, and the prosthetics B, cardiovascular, that they're all prosthetic devices, within the definition of the term, replacing a missing part of the body as that term is used in the revenue regulation. Okay. The second part of the test is that the sale must require a prescription. When I began, I talked about the fact that the parties have agreed that all of the prosthetic devices were type two and type three. Type two and type three are FDA regulated devices. And it's fair to mention right here, Your Honor, that we filed notice of foreign law; and in South Carolina for purposes of South Carolina, federal law is foreign law and that we're going to rely upon federal statutes and federal regulations. The State did not object to that. In fact, the affidavit

that you have just admitted relies upon federal law, so we think that the court then is free to take judicial notice of the federal statutes and regulations. Okay. So, the federal statute issue here is 21 U.S.C. 360E, and that statute says, and I'm going to read it, the Secretary may, by regulation, restrict the sale of class two and class three devices only upon the written or oral authorization of a practitioner licensed by law to administer for use such devices. That's the enabling clause in the federal statute. In 21 CFR 801.109, the Secretary did in fact put into place that authorization by saying that the device is to be sold only to or upon the prescription or order of such practitioner for use in the course of his medical practice. These are the devices that are an issue in the case. These are the devices that the federal statutes and regulations address, and these are the devices -- these are the statutes and regulations that regulate the purchase, sale and distribution of these devices. The FDA controls every prosthetic device in this case. South Carolina Department of Revenue has no regulations with

regard to what a prosthetic device is or when a prosthetic requires a prescription. The stipulating prosthetic devices at issue in this case are the types of prosthetic devices addressed by the federal statutes and there -- and the statute basically says, they can only be sold upon the prescription of a physician. Every stipulated -- every stipulated prosthetic device in this case also is implanted into the body in this case and may only be sold on the oral or written prescription of a physician who is otherwise certified, and we talked about the fact that Dr. Baker and Dr. McCrosson are board certified in their areas. What FDA regulations do not do, Your Honor, is they don't carve out an exception for hospitals or other healthcare facilities to purchase these prosthetic devices without the order of a doctor. So, a hospital is required to have the order of the physician in order to make the purchase. That's the only way it's done. That's what the law requires. It would be unlawful for the hospital to purchase any of these stipulated devices without the lawful order of a physician. The product would be misbranded as -- in the

federal parlance, because if there is no doctor's prescription or doctor's order, you don't know if the device is in the hands of someone who can use it safely, and the restrictions are for the purpose of keeping these devices from harming the public. That's why the regulations are in place. Therefore, Your Honor, the sale of every prosthetic device to your petitioner in this case was made pursuant to the federal statutes and regulations, and those statutes and regulations require a prescription before the sales transaction can occur. So, we have the two legs of the test, and that is we have a prosthetic device and we have the requirement of a prescription. The third layer of the test is the device must actually be sold by a prescription. All right. Dr. McCrosson, who is an orthopedic surgeon at Roper Saint Francis -- Dr. McCrosson has been doing this for the last 20 years. Dr. McCrosson testified -- or in his affidavit and his deposition described how he goes about ordering these devices. On the day of the surgical procedure, he opens up the patient on the operating table, he does a

physical inspection of the patient. And at that time, Dr. McCrosson turns to the manufacturer's representative, who is in the operating theater, and the manufacturer's representative has a number of these boxes on a tray table, and Dr. McCrosson may turn and say, I need a left hip. When Dr. McCrosson says that, that is his oral order; when Dr. McCrosson said that's my prescription. It is at that point that this device changes possession and changes ownership. He gives it to the operating room nurse, she sterilizes it and hands it back to Dr. McCrosson, he inserts it in the patient. That's the only point in which Dr. McCrosson knows what he's going to use because he's eyeballed the patient. So, Dr. McCrosson speaking directly to the representative of the manufacturer in the operating theater. Similarly with Dr. Baker, Dr. Baker said, you know people come in for a heart attack -- with a heart attack, that's an emergency situation. That's a trauma situation. Most people are scheduled, and what will happen with Dr. Baker is same thing with Dr. McCrosson. He will open them up on the

operating table. He will see the physical condition of his patient, and at that point, Dr. Baker can determine which device will provide the level of electrical stimulation that will keep the heart of that patient in rhythm. Dr. Baker has to know the weight of the individual. He's got to know their age. He's got to know their physical condition. And all of those factors come in to determine what device he uses and when. So Dr. Baker, similarly to Dr. McCrosson, turns to the manufacturer's representative and says, I need an ICD 1420, and that device is given to the operating room nurse. She sterilizes it and gives it to Dr. Baker. He implants it in the patient. The patient goes home. Both doctors described how the transaction is then memorialized in the doctor's records, in the patient's chart and in the records of the hospital. So, after the device has been implanted, the records are updated as to the type of device and the other requisites of the device. The oral order of the physicians who are board certified to use the devices in their practice are the prescriptions used in this

practice. Mr. Ferguson -- Mr. Truscott Ferguson, who is the materials director for your petitioner, described how he takes the information from the doctor's nurse and then issues a bill-only purchase order. The manufacturer then sends an invoice and the hospital pays the bill. The device has long been inserted and the patient has already left the hospital by the time that bill gets back to the hospital, but that's the procedure that's in place. Dr. Baker said, I do about five hund- -- I'm sorry. Dr. McCrosson said, I do about 500 of these a year and this is basically the way that these transactions occur. Mr. Ferguson, in his affidavit, also said that the trauma devices that I mentioned, the bone pins, bone screws and things of that sort, which are in fact a small number, are in inventory for emergency use, but Mr. Ferguson said we don't order anything without the order of a doctor. So, even those prosthetics-A trauma devices, the bone pins and screws, are ordered pursuant to a doctor's order, because Mr. Ferguson said if we didn't have a doctor's order, we could not get them in the hospital. The testimony of

Dr. McCrosson, the testimony of Dr. Baker, the testimony of Mr. Ferguson, is uncontroverted (sic). So, all the devices at issue in this case are prosthetic devices as that term is defined by the South Carolina Department of Revenue in its regulations. The devices are sold by prescription as the exemption status requires because the devices at issue require a prescription because they're type two, type three prosthetic devices regulated by the FDA, and the FDA says you can't sell them without the order of a doctor. The devices are in fact sold by prescription on the oral order of Dr. McCrosson of Dr. Baker and Dr. Ferguson. Now, Your Honor, that's all that's required to qualify for the sales and use tax exemption that's at issue in this case. Those three items. Anything else is a surplus issue. That's the burden that this plaintiff, that this petitioner, is bound to carry. And we believe that based upon the affidavits and the applicable law, that there is no genuine issue as to a material fact on any of these items and that the petitioner is due judgment as a matter of law. Now, I would stop here, but I do want

to comment a bit on the Department of Revenue's position that the courts going to hear. And what I'll say is that in their materials, they argue that a prescription must be written, that it can't be oral. What the Department of Revenue has done is cite the pharmacy code definition of prescription drug order. They've cited a Controlled Substances Act. They've cited the Patient Information Act, which is also in the pharmacy code. What they have not done, Your Honor, is cite the revenue code. This is a tax case. The is a revenue case, and if they don't have a definition of a prescription, if they don't have anything that elucidates that, they can't reach into the pharmacy code to pull it in. They can't do that, because in the whole medical case that the State says is dispositive of this issue, the South Carolina Supreme Court said the definitions in this chapter, 40-43-30, which is the pharmacy code, are for purposes of this chapter. And I will add only, when asked, they did not adopt the definition of the term prescription for the revenue code. Now, the Department of Revenue has a very good

definition of the term prosthetic device. If they don't have a definition of what is a prescription and they're trying to bring one in from the pharmacy code, they have not adopted that. They have not put the public on notice of that. No court has adopted that definition. The federal statutes simply say, on the oral or written order of a physician. We have the order, the oral order, of a physician, and we believe we have an operative prescription. The South Carolina Department of Revenue has not adopted any definition of the term prescription for the elucidation of taxpayers, the elucidation of its auditors or the elucidation of this court. The petitioner has been meticulous. What we have tried to do is to say, what is it that we are required to show, what is it that we are required to do, because we understand that this is a sales tax exemption and that we've got to bring ourselves within the four corners of that exemption. And we think that we have brought ourselves within the four corners of the exemption as it's plainly worded. The controlling federal statute only requires that a prescription be on

the order -- on the written or oral order of a doctor. In this case, the prescription is oral. The petitioner is in compliance with the law. The court, in interpreting of the court and applying the sales tax exemption statute must give that statute and the words in that statute its plain ordinary meaning. The legislature did not indicate that the term prescription was to be used in a technical sense. In the absence of anything further, we believe that it should be given as a plain ordinary meaning, and the plain ordinary meaning is that it's the order of a doctor. One more item before I move on to blood. This is not the first case where this particular sales tax exemption has been argued, 12-36-2120-(28)(a). The precursor of that section was 12-35-550. In a case of Dr. Boykin versus the Department of Revenue, that was argued in Aiken County in the Aiken County Court of Common Pleas, Judge Timmerman heard the same argument that you're going to hear from the court today. Dr. Boykin was a dentist, and Dr. Boykin took the position that the work order that he prepared to give the dental lab, the

specifications to the prosthetic device that he was going to implant into his patient, he said that work order was a prescription for sales tax purposes. That case was litigated. Judge Timmerman said a work order issued by a dentist for a prosthetic device is a prescription for purposes of section 12-35-550 as a matter of law. So, the work order of a dentist is a prescription. He also said that there was no credible construction of the statute that would restrict, in any manner, the persons who are intended to benefit from that sales tax exemption. So, the exemption for prescription devices sold by -- devices sold by prescription, is not limited in any terms. There's nobody who cannot qualify as long as you purchase it by prescription. We're asking the court today to hold that the oral order of a properly authorized physician is a prescription as a matter of law, as that term is used in the statute, because the Department of Revenue has not adopted any definition of the term prescription, and that would be in keeping with the federal statutes which are applicable here today. Your Honor, there's

another item here and that is the sale of whole blood in the state of South Carolina. The State will tell you it does not tax sales of whole blood. They're not taxing the Red Cross. They're not taxing Red -- blood banks. In the determination letter to this petitioner issued by the Department of Revenue, and looking at the documents from discovery in this case, the subject of whether or not blood and products derived from blood, human tissue, whether or not any of these items are subject to sales tax is a matter of discussion. It is a matter of confusion within the Department and has been for a period in excess of twenty years. The Anatomical Gift Act, Your Honor, defines blood products -- defines blood, products derived blood and harvested human tissues as a medical service and not a commodity for commercial purposes. So the sale of blood is not a sale of a commodity in the same way that the sale of tangible or personal property would be. Medical services are not specifically subjected to sales and use tax in the sales and use tax statute. Tangible personable property, to the extent not exempted, is subject to sales and

use tax. So, for services to be subjected to sales and use tax you really have to specifically say what services you're talking about, just as telecommunication services, personal or professional services, things of that sort. Otherwise, services are not included under the sales and use tax statute. Sales of medical services are not sales of tangible personal property, and therefore not under the definition of retail sales in the sales tax statute. They're not -- sales of medical services are not exempted from the tax. They are excluded from its coverage. In the same way, Your Honor, that when you sell a house, a house is not -- the sell of a house is not subject to sales and use tax. Why not? Because a house is real property. Real property is not tangible personal property. Therefore, it's not covered by the sales and use tax statute. In the same manner, the sale of a share of stock is not a sale of tangible personal property. It is not exempted from the sales and use tax. It is excluded because it is the sale of an intangible, not tangible, personal property. In the same manner, the

sales of medical services are excluded. Sales of harvested human tissue, bones, corneas, have been -- the first part of our refund claim had some bone, human tissue and things of that sort in the claim that we had paid sales tax on. That sales tax was refunded to the petitioner. The determination letter to the plaintiff said these items are not taxable per the Anatomical Gift Act. The provision in the Anatomical Gift Act where harvested human tissue, bone and corneas are listed, also lists blood, products derived from blood and blood products. There is no policy statement. There is no document. There is no information going out to the public from the Department of Revenue on whether or not blood and products derived from blood are subject to tax. When we asked the head of policy with the Department of Revenue what is the policy of the Department in regards to the taxation of blood, he did not have an answer. The auditor who conducted the audit testified in her deposition that she had received no special training, no instructions, no supervisory directions on whether blood or blood products were taxable or not. There are

no documents coming out of the Department on this issue at all. So, what you have is some auditors may be taxing blood and some may not be. Some may be taxing products derived from blood, some may not be. They have not issues any directions to the public or to the audit staff. So, Your Honor, the legislature has defined sales of blood and products derived from blood as the sale of a medical service and not the sale of tangible personal property. If the Department of Revenue wants to tax sales of products derived from blood, what it's going to have -- it has the burden of showing that they are included in the definition of the term retail sale. Under the rules of construction, the burden is on the party who wants to show that the statute covers the transaction, not an exemption. This is not an exemption. This is a coverage issue. There is no statutory or regulatory basis for the distinction between whole blood and products derived from blood. Once again, since there's nothing in the Department of Revenue for them to say we'll tax blood or we won't tax blood and we'll tax a product derived from blood, there's nothing

that justifies that distinction. There's nothing that goes out to the public and instructs the public that these items are taxable or not. Your Honor, if products derived from blood are subjected to tax by this court, South Carolina would be one of the only states in the union taxing whole blood and blood products. Your Honor, thank you so much for allowing me to argue this morning, and I want to wrap up by saying this is -- this case is not about durable medical equipment. It's not about certificates of medical necessity. It's not about random prescription medical devices that can be purchased by a pharmacist. It's not about storage of prosthetic devices. The case is about hospitals and whether or not hospitals can make purchases of type two and type three prosthetic -- prescription prosthetic devices on the order of a physician and whether or not blood products or products derived from whole blood are in fact excluded from the sales and use tax statute. Thank you, Your Honor.

THE COURT: Thank you, Mr. Carpenter. Mr. Marinelli?

STATEMENT BY MR. MARINELLI:

MR. MARINELLI: Thank you, Your Honor. Before getting into my main presentation, there's a couple of points that the petitioner brings up that I need to clarify. First, I'm very glad that he brought up the case of Boykin, which was in Circuit Court. The Boykin case is important because A, it did state that work authorization from a dentist to a dental lab would constitute a prescription. Unfortunately for the petitioner, Title 40, Section 15-280, clearly indicates that a work authorization for dentists is a prescription. That is a specific statute for that specific purpose. It doesn't say that all work authorizations from a physician would constitute a prescription. And if you go to page three of the Boykin decision, it even goes so much as -- so far as to state that a purchase order is not a prescription, and later on when we get into my presentation you'll find out that that's the only document that's ever sent to the manufacturer. Now, there's a lot of discussions about the fact that the Department of Revenue has never adopted a definition of a prescription, and

he's absolutely correct. Title 12 does not define the word prescription. And he relies on home medical to say that the Department of Revenue cannot look elsewhere for supporting definitions when it makes determinations in matters like these. So, he relies on home medical for his purposes but we're not allowed to for ours, but it's important to note that home medical is applicable for this case first and foremost because it interprets the exemption statute at issue. The Supreme Court took the steps to look at our revenue rulings and rubber-stamp them in regards to the requirements related to the prescription exemption for sales of prosthetics and medicines. So that's why home medical controls this case. The durable medical equipment aspects of that case are completely unapplicable, but the aspects related to the exemption statute are. Now, the Department will posit today that the definition of prescription is not within Title 12 and therefore we must look elsewhere. In home medical, the definition at issue was medicine, and in Title 12, medicine is actually defined

and therefore that had to be the controlling definition. But since there is no definition of prescription in Title 12, we look elsewhere. That's why we went to the Pharmacy Act. It's why we went to the Patient Act, and, in fact, that's why we went to the FDA's own only definition of prescription, which is found in the Controlled Substances Act, and we'll get into all of that as we go on. So, the first issue today is prosthetic devices. As the petitioner stated: the sales of drugs, prosthetic devices, any of the supplies that they use at a hospital that are furnished to patients as part of the services rendered, are considered to be retail sales. A hospital is deemed the end user of these products and therefore everything that they purchase is subject to sales tax, unless there is a specific exemption. This is further clarified in the Regulation 117-308.3, which states that sales of supplies and equipment to doctors are retail sales and subject to sales tax. This is further clarified in 308.8 which goes on to explain the same thing, but the in-state sellers, all these manufacturers that come to

the hospital and sell these items, they're required to collect sales tax from the hospitals, and that's what happened in this case. So the hospital is then paying sales tax on all these items to the vendors, and in order to make the refund claim that they made, they had to get assignment of rights from all these vendors before they could make that claim, because the in-state sellers were properly doing their job according to law and remitting the sales tax on behalf of the State. Now, the exemption at issue today is very clear. It's medicine and prosthetic devices sold by prescription, and as I stated home medical clarified our revenue ruling, which was 03-2, which was later superceded by 11-3, which states there are four requirements to come into the four corners of this exemption: one is that the device must be one that requires a prescription, two, the sale must require a prescription and three, the sale must actually use a prescription, and finally that the prosthetic device must actually replace a missing body part. And here they are right here. That was the holding of home medical.

That's the aspect of the case that we want you to really focus in when we're discussing home medical, but essentially we're going to show that the only -- that the two and three aspects of this four-pronged test are failed by the petitioner and therefore they should not receive the exemption and the refund claim should be denied. Now their proposed expert, Mary Pendergast, who is a paid consultant who used to work at the FDA almost twenty years ago, states that as far as the FDA is concerned, a prescription is simply an order or instruction from a physician that a device can or should be used for a particular patient for a particular purpose. Two things about this, one it's overly broad. It's not true. The FDA doesn't say that. In fact, if you look at Steven Silverman's affidavit, who is the Director of Compliance for the division within the FDA that regulates all the devices in issue in this case, his sworn affidavit, the man who's in charge of enforcing the regulations they are attempting to invoke, clearly says that that's not the case. Furthermore, Mary Pendergast's idea of what a prescription is, is

limited to the use. The Department's position today is that we are discussing the sale of tangible personal property between a corporate entity and a hospital. We're not talking about the administration or use of these devices. The Rx only that's on the two boxes that the petitioner has on his desk is related to when you open that box and use the device, not to the purchase of a device by an entity that's licensed to practice medicine. A facility license is given to hospitals the same way a medical license is given to a doctor. They are properly licensed to have medicine practiced within their walls, and therefore they are allowed to purchase and possess all the items that need to practice medicine. Home medical also stated that a certificate of medical necessity was not to be considered a prescription. Now, we've attached a copy of what a certificate of medical necessity looks like, and I'm sure you've had plenty of DHEC cases that have involved these documents, but they are highly detailed. They have express orders from a physician, a signature of a doctor, authorization for certain types of

products or medical services that go to a specific particular patient, and that did not qualify as a prescription. In South Carolina, the Supreme Court is held that Mary Pendergast's definition of prescription is not true. Not everything that a doctor does or says is considered -- is considered a legal prescription and the petitioner wants you to look at the federal regulation -- or the federal statute, I'm sorry, 360j as dispositive proof that the federal government would agree that a prescription is in oral form, but if you look at that code section, there is nothing in this code section that says a prescription is this. All it says is, restricted devices under subsection E, the Secretary may, by regulation, require that a device be restricted to sale, distribution or use to these two things, one, only upon the written or oral authorization of a practitioner licensed by law to administer such or use such device. That's important. If you note, the three aspects the Secretary can regulate are sale, distribution or use. That first prong that the petitioner tried to invoke just now is limited to use. So we're not

talking about sale when we're talking about the written or oral authorization of what the federal statute says. The second prong is upon any other conditions the Secretary may prescribe by regulation, and that's important to understand because we're going to get to section 801.109, under the federal regulations, that has three express exemptions to when adequate directions for use are not required. Getting a little bit clear as to what a prescription is, there are three specific definitions in the Pharmacy Practice Act that will explain what a prescription is and what it is not. The first is a medical order, and a medical order would fit Mary Pendergast's definition. It is a lawful order of a practitioner, but it may or may not include a prescription drug. Not everything that comes out of a doctor's mouth is considered a prescription. Go a little bit further. A prescription drug order is a lawful order from a practitioner for a drug or device for a specific patient. It's important to always note that prescriptions in every code section, federal or state that you look at, a

prescription is issued for a particular person. So, all the items that their client has purchased for inventory purposes -- Scott Ferguson testified that, I don't order anything without an order of a doctor. How do you keep inventory items for a specific patient? These are for -- if there was a ten car pile up on highway 126 and all thirty people show up to the hospital and need broken bones fixed and are bleeding, they're going to need a lot of prescription devices. They're not going to be able to provide their services unless they have things in inventory. My question I posit to you today would be, how do you purchase items to keep in inventory if they can't be sold without a prescription when a prescription requires a specific patient in mind? The answer is there is there is no law or regulation that enforces a hospital to buy them by prescription, Your Honor, because it would dampen the effect of the public health. There wouldn't be the ability to provide the medical services needed if they had to purchase everything for specific patients. A chart order, this is important. A chart order is a

lawful order from a practitioner for a drug or device for patients of a hospital. Now, Dr. McCrosson's testimony in his video deposition, since that's now admitted to the record, is important to note. If you look at page 56, I questioned him -- or Lauren actually questioned him: so, just to describe again what you believe is prescription in the operating room, you make an order for a device and that order is then administered or implanted in a hospital patient, correct? He stated, that's correct. If you go a little bit further on page 63, he states on line 14, so I was wrong, according to the state of South Carolina, when I said a chart order is a prescription. He said he was wrong. He admitted it, because we showed him the definition of a chart order. And if you go to the federal regulations -- the federal statute rather, if they want to argue that the federal codes are the ones that take over, the only definition found in the statutes federally, that the FDA relies on, states verbatim, in order to dispense a drug to a bed patient for immediate administration in a hospital is not prescription. That's because

it is considered a chart order. Dr. McCrosson, when the petitioner was arguing just now, stated that it was memorialized in various ways. One of those ways was writing it on a patient's chart. That's not a prescription, that's a chart order. He's got a patient cut open on a table that's already been anaesthetized -- that's a difficult word to say -- and he immediately orders the device to be implanted on site, and therefore it is akin to a chart order and not a prescription. Now, Mary Pendergast stated the following in her affidavit that prosthetic devices can cause harm, that's why they're regulated and restricted, and that they are limited to sale only by prescription or other order, and it's important to note that there's a distinction in the federal regulations. Why would they make the distinction between a prescription or other order if every sale required a prescription? It doesn't make any sense. Hospitals can purchase such restrictive prosthetic devices only upon the lawful prescription or other order. She said that twice in her affidavit, and if you look to the regulation that's at

issue in this case, the petitioner would consider it as positive proof that these sales do require a prescription, it mimics the exact same language. It says that these items are only to be sold to or on the prescription or on other order of such practitioner. There's three separate ways these items can be sold. Only one of those is a prescription. Now, it's important to note that the second prong in the home medical test states that the sale must require a prescription. We have a code section in South Carolina that states very clearly that nothing in this chapter can be construed to require or per -- a permit of or to prevent a license practitioner, as defined under that code section, from possessing or administering drugs or devices. That's so if the DEA or the feds raided a hospital and found them to be in possession of a bunch of controlled substances or devices they're obviously not going to be arrested, because the medical facility which has a license issued by DHEC the same way a doctor and a solo practitioner's office has a medical license, to practice medicine. Now, they want you to make a distinction between a

hospital and a single medical practitioner. I would present to the court today that there's no appreciable legal difference between a large building like a hospital that's full of medical practitioners and a single doctor operating his own private practice at his office. There really is no practical or legal difference between the two other than the different licenses that they hold. The facility license and all the doctors therein are licensed by their own board of medicine, and then you look at the doctor's office and it's just one doctor. The reason why you can't force the hospital or the medical doctor to purchase these things by prescription every time is because they couldn't practice medicine. They need all of the drugs, devices, all of the supplies to furnish those services rendered. Now, if you look to page four and five of the petitioner's memorandum in opposition, they concede that the law allows physicians to possess and make purchases of prescription devices without a prescription. So now, your job today is to determine whether or not, is there an appreciable legal difference between

a doctor practicing on his own or a hospital that is full of medical practitioners. There is none, and the practical effect of making that legal distinction, Your Honor, will have a dampening effect upon the ability of a hospital to practice medicine. And that's why Steven Silverman filed that affidavit. That's why he went under oath and wrote the affidavit. The FDA is not a concerned party in this tax litigation. They don't care if a hospital gets a refund claim or not. Steven Silverman was not paid by the Department. I did not try to persuade him in anyway to issue this affidavit in a particular manner. If you look at the subpoena that we issued to the FDA, which was attached to our, I think, response to their Motion to Exclude and if you look to the email that I sent to their office of general counsel, the only ways in which I posed this question to them was objectively. I asked them verbatim whether or not a hospital can make these purchases without a patient specific informa-- patient specific prescription, and if you read the affidavit it's invariable clear that the FDA does not agree with the petitioner's

decision. Now it's important to note the definitions that we have in our South Carolina code for administer and dispense. Administer means the direct application of a drug or device, pursuant to a lawful order, to the body of the patient in various -- in any manner that they need to. Dispense means the transfer of possession of one or more doses of a drug or device by a licensed pharmacist or person permitted by law, the ultimate consumer, but if you go further down the definition of dispense, it clearly states the actual sales transaction and delivery of a drug or device is not considered dispensing and the administration is not considered dispensing. So the federal code section that they want to invoke as dispositive proof that requires prescriptions for all of these sales had two prongs if you don't re- -- if you recall, and the Secretary may issue regulations that require that a device be restricted to sale, distribution or use on these two aspects. One that only upon written or oral authorization of a practitioner licensed by law to administer or use such a device. That's the only aspect of the federal

code that involves an order of a doctor, when it's being used. Now if you look at the definition we have for dispense, we're not talking about use of these devices. The implantation of these surgical devices happens the way it happens because of economic reasons. If you look at Charles Truscott Ferguson's deposition, he clearly states that one of his main job functions is managing overhead. This box right here is in the range of $6000 to $7000 a piece. There's a reason why the doctors and hospitals don't buy these things to keep them in their inventory, it's because they're so expensive. Dr. McCrosson's own deposition even discussed various prescription items that he did keep in inventory when he was in private practice, and then some that he chose not to because they were so expensive. The hospital purchases them in the manner that they do, A, because the vendors are so competitive that they want to be convenient. They want to be in the operating room. The vendors are there with whatever the doctors need because they're $6000 a piece and they want to sell them and make those commissions.

And a hospital doesn't want to buy a storage room full of these things because they want to manage their overhead, and they don't have to because the vendors are in the operating room doing it exactly the way they are. Just to clarify, let's look back at 801.109. This is the regulation that exempts purchasers of these devices or people engaged in the sale of these devices from the labeling requirements of the federal code sections. Now labeling requirements simply mean adequate directions for use. When you buy your prescription medicines from the pharmacist, it comes with a label that says take two every four hours and various things that you shouldn't eat or do when driving a vehicle, these are adequate directions for use that give you, the lay person, the ability to understand what you're putting in your body and that you're not going to be damaged if you follow the instructions. The exemptions to those adequate directions for use -- just to back up for a moment. That's the practical reason for a prescription, Your Honor. I mean, the only two reasons why you would ever need a prescription are one, to have

adequate directions for use. If you look at -- if you can read a prescription, sometimes it's difficult to, but usually the doctor will also write take two, yada, yada, yada, however many you need, and put those directions of use on the actual prescription. The other aspect that you would need a prescription, the only reason why, would be to prove it to a third party. When I go to a pharmacist, I can't buy morphine pills unless I have a prescription from a doctor saying that I can. Those are the only two instances when you need a prescription. When you're in a hospital and a doctor is performing a surgery on site and you're already under, there's no need to prove anything to a third party, the doctor's there. It's a chart order, it's not a prescription. But if you look at the 801.109, it's very clear that the exceptions, the adequate directions for use requirements under federal law, except a hospital from the purchase of these devices, and Steven Silverman's affidavit rubber-stamps this interpretation, anyone engaged in the regular storage of these devices. Scott Ferguson, the manager of material services for

the hospital, purchases items that he keeps in inventory, so-called trauma devices. These included pins, screws, plates, nails, heart products, heart valves that he kept in inventory, everything he would need in case that ten car pile up on 126 happened. These items are type two and type three regulated devices, the same ones that are issued like these boxes right here, but yet he purchases them and keeps them in inventory. The hospital is regularly engaged in the storage of prescription devices, but if you go further, ii. I guess that is, it's hard to see. In the possession of a practitioner, the Department would posit again today that there's no appreciable legal difference between a single practitioner or a medical facility like a hospital that's full of practitioners. They are allowed to possess these items with exemptions from the federal code sections that demand adequate directions for use, but the second prong is the most important, Your Honor and I've already discussed it once before but it bears repeating. It is to be sold only to or on the prescription or other order. There's

three separate ways that these items can be sold. Only one of them is a prescription. The Department will posit today that being sold to a hospital would be exempt from the labeling requirements under federal code statues. And Steven Silverman, the Director of the Office of Compliance, Center for Devices and Radiologic Health at the US Food and Drug Administration, clearly states that under this regulation properly licensed healthcare facilities such as hospitals may purchase and store prescription devices provided that they are ultimately to be used on or distributed to patients by a physician. He recognizes the exact same thing that I stated earlier, Your Honor. When you're talking about the use or the administration of these devices, absolutely a doctor needs to be involved. I wouldn't want anyone else installing a hip replacement in my body. You want someone who's trained, gone to medical school and knows how to put them in. But there's nothing that stops a hospital from purchasing these things prior to that implantation, prior to the administration. Once again, our code sections in South Carolina

distinguish between the sales transactions and the dispensing of such devices. It's important to note, Your Honor, that the transaction at issue today, the one to which the sales tax attaches, is the transaction between the manufacturer and the hospital. It's not between the patient and the manufacturer. It's not between the patient and the hospital. That's a completely separate transaction. That's a transaction for medical services, and he is absolutely correct, but that is not subject to sales tax. Juxtapose what Steven Silverman says with Mary Pendergast, their paid consultant who used to work for the FDA, she says hospitals can only purchase such restricted prosthetic devices upon the lawful prescription or other order. Once again, she says there's two separate ways they can buy them, by prescription or other order. Kind of a blurred line, what a prescription is. She goes on to say that hospitals that purchase these devices are subject to prosecution under federal law. I have yet to see any code section that would support that statement. Mr. Silverman completely closes the door on that

proposition, Your Honor. He says there is nothing in the act, and that act is the Food and Drug Cosmetic Act, or its regulations that prohibits device manufacturers from selling prescription devices to properly licensed healthcare facilities that do not have patient specific physician orders for such devices at the time of purchase by the healthcare facility, to be stored in inventory by the facility for ultimate distribution or use on a patient by a licensed practitioner. He even goes so far to clarify this further, and this is the reason why the FDA got involved in this case. Just to back up for a moment, nothing precluded the petitioner from going down the same path, Your Honor. They could have asked the actual agency in charge of administering the regulations that they say -- claim that these sales are restricted to prescriptions and gotten the same answer. Nothing stops them from doing so. I don't know why they didn't. They went and paid an ex-employee from the FDA to testify the opposite, but the acting Director for the Office of Compliance, the man in charge of enforcing the very regulations at

issue in this case, states that to prohibit the sale of prescription devices to properly licensed healthcare facilities in the absence of a patient specific prescription for such device would be adverse to the public health because such facilities need to have certain prescription devices, for example infusion pumps, ventilators, cardiac pacemakers, one of the items at issue in this case, and dialysis equipment in their inventory for immediate access to render care to their patients. It's practical, Your Honor. There is no way that a hospital could practice medicine if it could only purchase items by prescr- -- by pre- -- excuse me, by prescription, and prescriptions require patient specific information. A chief of surgery telling Scott Ferguson to buy 1,000 pins and screws does not constitute a prescription. That's the chief of surgery simply storing items on site for future prescription use. We even went so far as to issue a 30(b)(6) deposition notice to one of the manufacturers at issue in this case, Zimmer. Melanie Hutcherson, who is their national sales manager, who used to be boots on

the ground sales rep and did the exact same thing as the rep that the petitioner described earlier, she was in the operating room selling these devices to doctors stated that when I questioned her and in the instances where the hospital owns that inventory, what type of documentation did Zimmer require to make that sell. She said a purchase order. That's it. The Boykin case in Circuit Court clearly stated that a purchase order is not a prescription. That's the only document that's ever sent to the manufacturer's rep, and in fact, throughout the process of discovery, not once had the petitioner provided any semblance of a document that would be purported to be a prescription. Charles Ferguson also described the items that he does keep in inventory, and when I asked him just to reiterate, these items are purchased without a specific patient in mind? And he said yes, that's exactly what we do. The trauma items are needed because of emergency situations, and they don't have patient specific information at that time when they make those purchases. So really, if a hospital can buy some items that are prescription only

but not all of them, there really is a disconnect here in the logic of the petitioner's case. There's no law or code sections they've pointed to that said a hospital can buy trauma items without a prescription, but not these that are used in surgeries that are not emergency situations. There is no law because it would not make sense. It flies in the face of logic, Your Honor. One of their witnesses, a board certified oncologist out in the lobby, even went so far to state that in his private office, he has an offsite oncology office, he's got a device that automatically orders prescription items when it runs low. He's got a storage cabinet that's connected to the internet. It basically shoots an order to the vendor and they deliver prescription drugs directly to his office. Is that a prescription? I don't think so, Your Honor. McCrosson, the board certified orthopaedic surgeon, the guy implanting these devices, when he was in private practice as I stated earlier, he kept cortisone and local anesthetic on site. These are prescription items. He didn't keep

the spinal joint fluid because he lost money when he kept it in inventory. That's the real reason why they don't purchase it any other way than they do, Your Honor. These items are highly expensive. The vendors are very convenient, and they're always on site, so they don't have to buy these things except when they need them. That doesn't make it a transaction that requires a prescription. It's also important to note, Your Honor, the hospital is a corporate entity. It could never be written a prescription, and so when the Chief of Surgery orders Charles Ferguson to buy all these trauma devices, if that's to be considered a prescription, to whom is he prescribing? You have to have a doctor patient relationship, and you cannot establish that with a corporate entity. A doctor can't even prescribe something for himself, so a hospital can never buy things that would require a prescription because a hospital can never be written a prescription. Mr. Ferguson was questioned a little bit further and I asked him has he ever seen a prescription whenever he makes these purchases, for whatever the device,

and he stated I've not seen the prescription, a written prescription, that's correct. And I asked him, so what do you forward to the manufacturer, let's say Zimmer, and he said only a purchase order. Melanie Hutcherson also testified, she's the sales rep for Zimmer, that the only documents she's ever seen when processing these orders is a requisition sheet and a purchase order. There's no prescription ever communicated to the manufacturer because no prescription is required. It's very simple. Just in the event that you determine that the statute at issue is ambiguous, the legislative intent behind the exemption statute is very clear when this letter was written from the former commissioner of the South Carolina Tax Commission to one of the senators that introduced the exemption to the house floor. This is to confirm our conversation of yesterday whereby a purely technical problem in the wording of the above named matter has been brought to our attention. The exemption as put into the above named subject on the floor of the House of Representatives was intended to exempt only prescriptions ordered by individual

patients from the drug store. I would be hard pressed to think that the legislature, when this exemption was originally passed, Your Honor, intended it to relieve the heavy financial burden of sales tax on corporate entities like the petitioner in this case. It was obviously meant for individual patients going to get their prescriptions, and back then in the 70's, the prosthetic devices at issue were probably, you know, the leg that you would slide on over your stomach that you go get at a brace and boot shop. That's what was really intended by that exemption, not the millions of dollars worth of purchases that a hospital makes when it's getting ready to provide all the services that it does. In summary for the prescription prosthetic issue, Your Honor, I urge you to look at our revenue rulings, both 03-02 and 11-3, that were both rubber-stamped by home medical. Steven Silverman's affidavit I think is the most important part of our case, Your Honor. This is the acting Director for the Office of Compliance, the man charged with regulating devices at issue in this case across interstate bounds, and he said verbatim that

nothing in the act prohibits a licensed medical facility like a hospital from purchasing these things without a prescription. To me, that's the end of the issue. Plasma derivatives. Now, tangible personal property, Your Honor, is defined very broadly as anything that can be seen, weighed, measured, touched, felt or anything perceptible to the senses. Now, the revised Anatomical Gift Act that the petitioner is relying upon today states very clearly, he is absolutely correct that these items are not commodities for sale and the transfer of these substances into the human body are considered a medical service. However, all of that is tempered by the fact that it starts with the implied warranties of merchantability and fitness. The only aspect of these blood derivatives at issue that makes them not a commodity for sale is that they're not a commodity for sale in regards to a breach of contract claim for the implied warranties of merchantability. Nothing in the blood shield law contemplates taxation. Nothing in Title 44 is even remotely related to taxation, and in fact, the petitioner was incorrect when he

stated that the Department has never issued any sort of document that says that the revised Anatomical Gift Act does or does not apply to taxation. The commission -- the tax commission in 1992 issued commission decision 92-26 that verbatim stated that Title 44 has no contemplation of taxation -- matters of taxation. Furthermore, it held blood to be a medicine that fit the definition of tangible personal property. He is correct that we've had sort of a shaky administrative history. We don't want to be the draconian state that taxes body parts, Your Honor. We exempt blood, bone, tissue, even go so far to exempt platelets, red blood cells and white blood cells, but the items at issue in this case, Your Honor, are plasma derivatives. They're taking from plasma. They're single items of protein, antibodies that are pulled out of the plasma, taken to a pharmaceutical warehouse where they're sterilized, introduced to a capalitic or buffering solution, put into little vials, slapped a label on for commercial sale and shipped out by the case and sold to these hospitals as a medicine, and just like in the

commission decision 92-26, the medicine is tangible personal property and unless there's some exemption, it's subject to sales tax. As I just stated, here's the summary of 92-26. But, Your Honor, the Anatomical Gift Act as I stated doesn't contemplate tax. It doesn't extend to matters of taxation. The only aspect that applies is the implantation, the transfusion, the transfer of those substances into the human body. That's what's considered medical service. Here you have a purchase by a hospital from a corporate pharmaceutical company of mass quantities of these protein strains. There is no medical service in the transfer of goods between those two entities. This is a sale of tangible personal property, Your Honor, that Title 12 controls, not Title 44. To that extent, we urge this court to -- oh, just briefly, in fact, there was a recent exemption that was passed last year that would include plasma derivatives. It's all injectable biologics are now exempt. That statute would be superfluous if these items were already to be exempt, so another aspect of legislative intent, Your Honor. The devices at

issue are not required to be sold by a prescription. In fact, the transaction at issue is not one that a prescription is actually used. As defined by our code section, what's actually being performed in the surgery rooms is considered a chart order. These are bedside administrations of devices within a hospital and therefore doesn't fit the definition of prescription. The petitioner has presented to you today no definition of prescription under any code section, not one. The only definition they provided was the definition, the very broad and vague definition of their paid expert -- proposed expert. Steven Silverman, the acting Director of the Office of Compliance closed the door on that entire affidavit and all of Mary Pendergast's testimony, Your Honor, and as I stated, Title 44 should not be held to control matters of taxation. So, we urge the court today to deny the Motion for Summary Judgment by the petitioner and to grant the motion by the Department. Thank you.

THE COURT: Thank you Mr. Marinelli. Now, Mr. Carpenter?

CLOSING STATEMENT BY MR. CARPENTER:

MR. CARPENTER: Thank you, Your Honor. Your Honor, as I indicated when I began this morning, this case is about type two, type three prescription prosthetic devices and prosthetic and cardiovascular devices. Whether or not those devices can be sold on the order of a physician as required by federal law, are sold by prescription as that term is used in the sales and use tax statute. That's what the first part of this closing is about. It's not about the pharmacy code. It's not about whether or not we know who the patient is. It's not about 99 percent of what we have already heard. The State has not presented factual information. As I indicated to the court, Dr. McCrosson, Dr. Baker and Mr. Ferguson have testified as to the precise procedures that they put in place. Those procedures are in keeping with the words in the applicable law. As a consequence, we believe that we have carried our burden of showing that the devices that are at issue in this case are prosthetic devices. They require a prescription to be sold and they are sold by prescription. One other -- two other points

that I would make and I won't be long. The State's attorney did in fact show you a copy of a letter written by the South Carolina Tax Commission in 1974 to the Senator Rembert C. Dennis, State House Columbia, South Carolina, and he quoted the first part of that letter which basically said that what the Department was trying to do was to limit the exemption statute to sales of drugs from CVS. That is what they were attempting to do. The part of the letter that he did not quote this morning goes on to say that -- goes on to say that it appears, however, that in preparing the wording of the statute, the statute is much broader in scope and would include all drug sales to hospitals, doctors and nursing homes. That's the Department of Revenue telling the legislature that the petitioner this morning has every claim to the exemption. The words in the statute of 1974 are the same words that are there now, but the letter goes on. Instead of the Department giving the legislature corrective language so that hospitals would be excluded, what they did was told the legislature to increase the revenue estimate

because hospitals and others would apply for the exemption. Now, I have not seen, and I'm sure that the Department may have done something about this, since 1974, come up with better language if that's what they want to do. They haven't done that, and this letter says legislature, you're on notice that hospitals may in fact apply for and be granted this sales tax exemption. So, I don't know what else a tax payer could do. We don't write legislation, and the tax payer who brought himself within the definition of the revenue statute -- the State's attorney spent a great deal of time in the pharmacy code and in all of the other definitions of terms outside of what the revenue Department is charged with doing. The revenue Department is charged with administering the tax and revenue laws of the state, not the pharmacy code, not the Patient Information Act and not controlled substances. Mr. Ferguson said, I don't buy anything without the order of the doctor. Dr. McCrosson said, I issue my order directly to the manufacturer's representative, as did Dr. Baker. Those are the operative facts that are still

uncontroverted (sic) for this court. Your Honor, I don't know what to make of Mr. Silverman's affidavit. I would like to cross-examine Mr. Silverman to see what his understanding is, because I do not read his affidavit to say that a prescription is not required. He does say that a hospital can make a purchase without a named patient, and we've never said you couldn't, but that's what the emergency trauma devices are for. Even if we purchase those trauma devices though, without a named patient, those trauma devices are purchased on the order of a physician in the hospital as required by the federal statute that is -- that is controlling in this case. Because we don't have a Department of Revenue regulation or anything of that sort.

THE COURT: Mr. Carpenter?

MR. CARPENTER: Yes, ma'am?

THE COURT: Let me ask you, are you then saying that the prescription that is written by the doctor, while that is issued, is an oral prescription that is issued by the doctor while he's in the operating theater, that that prescription is being issued to the patient or is that

prescription being issued to the hospital?
MR. CARPENTER: Your Honor, the doctor is an employee of the hospital. The prescription is being issued to the manufacturer to allow the manufacturer to sell the device to the hospital, and Your Honor, let me go on one step further. This is a sales tax case. The sale to the hospital is a final retail sale. There is no subsequent transaction. There is no subsequent sale. There is -- whatever happens between the doctor and whatever happens with the doctor and the patient or the hospital and the patient is not cognizable by the sales tax statute. That's why the legislature said the hospital is the deemed consumer, because that's where the sales tax transaction ends. So, no -- whatever happens with the patient is irrelevant to a determination of the issues in this case. If this were a value-added tax case or a goods and services tax case, that inquiry would be relevant, but because of the fact that it doesn't -- this is a sales tax case and the transaction with the hospital is defined by law as the final transaction, then nothing happens for sales and use tax purposes between the

patient and the hospital. We do say that the hospital is a seller of medical services, and we have argued that the sales of blood are in fact medical services. If I can -- if I can go back to Mr. Silverman for a moment. All I want to say on that is, is if Mr. Silverman's testimony is as pivotal to the State's case as they say it is, then we need an opportunity to cross-examine Mr. Silverman. We don't know what question Mr. Silverman was addressing. Mr. Silverman does not mention type two and type three prosthetic devices. Mr. Silverman does reference the same statute that we reference. We read that statute completely different than Mr. Silverman does and our expert, who was the highest ranking civil servant in the Food and Drug Administration at the time that she worked there, has said that law requires a prescription for its sale. Now, if Mr. Silverman is saying that that is an error, that is wrong, then we need to inquire as to on what basis does Mr. Silverman make that determination. So, Your Honor, at most, we need to have an opportunity to cross-examine Mr. Silverman if that is what he is saying.

Once again, we don't know what question he is answering in the petition. I'll say one word about home medical. We indicated to you that home medical was a case that the State would rely upon. We indicated very early in these proceedings that the issues involved in home medical involved items that were not prosthetic devices. They were durable medical equipment, none of which was implanted into the body of anybody, and so to the extent that the items in home medical were not prosthetic devices, there is no way that any of the language in home medical is applicable to a determination of the issues in this case. Thank you, Your Honor.

CLOSING STATEMENT BY MR. MARINELLI:

MR. MARINELLI: Very briefly, Your Honor. First, I'm going to deal quickly with the Steven Silverman affidavit. I think that is the most important part of the case. As he correctly stated, it is essential to our case, and it should be because like I said, this is the guy in charge of enforcing all these regulations. This is his job. Mary Pendergast's job is to be a paid consultant and provide the testimony that she was paid to provide. That's the

difference. The question that was posed to the FDA -- and once again, nothing precluded the petitioner from going down this path. If they wanted to, they could've asked this agency the exact same question or a multitude of questions to determine if they were right in bringing this refund claim. They chose not to do so. The Department of revenue did. It took me about 150 phone calls before I got through the bureaucratic red tape of the Food and Drug Administration, I finally reached a Ms. Lauren DiPaola, and the email that I sent her, which is attached as Exhibit A to the response to their Motion to Exclude this affidavit stated verbatim, as we discussed, the crux of this case is the question whether or not a doctor or hospital can legally purchase and possess class two and class three regulated devices prior to their use or administration on a patient without writing a prescription. I don't think it can get any more objective, anymore clear, about what I was posing to the Food and Drug Administration, Your Honor. It is the exact question that is a central issue in this case, and they answered it very clearly. The

subpoena, which is attached to that email, also was objective. I subpoenaed the FDA to answer the following three issues: one, US food and drug administration's applicable laws and regulations pertaining to prescription devices, two, the sale, not the use, administration or dispensing, et cetera of an orthopedic surgical implant from a manufacturer to a hospital and/or physician and whether that sale requires a prescription, and three, the record keeping requirements the FDA imposes on manufacturers and/or hospitals and/or physicians for the sale, not the use, administration or dispensing of an orthopedic surgical implant. That's what I asked. That's exactly what this case is about. It's not unclear. His affidavit didn't answer some vague misleading question that I posed him. I asked him verbatim, can a hospital purchase these class two and three devices without a prescription, and he answered it. Now, he deals very quickly with how we rely on the Pharmacy Practice Act. First, I would remind the court that the construction of a statute by the agency charged with executing it is entitled to the most respectful

consideration. It should not be overruled without cogent reasons. That was Poole v. Saxon Mills. The Board of Pharmacy, an arm of LLR, is in fact the agency charged with regulating the practice of medicine in South Carolina, the practice of pharmacy. The Board of Medicine is also the arm of LLR that does -- practices medicine. Those two boards are the ones that regulate prescriptions and prescription devices within South Carolina. They define prescription, and we're relying on that definition, and that reliance is placed properly because as he was right, we don't have a definition of prescription in Title 12. He has yet to provide this court with a definition of prescription. He would have you believe that an oral order, anything that a doctor does, is essentially Sampson turning things to gold. That would be a prescription. It is simply not the case. What Dr. McCrosson does in the operating room is bedside administration, immediate use. That is considered a chart order under the Pharmacy Practice Act. It's also considered a chart order, or at least not a prescription, under

the Food and Drug Administration's Controlled Substances Act. There is no definition in the Food, Drug and Cosmetic Act on -- at the FDA level. So we are forced to rely on our state's definitions, and in fact, the Food and Drug Administration is not engaged in regulating the practice of medicine. It's verbatim on their website. If you go to their website and look at their mission purpose, the mission purpose of the Food and Drug Administration is to promote public health and safety. It's not engaged in regulating doctors and practicing medicine. That is delegated to each state's board of medicine and pharmacy. Now, the important thing to take away from this case, Your Honor, is that the definition of prescription -- what is a prescription, and is the sale requiring that prescription, are the two most important aspects of this case. I would posit to the court today, that's what taking place in the operating room is not considered a prescription under our state law or federal law. The petitioner has not provided any aspects that would be any law that would support what they call a prescription.

The only thing they say that supports their definition of prescription is Mary Pendergast's testimony and 360j under Title 21 of the US code, and if you look at 360j, there is no definition of prescription in this code section. All it states is that the Secretary can regulate these devices and restrict them to the sale, distribution or use on two separate aspects. One, related to the use, is the written or oral order of an authorization of a doctor, and second is upon the other conditions that are described in 801.109. I've already gone over those at great length, Your Honor, and it's the Department's position today that the devices at issue are not purchased by prescription. There's no actual prescription being used. It's not a sale that requires a prescription, because like Steven Silverman states in his affidavit, if you require a hospital to have patient specific prescriptions for every purchase that they have, it would be an immediate dampening effect and damage the public health, and to that extent, Your Honor, we urge that you deny their motion and grant ours. Thank you.

THE COURT: Thank you. Mr. Carpenter, I've got one more question for you.
MR. CARPENTER: Yes, Your Honor.
THE COURT: How do you make a distinction between the oral orders that you termed as prescriptions as opposed to Mr. Marinelli terming them as ---
MR. CARPENTER: Your Honor.
THE COURT: --- chart orders?
MR. CARPENTER: Your Honor, there is no distinction. The statute says the oral -- the written prescription or other oral order of a physician, and the -- a prescription is the order of a physician. If it's written down, it's written down, but it's the order of a physician, so there is no distinction. Now, for purposes of practice of pharmacy, a pharmacist must have a prescription to dispense items, and that's why the pharmacy code is inapplicable to any consideration in this matter. This case is about prosthetic devices. Prosthetic devices are not dispensed by pharmacists at the local CVS. If Dr. McCrosson was going to order a prosthetic device, he would not send his patient down to

CVS to get it and bring it back so that he could implant it. There's no set of facts under which a prescription for a pharmacist comes into the ordering of a prosthetic device, and Your Honor is well familiar with the fact that sometimes in a doctor's office he will say I'm going to prescribe some medication for you. I will call it in to the CVS. Just go down there and pick it up. You may never see a written prescription by a doctor for some items because he simply calls it in to the pharmacist. The pharmacists inputs it into his system, and that's the way that works, but Your Honor, all of that is extra to the issues before this court, because prosthetic devices do not go through or around or into pharmacies. That's why the pharmacy code is unrelated to this. That's why -- that's why the statute requires that the physician be certified to use this item. There's no set of facts under which a patient can purchase the prosthetic devices that are at issue here. As the State's attorney has said, the reason for that is that those devices can cause harm. Now, once again, I don't know what Mr. Silverman is looking at,

but and we will give you the affidavit of Ms. Mary Pendergast, who once again was the former deputy commission, and basically she said I can find no support for the position that hospitals are storage facilities within the meaning of 21 CFR 801.109, because a hospital is not a storage facility, and a manufacturer can sell prescription prosthetic medical devices to a hospital without a prescription without violating the misbranding provisions of the Food and Drug Administration. Now, the provision that was cited with regard to storage at a hospital really is about manufacturers temporarily storing the devices and drugs while they're in shipment. It has nothing to do with the hospital storing drugs. That is all in the chain of commerce. But once again, Your Honor, if there is a provision, if there is something within Mr. Silverman's affidavit that goes to the heart of this case, the most that it does is create a fact issue, because we have an expert that has said -- and that expert has been certified as an expert on FDA matters in other courts, and she has said that you can't get this stuff without the order of a doctor,

and we have also said that the Department of revenue, if it wanted to define what a prescription was, has all the authority in the world to do so. They can simply write a prescr- -- they can write a regulation that says a prescription is -- requires these different things and we have to have it in triplicate, and if you don't come in here with the blue copy of the prescription then you don't get the exemption. They have every authority to do that, and we would have to comply with that. We can't comply with 15 different pharmacy definitions that they pull out of their hat at the last minute. We complied with the definition of prosthetic device because it's in the revenue code, and we complied with the three-pronged test in revenue Regulation 117-332. So that, Your Honor, is the reason why the Supreme Court in home medical said look, the pharmacy code is the pharmacy code and those definitions are limited to the pharmacy code. The Supreme Court in home medical could have adopted the pharmacy code definition of prescription as a prescription for sales and use tax purposes.

They chose not to do so. Your Honor, I want to give you the original of Ms. Pendergast's -- do I have the original?

MR. MARINELLI: Yeah.

MR. CARPENTER: Yeah, okay. And I believe that you're not now contesting the entry of the video deposition?

MR. MARINELLI: Well, if I did, I don't believe it'd be granted but ...

MR. CARPENTER: Okay. That's the original of the video depositions.

THE COURT: Video depositions. Okay.

MR. MARINELLI: Your Honor, I would just for the record reiterate my objections, for preservation.

THE COURT: Okay. Thank you.

MR. MARINELLI: Just briefly, may I respond Your Honor?

THE COURT: Yes.

MR. MARINELLI: Thank you. Since I was second, I should get the last word. What he wants you to do today is to believe him, his word and Mary Pendergast's, that every order of a physician is a prescription. That's what he's asked you to do today, because he's not provided you one

single law that defines prescription. He's absolutely correct that we had to reach elsewhere in Title 12 to get a definition of prescription. We first looked to our states Board of Pharmacy because that's the best place to look for the definition of prescription. But if you disregard all the State's definitions that are provided, you can look to the federal definition, the only definition that's in the -- that's used by the Food and Drug Administration, and I'll try to find it real quickly on the slides just to reiterate what it says. That an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription. If that applies to a drug, why would it apply to a device? And that's -- it doesn't make any sense for him to say today that everything that comes out of a doctor's mouth is a prescription. When he's discussing home medical that clearly held -- the Supreme Court of South Carolina clearly held that a certificate of medical need is not a prescription, and that's an order of a physician. That one is actually written down,

and that wasn't held to be a prescription, so how can every order that comes out of a doctor's mouth qualify as a prescription? The answer is, it doesn't. South Carolina defines a medical order as a lawful order of a practitioner which may or may not include a prescription drug order. It's three separate distinctions. There's medical order, which is everything that the doctor does, and that's what he wants you to believe is a prescription. The prescription drug order, which is very clearly defined as what a prescription is and then the chart order, and a chart order is what is happening in the hospital. The doctor calls for the device, immediately implants it into the patient and that's what's happening, and that fits the definition of the State definition of chart order, and it clearly fits in the Food and Drug Administration's definition of what does not constitute a prescription. So, Your Honor, it's clearly up to you today to decide whether or not everything that comes out of a doctor's mouth is a prescription, or look elsewhere for some sort of guidance, and there is clear-cut case

law that says that not everything a doctor does is a prescription. Home medical says that verbatim. CMN's are not prescriptions, and those are highly detailed written documents signed by a lawful practitioner. So, we urge you today to basically make your decision based on the law, not the proposed definition by their expert. Steven Silverman has essentially closed the door. He's the Director of Compliance of the FDA. I don't see anyway that they can get around it. If that presents some sort of issue to fact, they're certainly allowed to issue a subpoena and try to depose him. It's my understanding that sovereign immunity will be claimed, and they're not even going to show up even if you attempt to force the subpoena, but to the extent that the affidavit is impeachable evidence against their expert's testimony, I will be happy to cross-examine Mary Pendergast as well. So, it's up to you to decide whether or not there is a material fact. I would posit that there is not. This is a question of law, Your Honor. We urge you to grant the Department's motion and deny the petitioners. Thank you.

MR. CARPENTER: Thank you.
THE COURT: Mr. Marinelli?
MR. MARINELLI: Yes?
THE COURT: I'll be honest with you. During your argument, there's been heavy reliance on the affidavit provided by Mr. Silverman.
MR. MARINELLI: Sure.
THE COURT: And the fact that the petitioner's have not been given the opportunity to cross-examine him or examine him at all, that is rather troublesome for me.
MR. MARINELLI: You can remove his affidavit from the record, Your Honor, and it would be my position today that the law still supports the Department's position wholeheartedly. If you take Mary Pendergast's definition and look at their argument in a vacuum, without Steven Silverman's reputation of that affidavit, they provide you no definitions, no law, no code section whatsoever that supports their claims. If you look at 360j, the federal code section that they were relying upon, which is the restriction of devices for adequate directions for use, and you juxtapose that with Regulation 801.109, which is the regulation that exempts

these devices from adequate directions for use and those labeling requirements, it is very clear, very clear, that not every transaction requires a prescription. Look at 801.109. If everything a doctor did, everything he said in a practice of medicine constituted a prescription, why would subsection two under A include the language, to be sold only to or on the prescription or other order of such practitioner? There's a distinction there. If everything was a prescription, it would just say only be sold on a prescription. It doesn't. The Silverman affidavit really is immaterial, Your Honor, if you look at the law. The Silverman affidavit interprets these laws properly, unlike Mary Pendergast did, but if you want to throw it out, throw it out and look at the regulation itself. It clearly says that not everything a doctor does is a prescription. That -- there's no reason for the three separate distinctions if that was the case. So, Your Honor, it's my opinion that there is no material question of fact. They don't like the Silverman affidavit because of the damning nature it has upon their case, but it really is

immaterial to the State's case if you look at the language and letter of the law. So, I leave that up to you, Your Honor, to decide. If we need a full blown trial and to spend that time and resources, we can, but I would posit today that you don't need to, because even the code section that their invoking as dispositive proof clearly distinguishes between three separate aspects of a practitioner's order. You can buy them directly, the items can be sold by prescription or the other order. That other order language is everything else in between and that includes a chart order, and that's what takes place at the hospital. And it's the State's position today, Your Honor, that the law clearly supports our case. These sales do not require a prescription and one is not actually being used. Thank you.

THE COURT: Thank you. Okay. Thank you all for coming and you've given me a lot to consider.

MR. MARINELLI: Just for your review, the slides are right there in front of you if you didn't get a copy of my paper.

THE COURT: Okay. Thank you. This concludes the hearing, and I will be in touch with you all

very quickly to give you directions or a ruling.

(There being no further questions, the hearing concluded at 11:54 a.m.)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA

CareAlliance Health Services d/b/a Roper St. Francis Healthcare, Plaintiff, vs. SOUTH CAROLINA DEPARTMENT OF REVENUE, Defendant.	) CIVIL ACTION NO: 12-ALJ-17-0405-CC

* * * * * * * * * * * * * * * * *

DEPOSITION OF: BRETT M. BAKER, M.D.

DATE TAKEN: June 25, 2013

TIME: 2:40 P.M.

PLACE: Roper St. Francis
125 Doughty Street
Charleston, SC

REPORTED BY: DENISE LAUDER
Registered Professional
Reporter and Notary Public

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are you authorized to prescribe something to?

A. I mean, I guess it would be a patient under your care, where, you know, you have the appropriate background and training to recommend a remedy or treatment.

Q. Can you prescribe something to a hospital?

A. In terms of saying -- I don't know that I would understand.

Q. Can you form a doctor/patient relationship with a hospital?

A. No.

Q. Okay. So you couldn't write a prescription to a hospital, then, correct?

A. No. I mean, it doesn't seem like...

MS. ACQUAVIVA: Let's take a break.

(A recess transpired.)

BY MS. ACQUAVIVA:

Q. What do you consider to be a body part?

A. In terms of -- I mean, I guess it would be a structure in the body.

Q. Do you consider the heart's electrical system to be a body part?

A. I think that it's -- it's a combination of things. I mean, I think that I would argue that

CERTIFICATE OF REPORTER

I, Carol Denise Lauder, Registered Professional Reporter and Notary Public for the State of South Carolina at Large, do hereby certify that the foregoing transcript is a true, accurate, and complete record.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof.

Witness my hand, I have hereunto affixed my official seal this 26th day of June, 2013 at Charleston, Charleston County, South Carolina.

Carol Denise Lauder
Registered Professional
Reporter, CP
My Commission expires
August 2, 2017

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA

CareAlliance Health Services d/b/a Roper St. Francis Healthcare, Plaintiff, vs. South Carolina Department of Revenue, Defendant.	) CIVIL ACTION NO: 12-ALJ-17-0405-CC

* * * * * * * * * * * * * * * * *

VIDEOTAPED DEPOSITION OF:	BRETT M. BAKER, M.D.
DATE TAKEN:	July 2, 2013
TIME:	2:43 p.m.
PLACE:	Roper St. Francis 125 Doughty Street Charleston, SC
REPORTED BY:	DENISE LAUDER Registered Professional Reporter and Notary Public

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ALSO PRESENT: Doug White, Videographer

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say that we implant.

Q. Okay. Let's see. I show you what's been marked for identification as Plaintiff's Exhibit 2 and ask if you'd identify that document.

A. That's the preprocedure order form for the cardiac rhythm management devices we've been discussing.

Q. And can you tell us anything about that form, what information is on there and when you fill it out, how you fill it out?

A. So this is a form that we use prior to the patient coming into the hospital, and it has information regarding when the procedure is scheduled. It has information regarding the type of device, and it also has recommendations for preparing the patient for the procedure in terms of preparation, skin preparation, nursing preparation with IV lines, lab work, preoperative antibiotics, some medication orders.

Q. Okay. Who sees that form?

A. Well, I would initiate it. It's something we initiate after seeing the patient in the office and scheduling the procedure and then that would be sent essentially to the hospital.

Q. Okay. Do you sign that form?

A. Yes.

Q. Once you have completed the form, how do you go about ordering the device that you have selected for the patient?

A. So we've done the form, our history and physical goes into fairly extensive detail in terms of, you know, what our thinking is, what the patient's medical conditions are, and the discussion we've had and what we're planning to do. So that would document what form of device, you know, we would be recommending to the patient.

We do communicate with the manufacturer so that we can have -- because there are nuances in different sizes and makes and feature mixes of the various devices we have in any of these categories. We contact that individual and they bring a -- sort of a portfolio of -- of the different components to the procedure.

Q. Okay. Can you describe that communication between yourself and the manufacturer?

A. So I most commonly will contact them, you know, the afternoon or evening before the procedure and give them information on the timing of the procedure and then what I anticipate and any

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pertinent information regarding the particular conditions we may be dealing with specific to that patient.

Q. Okay. And how does the device or the devices that you might install or implant get to the hospital?

A. So there -- the representative from the vendor will actually come with a big sort of duffel full of devices. So there may be -- if we're implanting a pacemaker, for example, there may be 20 different pacemaker generators and perhaps 25 to 30 different leads that they may have in this bag. There are also other parts and pieces of equipment that we use to try to get those into different locations in the heart.

Q. So that would be the place where you would get the devices that you would implant in your patients?

A. Yes.

Q. Okay. Do any of those devices come from the inventory of the hospital?

A. I know that they bring this big bag of things to the -- I'm not aware of an inventory that the hospital keeps. I'm not involved in their inventory system, no.

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Q. Okay. Is mostly your communication with the manufacturer or the manufacturer's representative oral communication?

A. Yes.

Q. Okay. Do you -- at what point do you give a definitive order to the manufacturer's representative for the devices that you're going to implant?

A. So when we're doing the procedure, basically we'll actually order the specific component, typically by its model number, as we move through each phase of the procedure. So, for example, it's very common for me to start with a lead that goes in the ventricle. And I'll ask for a specific lead size and model number.

And then we'll go to a different chamber, the atrium perhaps, and then the -- and then the generator's usually the last component, but it's at that point that we determine specifically what we're going to use.

Q. Are you communicating with the manufacturer's representative during that process?

A. Yes.

Q. And how are you communicating with him?

A. Just verbally.

Q. Okay. And how does he deliver to you the device that you -- or the device and its components that you implant into the patient?

A. It will be essentially taken out of that. So usually we'll -- we'll know with some level of likelihood what we're going to use and he'll bring those into the room. He may have to, you know, go back out and pull something else out of the bag depending on how what we've selected works or what we -- you know, if there's a change in the game plan based on information we get during the course of the process.

Q. Okay. At the conclusion of the operation how do you memorialize what devices you have used in the process?

A. So we do a detailed report right at the time that we're finished, detailing model numbers, serial numbers, location in the heart, electrical measurements that we obtained as a result of testing during the procedure. And then, again, that's all in a report that goes in the medical record that I sign off on.

Q. Okay. Do you have any idea what happens to those records, where they're kept in your office or in the hospital?

A. In terms of my report?

Q. Yes.

A. Okay. So one is sent to my office, one stays in the medical record. I typically will send a copy of it to other physicians that are involved in the patient's care. I know those things for a fact.

Q. Okay.

A. Beyond that, I -- that would be what I know.

Q. And it's part of your normal business practice to prepare such documents after each procedure?

A. I have to. I'm obligated to --

Q. Okay.

A. -- as part of my privileges at the hospital.

Q. Okay. And it's in the normal course of your practice to do that?

MR. MARINELLI: Objection; leading.

THE WITNESS: If I didn't prepare reports, then I would not be allowed to practice at the hospital.

BY MR. CARPENTER:

Q. Okay. Is your practice audited for

had been missing an entire part of their electrical system?

A. No.

Q. So is it safe to say that by looking at invoices, you wouldn't be able to tell if the pacemaker was replacing something or not?

A. I mean, it just really says what equipment was ordered. So it doesn't give any information about the patient.

Q. Now, I would like to talk to you a little bit about prescriptions. You write prescriptions in your practice, correct?

A. Yes.

Q. And you e-scribe and you orally prescribe things?

A. Yes.

Q. And would you define a prescription as a therapeutic recommendation that a physician or appropriate healthcare provider would give to an individual regarding their care?

A. Yeah. I mean, it basically is a -- it's -- essentially you're making a recommendation for a medical remedy or treatment, yeah.

Q. Okay. And you stated during your direct examination, that you ordered a pacemaker or

ICD by calling the manufacturer's representative and telling them what you need?

A. Well, I mean, it's the whole process of we have the order sheet -- I -- actually, probably the most detailed portion of things is actually in my history and physical where I go over why I think I need what they need and the conditions that we're concerned about that they have.

And, you know, it's basically at the point though where we're putting it in where we select the -- you know, we would make decisions on the sorts of things that you see on the invoices.

Q. Okay. Do you give any patient-specific information to the manufacturer?

A. I -- what I would typically do is say -- I don't give them -- I might say that these are the specific issues that I'm concerned about or this is what we're trying to accomplish, this is the condition. I would say that -- typically, what I will say is that I oftentimes contact them the afternoon or evening before a procedure the next day.

And then I would say, you know, we've got a patient who needs, let's say, a dual chamber pacemaker and, you know, I'm concerned because, you

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know, they have this or that issue and I want you to make sure you have X, Y, and Z. And then they would bring this big duffel bag full of the equipment.

Q. Okay. Do you give any kind of documentation to the manufacturer's representative?

A. No, I do not.

Q. Okay. So I believe it's Petitioner's Exhibit 1 -- 2, the checklist that he showed you, do you give that to the manufacturer?

A. I do not, no.

Q. Do you know if the hospital gives that to the manufacturer at any point?

A. No, I don't.

Q. Is the manufacturer's representative always there in the operating room?

A. Yes.

Q. Every single time?

A. Yes.

Q. Even in a case of some kind of heart trauma where it's an emergency?

A. There -- these are, you know, basically procedures that are -- if -- if we have to do them emergently, we call them in. Yeah, they are.

Q. Okay. So you would wait for the

manufacturer to get there before you did the surgery then in an emergency?

A. Yeah. Yeah.

Q. Okay. And now, you said that you give your final determination of what you need in the operating room?

A. Uh-huh.

Q. How do you do that?

A. Well, so from our initial assessment of the patient, we -- you know, we have the recommendation for the device, but specifically what we use -- what components we use is dictated by what we -- you know, observations we make particularly regarding the patient's anatomy and measurements that we make regarding, you know, the device function within the patient.

So we might initially use, for example, a 1581 lead, but then based on the performance of that lead during the implant process, we might determine that that's not appropriate and, you know, a 6947 lead might be appropriate. Sometimes you might even have to call another manufacturer to get what you think is best for the patient.

Q. And so in the operating room you just tell the representative the part that you need?

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A. Uh-huh.

Q. And do you consider that to be a prescription?

A. Well, I mean, yes. I'm picking a very specific, you know, piece of equipment for an individual based on what I know about them and what I'm observing during that whole process, so I would say, yes.

Q. And in that situation, who would you be prescribing the pacemaker or ICD or lead to?

A. Well, it's the patient who gets it, so...

Q. Okay. And who purchases this equipment?

A. Well, I think ultimately the patient pays for it. There's an interaction, I mean, between the hospital and the manufacturer, but that's not part of the process I'm involved in.

Q. Okay. But the transaction at issue in this case is between the manufacturer and the hospital, correct?

A. I assume so, yes.

Q. Okay. And those invoices are to the hospital, correct?

A. It appears so. Again, first time I've

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CERTIFICATE OF REPORTER

I, Carol Denise Lauder, Registered Professional Reporter and Notary Public for the State of South Carolina at Large, do hereby certify that the foregoing transcript is a true, accurate, and complete record.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof.

Witness my hand, I have hereunto affixed my official seal this 15th day of July, 2013 at Charleston, Charleston County, South Carolina.

Carol Denise Lauder
Registered Professional Reporter, CP
My Commission expires
August 2, 2017

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Transcript of the Testimony of
CHARLES PRESCOTT FERGUSON

Date: March 29, 2013



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STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT DIVISION
Docket No. 12-ALJ-17-0405-CC

Roper St. Francis Medical Healthcare, Inc.,

Petitioner,

v.

South Carolina Department of Revenue,

Respondent.

DEPOSITION OF
CHARLES PRESCOTT FERGUSON

****

Friday March 29, 2013
9:10 a.m. - 10:40 a.m.

The deposition of CHARLES PRESCOTT FERGUSON, taken on behalf of the Respondent at Roper St. Francis Healthcare, 125 Doughty Street, Suite 720, Charleston, South Carolina, on the 29th day of March, 2013 before Sara L. Quattlebaum, Court Reporter and Notary Public in and for the State of South Carolina, pursuant to Notice of Deposition and/or agreement of counsel.

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(retained by Counsel)
Defendant Exhibit Number 3 4
(40-43-60)
Defendant Exhibit Number 4 4
(Pre-Op Planning Checklist)
Defendant Exhibit Number 5 4
(Purchase Order)

STIPULATIONS

It is stipulated and agreed that this deposition is being taken pursuant to the Administrative Procedures Act and the South Carolina Rules of Civil Procedure.

It is stipulated by and between counsel and the witness that the reading and signing of the following deposition be, and the same are, hereby waived.

(Defendant's Exhibit Numbers 1 - 5 were marked for identification purposes.)

CHARLES PRESCOTT FERGUSON, having been duly sworn, testifies and deposes as follows:

MR. FERGUSON - EXAMINATION BY MR. MARINELLI:

Q: Mr. Ferguson, my name is Adam Marinelli, and I work for the South Carolina Department of Revenue. Today we are taking your deposition in the case of Roper St. Francis, I believe is the taxpayer's name, versus the South Carolina Department of Revenue.

MR. MARINELLI: I'm assuming we're going to stipulate that this deposition is being taken in accordance with the rules of South Carolina Civil Procedure and the Administrative Law Court rules.

Q: I'll try to be as clear as I can. If I ask you any questions that you don't understand or that you need to have clarified or restated, feel free to do so. Any question that you do answer, I am going to assume that you understood it. Have you ever taken a deposition before?

A: Yes, I have.

Q: This is a standard question; take no offense.

Are you under the influence of any drugs or have a disability that would impair your understanding of questions or the ability to answer questions in any way today?

A: No.

Q: Please state your full name for the record.

A: It's Charles Prescott Ferguson.

Q: And briefly go through your educational background.

A: I have an undergraduate degree in business administration with marked emphasis from Whittenburg University. And I have a master's degree in health care and hospital administration from the Ohio State University.

Q: Okay. And who are you currently employed with?

A: Roper St. Francis Health Care.

Q: And what is your position currently?

A: Director of material services.

Q: And could you give me a brief job description for that title?

A: I have responsibility for the purchasing and distribution of all medical, surgical, and administrative supplies and equipment across the system.

Q: And how long have you held that position?

A: Ten years.
Q: And who were you employed with prior to that?
A: I was employed by Covenant Health, a system up in Knoxville, Tennessee.
Q: And what was your job title there?
A: It was the vice-president of materials management.
Q: And before that?
A: Before that I was the -- I'm trying to remember because I was a -- what my final title was. I worked for a consulting firm in Knoxville called Pershing Yoakley, and I was a supervisory consultant with them.
Q: How did you become involved in this case?
A: Certainly, as far as --
Q: What brings you here today?
A: What brings me here today? Well, basically my boss asked me to.
Q: And who's your boss?
A: I work for Brett Johnson, who is the CFL assistant.
Q: And he was alerted to the fact that there is a pending lawsuit?
A: Yes.
Q: And he said that you needed to be a witness in

this case?
A: Yes.
Q: Were you approached by him first or the attorneys in this case?
A: To be honest with you, I am not aware of who I was approached by. If it was -- it may have been -- at that point, I think it was probably on the finance side. It was somebody -- I don't remember specifically, but it was somebody from the finance side that said they would like to have us included in it.
Q: And what type of conversations did you have regarding this case prior to being brought on?
A: I really had no conversations until I was brought on.
Q: As you understand it today, what are the issues in this case?
A: My understanding is, you know, the question of is, you know, with the medical devices they were currently purchasing, are we purchasing those under a physician's order?
Q: Are you being paid for your testimony?
A: No.
Q: How were the issues conveyed to you in this case? Were they in writing or just

conversations in a conference room somewhere?
A: Just conversations.
Q: Before we get into the nuts and bolts of the case, let's give a forest-for-the-trees type perspective. Are you familiar at all with South Carolina tax law?
A: I would say a very, very cursory idea. Most of it comes from simply just, you know, talking to individuals, legal representation and other -- but I've not sat and read specific statutes or regulations or anything like that.
Q: So in your day-to-day operation of being material services manager, you don't contemplate or handle any tax matters; is that correct?
A: That's correct.
Q: How did you prepare for the deposition today?
A: I just spent about 30 minutes previous to this with the folks in this room.
Q: And what did those conversations entail?
A: Generally, we just talked about the issues that related to the case.
Q: Could you be more specific?
A: We talked about, you know, what is a physician's order versus a prescription. We

talked about that. We also talked about, you know, some of the different types of, you know, of implants because we, obviously, purchase a number of different implants across the system.

Q: As you understand it, what is the difference between a physician's order and a prescription?

A: In my world, there isn't a difference.

Q: Okay. Let's talk about your world. Go through the day-to-day operation of the material services manager.

A: Can you be more specific? Because I could spend the next three hours talking about that, and I don't think you want to hear all that so --

Q: You're probably right. Say a doctor needs a hip replacement for a patient, how does he go about getting it?

A: Well, there are two things. If it's not an approved item --

Q: Approved by whom?

A: Approved by the system. Then he or she must submit a specific request that details why they want the implant, and it only can be submitted by a physician. There is nobody else who can submit it. And then we do have a

formal process where we will review that request; make sure it's -- it has appropriately met the approval, etcetera and then any financial impact. And so there is a formal process for a physician requesting an item.

Q: Let me interrupt you right there. When you say there is no -- a financial impact. What does that specifically mean?

A: Well, if we're buying Implant A and that is the same thing, and Implant B costs twice as much. And so we look at the --

Q: The cost benefit analysis type thing?

A: Correct.

Q: Do economics play a large role in your decision-making process?

A: They are significant, but they are not the only thing. I mean, that is a fairly good rule where we focus primarily -- that's really -- it really comes secondary. We look at the quality, the patient first before we focus on the financial side of it.

Q: Are you in charge of keeping inventories of various items and supplies in the hospital?

A: Yes.

Q: And does the system that you've created

incorporate economics into that system or into that inventory process?

A: I'm not sure I understand the economics -- what your question is.

Q: Is it part of your position to keep overhead low?

A: Yes.

Q: Okay. Backing up just a moment. Have you reviewed any documents in preparation for this deposition?

A: I certainly didn't review any today. We talked about this a couple of months ago. I may have reviewed some. Honestly, I don't remember if I reviewed anything.

Q: That's fine. So assuming that the item has been approved and it's in the system, how does the doctor get it?

A: If -- it depends what it is. But, for example, if it's an orthopedic joint component, the vendors have available stock. The hospital has no ownership, no association with it. The physician -- once the physician schedules the case, the physician's office will notify the rep, the vendor rep that this is what I need for this case. The vendor has that implant

available the day of surgery. The physician implants it. Then after the case, we're notified via the OR nurse in the case what was implanted. And then we pay for that device, whatever was implanted at that point in time.

Q: So when you say the vendor holds the stock that we have no ownership in. So your overhead is limited by allowing the vendor to basically act as a warehouse for you where you pick and choose what you need at any given moment?

A: Well again, we don't pick and choose. We have no association. We do what the vendor -- in other words, they are the ones that really choose, based on the physician's order.

Q: How does the hospital choose what vendors it deals with?

A: The vendors, frankly, are chosen by who the physicians want to use. Our role in it simply is we negotiate the economics of what we are going to pay for that device.

Q: Are there agreements, written agreements, between you and the vendors?

A: We have pricing agreements. And again, it depends on what type of devices you are talking about. But we do have some pricing agreements.

Q: Have you provided those to your counsel?
A: I'm not aware of what -- I'm not aware of what we've provided at this point. I'm not sure we have provided those pricing agreements.
MR. MARINELLI: Could we get those from just one particular vendor, say like Zimmer?
MR. CARPENTER: I'm sure we could.
MR. MARINELLI: That would be good to see.
A: And these are essentially more of a matrix type; they are very short and sweet because it just establishes the pricing schematics of who will pay for the device.
Q: What type of documentation is forwarded to -- let's say we are talking about Zimmer. Say you need a joint replacement from Zimmer, what do you send them? Do you call it in? Is there an email? Do you ship them an invoiced purchase order? What is it?
A: Well, what happens after the case in the room, and the vendor rep is almost always there essentially because they are pulling the supplies used by the physician for the implants. They fill out what's called a special purchase request.
Q: Who is they?

A: They being the vendor rep.
Q: Okay.
A: They fill it out saying this is what was used. The circulating nurse in the room signs off on it, you know, initials that request. And then that in turn goes to purchasing where we then actually -- we will take that. And based on that, we will submit a purchase order to -- for example, in the case of Zimmer, to do whatever company we buy it from.
Q: But this is all subsequent to the actual implantation?
A: Correct. It all happens after.
Q: Okay. And so the vendor rep is in the room for all of this?
A: Yes, a majority of it, they are in the room.
Q: And do they have all materials that they need for the surgery at that point --
A: All the implants; that's correct.
Q: -- without knowing what was needed at the time? So -- I'm slightly confused.
A: Well, just if you -- you may recall what I previously mentioned is that when the physician's office schedules the case, they notify the vendor rep what implants they are

going to use. So the vendor rep, they may know two or three weeks in advance.

Q: Okay. How does that notification take place?

A: There is a communication from the physician's office directly to the vendor rep. And it's usually -- I'm sure it happens a couple of different ways depending on the physician's office, if it's by fax or by email or via phone call.

Q: Okay. So it could be either oral or written?

A: Yes, that's correct.

Q: For the written orders, what does it look like? What type of document does it have?

A: I'm not familiar with exactly what they look like.

Q: So you've never actually seen one; is that correct?

A: If I have, it's been a long time. So I don't recall specifically if I've seen a specific order that was sent to a vendor.

Q: All right. I'm going to hand you what's been pre-marked as Defendant's Exhibit Number 4. Would you take a look at it and identify that document if you can for the record, and whether or not you have seen one of these?

A: This specific one or this one, I've not seen before.
Q: But have you seen documents like this?
A: No. I mean again, if I had seen something like this many -- a number of years or months ago, I don't recall. This is not something I generally would be -- that I am going to be looking at.
Q: Okay. Do you have any idea what it is?
A: By just reading at the very top, it's a pre-op planning checklist. That's how I know what it is.
Q: So you have no idea of knowing if this is the type of communication that goes from the doctor to the vendor?
A: Again, as I mentioned before, I don't routinely see that type of communication.
Q: Okay.
A: But I know that there is something that goes to the vendors.
Q: So as far as your day-to-day job function is concerned, everything has already happened when you are brought in?
A: Correct.
Q: So it's already been implanted. It's already

been sent from the vendor. You're simply making sure that they are being paid for what's happened; is that correct?

A: Correct.

Q: Okay. Have you ever seen a prescription, a written prescription, in regards to the purchase of one of these joint replacements?

A: I've not seen a written prescription; that's correct.

Q: Okay. Do you know what a prescription is?

A: Having been a patient myself, if you're talking about particularly for medications, I mean, I know what that kind of prescription is, yes.

Q: Could you tell us what, in your mind, a prescription would be?

A: A prescription is simply a means of a physician ordering whatever it is with that patient care. It could be, again, a number of obviously medications, devices, what have you for that specific patient.

Q: I'm going to hand you what has been pre-marked as Defendant's Exhibit Number 3. All right. At the bottom of the page, do you see the Subsection E that starts, "a prescription drug order shall contain at the minimum?"

A: Yes, I do.
Q: And then there is a laundry list of various pieces of information that are required. Do you see that?
A: I do.
Q: Do you have any reason to not believe that that's the legal requirements for what a prescription should have?
A: I'm certainly not -- I haven't read this, and I'm not an expert on it, so I wouldn't -- I really can't answer that.
Q: Have you ever seen a document that contains all that information in regards to the purchase of the items that we have been discussing?
A: I have not.
Q: Okay. Do you handle all of the drug purchases, as well?
A: No.
Q: So you solely deal with joint replacements for --
A: As I mentioned before, it is the medical, surgical and administrative supplies and equipment; but I do not deal with the purchase of pharmaceuticals.
Q: Is there another person in your office that

handles solely pharmaceuticals?
A: No, there's not. That's done all through the pharmacy.
Q: You have an in-building pharmacy?
A: I'm sorry?
Q: Is it in the Roper Hospital?
A: Yes.
Q: And is it owned by Roper Hospital?
A: Yes, it is.
Q: So the pharmacist is employed by Roper?
A: That's correct.
Q: And when a doctor needs a drug from that pharmacist, how does that go about?
A: I can give you the general, but, again, that's certainly not my area. I mean, certainly, there has to be an order that is given for that particular medication. And again, in the clinical area, you know, how that order gets transmitted to the pharmacy, I can't give you the specifics.
Q: That's fine. How does the pharmacy order its drugs?
A: Since -- I can't tell you that because I'm not part of the -- because I don't -- the pharmacy orders their drugs specifically.

Q: Okay.
A: We don't -- in my area, we have no role in ordering the drugs.
Q: Would you assume that they do it in the same fashion that you order the medical supplies?
A: We have a whole range of medical supplies. We order anything from orthopedic implants to band aids. And the ordering process for those is very different.
Q: Does it vary from vendor to vendor or from item to item?
A: It's item commodity to commodity so --
Q: Is it safe to assume that the pharmacy handles those, you know, types of items? You guys do keep some sizeable inventories of various items?
A: Again, it depends on what type of item it is. Obviously, as you mentioned earlier, our goal is to keep -- limit our overhead or inventory.
Q: Sure.
A: But we obviously have to keep enough sufficient for patient care.
Q: Is that your primary goal, limiting overhead?
A: No, our primary goal is to make sure supplies are available to take care of the patient.

Q: Okay. And to do that, some inventories have to be kept; is that correct?
A: That's correct.
Q: Are any of the inventories that you order considered prescription-only items?
A: We do have -- we do have some of that; that is correct.
Q: Could you give me an example of one of those?
A: Well, and again, I'm going to use your term prescription only. For example, we do have some inventories of plates and screws. And we do not use them until a physician orders them. But we have to have those on standby. In other words, if a case comes in that is emergent, the physician needs them, we can't say, wait a minute, let's run down the street, we'll have to get them for you. So we will only replace that upon use by physicians. So we understand -- so if you are talking about physicians or whatever, we do have an inventory that is a physician order, you know, that would be one that is.
Q: And you consider plates and screws a prescription-only item?
A: Yes, in that we only use inventory by a

physician. We only purchase it if it is ordered by a physician.

Q: You would only purchase it?

A: Correct.

Q: Could I, as a common citizen, purchase plates and screws?

A: To my understanding, you could not.

Q: But you keep an inventory on these items, correct?

A: Correct.

Q: So they are purchased before there is any specific patient in mind?

A: They are, but back to what I indicated about how we have new products approved, we will only put an item in inventory in our formula if it's been approved by a physician for their use. But again, we have to have the standby use. It has to be there, you know, when a patient is brought into the ER or OR or whatever.

Q: But just to reiterate, these items are purchased without a specific patient in mind?

A: These specific items are because of the emergency standby nature of what we do.

Q: And how does that purchase take place? Do you just put in an order for 100 of one kind or

what?
A: Well, what we do on a routine basis, it's a little bit of a variation of what I told you related to the orthopedic joints is after the case is finished, let's say we use two screws, and we pulled those out of inventory. After the case is finished, we would reorder those two screws to replenish so we would have that in inventory.
Q: Okay. Are any of the actual joint replacements kept in inventory?
A: No.
Q: And why?
A: Those are strictly the responsibility of the vendor because we don't -- again, we're not going to know -- when the patient is coming into the hospital, the communication of what is needed is between the physician's office and the vendor rep. So we don't know what they are going to use until they come into the hospital.
Q: Is it safe to assume that they are very highly specialized items?
A: Yes.
Q: Each one is different size-wise, material-wise?
A: There are a number of variations, so that would

be -- yeah, that would be correct.

Q: And is it safe to assume that the technology regarding that field is constantly changing?

A: You know, I'm not -- I'm certainly not an expert on joints or orthopedic joints. There is a lot of different metallurgies that go into it. Yeah, it is changing.

Q: My $2,000 TV I bought two years ago is obsolete now. So I'm assuming the medical field is moving pretty fast.

A: It is. I think you have -- again, you have to look at your different type of items. And, again, I'm not the expert. But orthopedic joints would be a little bit different than your, you know, certainly a little bit different that some of your high-end electronic devices, cardiac rhythm, etcetera. So they are all a little bit different.

Q: Would you say that the reason that you don't pull an inventory on those items is because they are so highly specialized, or one reason?

A: I mean, the reason we really don't hold an inventory is that these are planned procedures. And we're only going to use these or purchase these upon a physician's order. And so because

we don't know what the physicians -- we know that the communication of what's needed will occur before the procedure. So there is no need to hold anything in inventory since we know what's going to be used.

Q: They are pretty expensive; aren't they?

A: Yes, they are.

Q: Is that another reason you don't keep an inventory?

A: That's certainly economically -- certainly that would be a part of it.

Q: If the hospital wanted to order a bunch of joint replacements, could it?

A: We -- my understanding is we cannot order it unless we have a physician's order.

Q: And who told you that?

A: You know, my general understanding, and I will be the first one to say I'm not a legal expert, but my understanding just from -- my understanding, you know, the FDA, and with respect also with some of the South Carolina pharmacy regs, you know, again, we need a physician order before we actually purchase these.

Q: I'm going to hand you what has been pre-marked

as Defendant's Exhibit 1. This is a copy of the federal regulations that have been brought to the attention of everyone at this table. I think it's in one of the Plaintiff's exhibits that we looked at yesterday. Let me find it in here. Now, obviously this is related specifically to prescription devices. And I don't think there is any question that people, like myself, couldn't just order one of these things from Zimmer. The question today really is can a doctor or a medical practitioner order anything that's generally limited to prescription-only purchases without needing a prescription for its purchase or use? And so if you will look down the page, do you see Subsection 2 under Subsection A?

A: Yes.

Q: Could you read that for the record for me? It's sort of a broken sentence, but we will clear it up.

A: "Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice."

Q: Now reading that fragmented sentence, why do you think there is a distinction or rather the

conjunction "or" placed between the sale to a practitioner in the use of his medical practice verus or on the prescription or order of? If it needed a prescription in every instance, why do you think that conjunction was needed in that sentence?

A: You know, looking at this, to be honest with you, I don't -- I mean, I'm not sure in reading this. I mean --

Q: If you look at that sentence, does it appear to you that as long as it's being sold to a doctor, it's okay?

A: Again, and this is my interpretation, if I understand what this is saying, it's -- there are two instances sold only to or on the prescription of. So there is a direct sale to the physician or on the order of a physician.

Q: And assuming that on the order of the physician, that would mean a third party with proof that the physician said, yeah, sell it to this guy; is that right?

A: I mean, again, I'm not -- in reading through it, that sounds reasonable, but I'm not -- this is the first time I've seen this one.

Q: Sure, sure. Well, this is the federal

regulation that's really going to be where the rubber hits the road here. So we're trying to figure out what it really means.

A: Okay.

Q: So if I lost my leg in Iraq, and I needed a new peg leg or whatever you call it, and I'm going to where they make these things, which is some durable medical equipment salesman rep, I can't just walk in and get a fake leg; can I?

A: My understanding is you can't.

Q: I would need a prescription; wouldn't I?

A: Right.

Q: And that would be the second part of that clause?

A: Uh-huh (affirmative response).

Q: Right?

A: Correct.

Q: The guy that's selling those legs, could he buy them from a vendor without a prescription? Let me ask it in a different way. Do you, in the course of your ordinary job function, do you purchase from third-party distributors in any instance; non-manufacturers, simply vendors?

A: We buy -- there are supplies that we have to -- you know, again, we buy a whole range of

supplies. And certainly a large number amount of our supplies are bought from distributors because that is an efficient way in the healthcare supply chain. But most -- the majority of those are not implants.

Q: Okay. But would any of those be prescription devices or medicines?

A: And again, we don't purchase any medicine or drugs, at least through my area. And again, from -- to my knowledge, as far as through distributors that, I mean, the majority of the implants we buy, we buy directly from the manufacturers, not -- to be careful -- or to be very clear is that a number of these orthopedic joint companies we work with are technically distributors.

Q: Okay. There's been some discussion that it would be illegal to even be in possession of one of these devices without a prescription. How do you think a distribution, a third-party distribution center, gets those prescription devices from the vendor?

A: Well, to be clear, when we're talking about these distributors, and to use your example, since you brought up the Zimmer, we'll use

that. These are authorized -- these are companies that work directly with the manufacturer. In other words, they are authorized for a certain, you know, and I'm not an expert in that area. But as far as -- they have a certain distribution area like all of South Carolina, for example. And so they are authorized -- they are basically an agent of the manufacturer in terms of selling, you know, in terms of selling. So it's more of sort of a sales arm, I guess I'd call it that. They're not -- they're not necessarily a warehouse of all of the product.

Q: Are all of the prescription devices that you are aware of that are at issue in this case, are they all handled in the same fashion with the vendor onsite?

A: Yes. And let me rephrase that a little bit because we, -- again, as we've mentioned previously, we handle -- there are different implants we handle a little bit differently. Like, for example, we talk about orthopedic joints. Those are only -- we don't own them, we're not inventory. The vendor makes them available the day of the surgery. Whereas we

do have, again, some inventory with the plates and screws that we do have. So there are going to be some different variations of how we handle it.

Q: What about pacemakers?

A: Those would be handled similar to what we have for orthopedic joints. In other words, the vendors have them; they are available. They are brought in a lot of times for the case. They do have -- normally in that case the vendor will leave because of late-night emergencies; they will have a few on the shelf as consignment. You know, so they are strictly -- they are not owned by the hospital, but they are there from again, a standby emergency, but we don't own the inventory.

Q: How many would you say you guys keep on the shelf under consignment on average?

A: I don't really know that. I'd have to look. I don't think it's a large amount, but I'd have to look. I am not familiar with how many.

Q: Yesterday there was some discussion of the fact that these joint replacements come in boxes with all of the components needed. Why would you need to purchase an inventory of plates and

screws if that was the case?
A: The plates -- particularly the screws, those are not going to -- those are not going to specifically come with the boxes. And again, to be very clear, those screws are used for other trauma surgery that we, again, we need to have those available.
Q: So there are multiple uses for these types of items?
A: For certain items, like plates -- for the screws and plates, particularly the screws, there would be some multiple uses for that.
Q: So if I shattered my leg in a motorcycle accident, you guys have enough on hand to --
A: Correct.
Q: -- rebuild me like a bionic man?
A: We hope to, yes.
Q: Me, too. I don't really ride motorcycles. So that's a good thing to know.
MR. MARINELLI: Can we take a five-minute break?
MR. CARPENTER: Sure.
(Off the Record)
Q: I have very little left. You're doing a great job so far. I'm going to hand you what has been pre-marked as Defendant's Number 5. This

is what appears to be a purchase order. Is this what you sent to the manufacturer?

A: Yes, this is what we send. That's correct.

Q: And to your knowledge, assuming the doctor orally transmitted what you needed to the vendor, is this the only documentation that would be sent to the manufacturer?

A: Yes, that's correct.

Q: Okay. Do you see a patient name on this document anywhere?

A: Hopefully, I don't.

Q: We had the HIPAA conversation.

A: Yeah.

Q: Do you see any redacted patient names? It could be that it very well wasn't redacted. I don't know. It looks like there might have been something down here.

MR. MARINELLI: Would you know?

MR. CARPENTER: Actually, this stuff was redacted before it ever got to me.

Q: How about this. Let's ask it in a different way. When you send a purchase order, does it have a patient name on it?

A: No, it does not have a patient name on it.

Q: Does it have any identifying information

whatsoever?
A: The one piece, and I can't tell you -- I would have to confirm. It might have been redacted. And this is -- we sometimes put a medical record number, but it is not -- there is no patient identifying information on this.
Q: And what would be the purpose of the medical identifying number -- identification number?
A: Just to make -- that would be to help the vendor make sure they've got the right patient.
Q: And accounting purposes, obviously?
A: Yeah. But it's not -- we wouldn't use it. But I don't -- I think as I mentioned previously with that special purchase request that is, you know, filled out by the vendor rep and given to the buyer for approval, that -- I don't know how the vendor would tie -- they may have a way to tie that to the purchase order request so that they can -- for the actual purchase request coming across.
Q: Do you still have Title 40, where it describes what a prescription should have in it? This is going to get redundant but just bear with me a second. I think it's Defendant's Exhibit 4. Let me see here. It's the first thing I gave

you, I believe. There it is.
A: This right here, Number 3?
Q: Number 3, I'm sorry. And I know I have asked you this once already. But in any of the documentation, including the one that you see in front of you, which has been pre-marked as Number 5, does any of that batch of information that's required to be on a prescription, is that ever incorporated in any documentation that you give to a manufacturer?
A: We're talking about whether your Exhibit Number 5, which you have given me?
Q: Yes, the purchase order.
A: It is not incorporated in that. Again, this Number 5 is not a physician's order.
Q: So in your mind, is the purchase of any of these devices completed when you send this? And is payment accompanied with this?
A: To just go -- there is a purchase and a receipt that occurs at the same time for these that have already been implanted. And so as soon as that occurs and the invoice is sent to us by the vendor, then that's when payment occurs.
Q: Do they send the invoice after you send them this?

A: Yes.
Q: And then you go check with your accounting department?
A: Correct.
Q: You don't wait for the patient to pay or their insurance provider?
A: No, no. And that's the same across the board. We pay based on our purchases of the supplies, not whether the physicians pay.
Q: You pay for the use of those supplies as opposed to -- the patient's transaction is completely separate from --
A: That is correct.
Q: Okay. I think that might be it. Is the device always implanted in the patient prior to the transaction being completed?
A: Can you say that one more time?
Q: Are the devices always surgically implanted in the patient prior to the transaction being completed between the hospital and the manufacturer?
A: Yes.
Q: So there's never ever a situation where you have purchased devices before putting them in a patient other than the plates and screws?

A: Other than -- if it's in inventory, that's correct. Again, we purchase a lot of stuff. So I should say that's correct to my understanding that we would do that.

Q: And your attorneys have told me that they can prepare sort of watered-down list of what exactly you purchased hopefully in some sort of categories that I can understand because I'm not a medical practitioner. Could you give me a roundabout idea of other than plates and screws, what types of items you keep in inventory?

A: Now, are we talking about --

Q: Prescription devices. Anything that you think in your mind would require a prescription that I, as a common citizen, could not buy on my own.

A: Again, this is to the best of my memory since we have -- we maintain a fairly large inventory of non-implantable devices. But we do have a few heart valves in inventory.

Q: How do you purchase those?

A: It would be the same process as we talked about with the plates and screws, that the physicians have to order it. You know, we work with them

to say --

Q: We would like this kind of heart valve.

A: But we have them to approve it. We work with them to approve what we are going to have and have it -- again, it has to be there on standby because if the patient needs it, they need it. We don't have time to go out. But it is the same process as plates and screws, as the ones that are used and implanted in a patient, then we would reorder that based on the use of that device. There may -- we may have a couple of other, you know, I think, spine products that we keep in inventory. There may be a couple of other things -- typoplastic, I think, is one I can think of. But -- and there may be some odds and ends of items. But we don't have that much except for -- the majority of the largest inventory we keep of implantable devices would be your plates and screws and rods for the -- most of that would be orthopedics.

Q: When you purchase these items, do you purchase them one at a time or do you take, like I say, the end of the week's orders and send them all at the same time? How does it generally work?

A: We generally drive it based on, again, when

it's used. We have set levels that we know that we have to keep to have. And we work based on what the physician will use in the case. And so we know what we have to have available. In particular, if it's a long week, you might have two or three -- a couple of prompt cases going on. And so we have to have enough to support the, you know, the patient care. But we -- at that point, we will only reorder what we need to bring our levels up to, you know, up to a point where we can support the patient care.

Q: And when you're talking about supporting the patient care for possible traumas, you're talking about the items you keep in inventory?

A: Correct.

Q: What about all of the other devices? Say you've got a bunch of hip-joint replacements. When do you send the purchase order, at the end of each one?

A: Correct. Those aren't -- the process, whether it's in inventory or not, are pretty much similar that we send the purchase order at the end of the procedure once it's been, you know, implanted in the patient.

Q: So you have a stack of surgeries on your desk that you need to pay the devices for; is that correct?

A: We have buyers who work in surgery. And so at the end of the day, yes, that's exactly right. They would have it from the day's transit. They would have a list of -- and again, theirs is triggered by when it's implanted in the patient, then they would -- and it's approved where it's across -- everything has been verified that it is the correct device, they would then submit the PO.

Q: I think that's it. Thank you.

MR. CARPENTER: No questions.

(There being no further questions, the deposition concluded at 10:40 a.m.)

CERTIFICATE

This is to certify that the deposition of **CHARLES PRESCOTT FERGUSON**, consisting of Forty (40) pages, is a true and correct transcript of the testimony given by said deponent after being duly sworn; said deposition was reported by the method of Stenomask with Backup.

I further certify that I am neither employed by nor related to any of the parties in this matter or their counsel; nor do I have any interest, financial or otherwise, in the outcome of same.

IN WITNESS WHEREOF I have hereunto set my hand and seal on April 18, 2013.

Sara L. Quattlebaum
Court Reporter

Notary Public for South Carolina
My Commission Expires: July 12, 2012

STATE OF SOUTH CAROLINA

ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a Roper/St. Francis Medical Healthcare, Inc., Petitioner, v. South Carolina Department of Revenue, Respondent.	) Docket No. 12-ALJ-17-0405-CC

DEPOSITION of MELANIE HUTCHERSON

DATE: Wednesday, May 8, 2013
TIME: 3:28 p.m.
PLACE: Faegre Baker & Daniels
111 East Wayne Street, Eighth Floor
Fort Wayne, Indiana

Called as a witness herein in accordance with the Rules of Civil Procedure before Tonya Esparza, Registered Professional Reporter and Notary Public

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Also Present: Lisa Dunkin

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Also announced as present: Raymond Carpenter
Bryson Geer
Lauren Acquaviva
Britt Dobbins

W I T N E S S I N D E X

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E X H I B I T I N D E X

(None)

A. We manage the oncoming customers and ensuring that we consult to them, we have their proper billing and shipping information set up, that we manage the surgeon, our surgeon master, and really the content around those and the relationships.

Q. Okay.

A. Yeah.

Q. All right. Do me and favor and just walk us through from the conveyor belt that these things come out of, hypothetically speaking, to the end result of them being implanted into a body, how does it go about being sold?

A. Sure. Well, the first thing that happens is the rep will work with the surgeon typically to schedule the case and review the materials for the patient, specifically like the X rays to ensure that we have the proper product that's needed for that -- that surgical case. They'll establish the date and the time of the case, and that information is entered then into our case scheduling system.

So once it's entered in our scheduling system with the inventory that's required for surgery, the local office the determine where to locate or source that inventory so that it can be delivered to the hospital in time for the surgery case.

Once the case has been completed, so the implant has been implanted into the patient, there is a requisition sheet that has the patient sticker put on it, identifies information about the patient, produced by the hospital, put on the requisition sheet, and then the rep will take the bar code stickers from each of the products that were consumed and put that on the sticker sheet, along with the pricing.

At that point in time they'll review that document with the OR nurse or the circulating nurse to make sure that both parties are in agreement to the product that was implanted into the patient, and then that requisition sheet then typically goes to a buyer to input the requisition into the system to create the purchase order.

At the same time our rep will the scan that stickers -- the stickers on the sticker sheet, and that will go into our system, so we recognize what products have been consumed or used in the patient.

And at that point in time we'll wait for the purchase order to reconcile between what the rep sent in and what the purchase order presented to make sure that both are intact. And then we will go ahead and add the purchase order so that we can generate the invoice.

Q. Okay. Is that how it happens every time?
A. It generally that's how it happens every time, so I'm speaking very generally about the process.
Q. The requisition sheet that you were discussing, can you tell me a little bit more about it and all the content on it?

And, Peter, if could you get us a copy of one of those with no patient information on it, obviously I would really appreciate it.

MR. MEYER: I'll consider that. I'll have to think about that.

MR. MARINELLI: Okay.

THE WITNESS: So the -- so typically, and I will have to speak in generalities here.

Typically there is a sticker, a patient sticker put on the sheet, that way they know that surgery date, the surgeon, the patient, the medical record number, things of that to be able to identify which particular case this product was for, and then the bar code stickers will be placed on that sheet along with a price.

And then if there's any product that does not have a bar code sticker, then those -- the product information will be handwritten on the sheet for the nurse and the rep to review and approve.

BY MR. MARINELLI:
Q. Do the reps -- are they employed by Zimmer or are they independent contractors?
A. They could be both. I mean, we have both types of reps in our organization.
Q. Okay. And what dictates hiring them as a full-time employee versus an independent contractor?
A. I --
MR. MEYER: Objection. I think this is probably outside the scope. I don't think the corporate structure of Zimmer is within the two noticed topics.
MR. MARINELLI: I mean, the process by which Zimmer sells prosthetic devices to doctors and hospitals, asking about the employee that is actually doing the face-to-face selling is kind of within that, I would say.
MR. MEYER: Is there a way that you can limit it to just the hospital at issue here?
MR. MARINELLI: Sure.
BY MR. MARINELLI:
Q. Are the reps -- are the reps in Charleston, South Carolina independent contractors or employees?
MR. MEYER: Objection. That's calling for a legal conclusion, I think.
MR. MARINELLI: Asking if the employees in

South Carolina are actually employed by the company is a legal conclusion?

MR. MEYER: I think the question of whether a particular person is an employee or an independent contractor is something that's always subject to debate. I mean, there's a lot of case law laying all these factors that differentiate between an employee and an independent contractor.

BY MR. MARINELLI:

Q. Okay. Well, what's Zimmer's position? I mean, I'm not asking for a legal conclusion. I'm just asking are these employees in South Carolina.

MR. MEYER: Again, I'm going to object. I think that calls for a legal conclusion.

MR. MARINELLI: Is it --

MR. MEYER: If she knows the answer to that, she can offer it.

BY MR. MARINELLI:

Q. Okay.

A. I -- I don't know.

Q. Melanie, do you know if they have a W2 or a 1099?

A. I don't know. I'm not familiar with the statuses of the reps.

Q. Okay. That's fine. Let's move on.

The generalities that you're talking about, you

say that's how it generally happens. How else can it happen?

A. That's typically the process flow that the folks use. The content and the manner in which -- the documents that are shared between facilities and the sequence in which things occur can be slightly varied, but that is the typical process that we follow across many, if not all, of our hospitals.

Q. Okay. Is the requisition sheet the only document that Zimmer receives from the hospital?

A. No.

Q. What other documents do they receive?

A. We receive a purchase order.

Q. Okay. And how is that different from the requisition sheet?

A. Essentially the purchase order provides a purchase order number indicating that they've authorized that product to be used and billable.

Q. Okay. So it's more of a accounting document; is that right? Is it a way to track the device as far as billing goes?

A. Yes.

Q. Okay.

A. It --

Q. And is that the only other document that the hospital

passes on to Zimmer?

A. Yes.

Q. Does Zimmer ever receive patient specific prescriptions when these devices are purchased?

MR. MEYER: Objection. I think the term prescription is something that's been debated in -- amongst the lawyers on both sides and kind of calls for a legal conclusion. And so I --

MR. MARINELLI: Okay. That's fine.

MR. MEYER: I would see if you could rephrase.

BY MR. MARINELLI:

Q. Does Zimmer request patient specific information before it sells its devices to a hospital?

A. I'm -- I'm not exactly sure how to answer that question.

Q. Let me pose it a different way.

A. Okay.

Q. If a hospital called you, if you were a sales rep, and said, "I want an inventory, a large quantity of these items," would Zimmer sell it to them?

A. We would, but after further investigation as to why a large purchase would be made. That's -- that's not our typical practice.

Q. Okay.

A. So we would determine why that large quantity was

needed first.

Q. Say, for example, for trauma victims they want to keep a stock on hand for trauma victims, would that be the extent of your -- tell me what the investigation would include, I guess.

A. I guess would department on your definition of a large quantity.

Q. More than one?

A. More than one?

Q. Yeah.

A. Yes, we would sell more than one without hesitation to a customer specifically for trauma product. But I guess my definition of large would be something much larger than one.

Q. Well, let's just go down that rabbit hole, I guess. How many would be too many?

A. Well, typically the distributor offices know the inventory that's at the hospitals. So if they ordered something that was exceptionally large from what they already had on stock or would typically need, there would be a question as to is there a change in practice, either at the hospital or with the surgeon that's performing the surgery at that hospital.

Q. Okay. Okay. And do most hospitals have an inventory of your products on site?

A. That varies hospital by hospital, but yes, a lot of hospitals do have our inventory on site.

Q. And are those owned by Zimmer or the hospital's already purchased those?

A. Both.

Q. Both, it just depends on --

A. It --

Q. -- the hospitals?

A. It does. It does.

Q. Okay. And in the instances where the hospital owns that inventory, what type of documentation does Zimmer require to make that sale to stock the inventory?

A. Purchase order.

Q. And that's it?

A. Uh-huh.

MR. MEYER: Can we make a distinction here between types of products? Because I think we're getting confused. At least I'm a little confused.

MR. MARINELLI: Let's just, for the rest of these questions, assume I'm talking about hip replacements.

MR. MEYER: Okay.

MR. MARINELLI: Does that work?

MR. MEYER: Yeah, that's fine, because I think the answers will likely vary depending on what type of product we're discussing.

MR. MARINELLI: Okay. And just for you-all's clarification, most of the products that Zimmer sells that are at issue in this case are knee, joints, and hip replacement, those types.

MR. MEYER: Okay.

BY MR. MARINELLI:

Q. So in the instance of a hospital that had an inventory that they owned, your testimony today is that the only thing that Zimmer requires is a purchase order?

A. Correct.

Q. And on that purchase order --

MR. VON LEHE: Let me ask -- this is John, if you don't mind my butting in here for a second.

I'm trying to go back to her initial testimony. That doesn't seem to -- I just want to make sure we know we're talking about the right thing. I thought she testified a little while ago that there was a process that was followed onto which these orthopedic devices were purchased.

MR. MEYER: I think the --

MR. VON LEHE: Did I hear all that?

MR. MEYER: Yeah, I think the confusion is we started talking about trauma products, and then we started talking about products that the hospital would own, and then we kind of shifted to hip implants, but

I'm not sure.

Are we still talking, when you talk about products the hospital owns, maybe it's good to sort out what type of inventory the hospital owns and what type is just kept on site but is still owned by Zimmer. Because I think the witness is a little confused about which type we're talking about.

BY MR. MARINELLI:

Q. Sure. Melanie, how about you distinguish that for us. What type of products are typically held in inventory verses which ones are not, and we'll go from there.

A. Sure. Sure. So owned inventory is typically at the hospital, and when the surgeon is reviewing the X rays with the rep, they will determine if there's owned inventory there at the hospital that should be used for that case.

There is also what we call trunk stock or carried in inventory that may also reside at the hospital, but it's considered our inventory. And so when they review the -- the X rays, they will determine if they can pull that inventory at the hospital that we own for that case. Or they will determine if we need to source that inventory from another desired location, if it's not readily available on site.

So that does tend to -- yeah, you do kind of have

to talk about the different inventory types.

Q. Okay.

A. Yep.

Q. Is there ever a situation where trunk stock is pulled to get the inventory of the hospital back up to its normal levels without any sort of patient specific information?

A. Not that I'm aware of.

Q. Okay. But you testified earlier that there are situations where Zimmer will sell its products to a hospital without patient specific data; correct?

A. If it's owned inventory, and they want -- if they want to buy the inventory, then it is a purchase order.

Q. Okay. And when you say owned inventory, owned by whom?

A. Owned by the hospital.

Q. Okay. What types of inventory would fit into that category? I mean, what types of products does Zimmer makes?

A. They could buy any -- any product can be purchased. Our standard methodology typically for implants is it's typically our inventory or inventory on consignment at the hospital, which is still our inventory, but there's nothing to prevent a hospital to buy the implants and leave them there on site.

Q. Okay. Do you know why that is?

CERTIFICATE

I, TONYA ESPARZA, a Registered Professional Reporter and Notary Public authorized to administer oaths and to take and certify depositions, do hereby certify that the above-named witness was by me, before the giving of their deposition, first duly sworn to testify the truth, the whole truth, and nothing but the truth to questions propounded at the taking of the foregoing deposition in a cause now pending and undetermined in said court.

I further certify that the deposition above set forth was reduced to writing by me by means of machine shorthand and was later transcribed from my original shorthand notes; that this is a true record of testimony given by the witness; and that said deposition was taken at the aforementioned time, date, and place, pursuant to notice or stipulations of counsel.

IN WITNESS WHEREOF, I have set my hand and seal this 2nd day of May, 2013.

Tonya Esparza

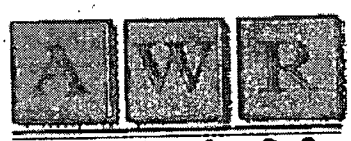
Tonya Esparza, RPR
Notary Public in the County
of Allen, State of Indiana
My Commission expires:
May 23, 2017

In The Matter Of:

CareAlliance Health Services, et al vs
South Carolina Department of Revenue

John McCormack
May 8, 2013

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STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

CAREALLIANCE HEALTH SERVICES
D/B/A ROPER/ST. FRANCIS MEDICAL
HEALTHCARE, INC.,

Petitioner,

vs. DOCKET NO. 12-ALJ-17-0405-CC

SOUTH CAROLINA DEPARTMENT OF REVENUE,

Respondent.

DEPOSITION OF: JOHN P. McCORMACK

DATE: May 8, 2013

TIME: 9:31 A.M.

LOCATION: Offices of South Carolina
Department of Revenue
300A Outlet Pointe Boulevard
Columbia, SC

TAKEN BY: Counsel for the Petitioner

REPORTED BY: WANDA K. CECIL
Certified Court Reporter

A. WILLIAM ROBERTS, JR., & ASSOCIATES

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ALSO PRESENT:

Britt C. Dobbins

(INDEX AT REAR OF TRANSCRIPT)

A. Yes.

Q. Did you have any association with it yourself in terms of drafting or reviewing or any other work in regard to that?

A. I probably drafted this one, being 2005, yes.

Q. Okay. So you were probably the draft person. What is the subject of that revenue ruling?

A. It concerns the sale of radioactive implant seeds by a company to hospitals, medical centers, medical practitioners for use in the treatment of prostate cancer as discussed in the facts.

Q. Okay. And, basically, does that revenue ruling say that a hospital can purchase implant seeds exempt from the sales and use tax?

A. Yes. It's saying they're exempt because they come under the exemption for the therapeutic radiopharmaceuticals that come under the exemption, that part of the exemption.

Q. Okay. Thank you.

(PLF. EXH. 9, SC Revenue ruling #96-4 (TAX), was marked for identification.)

BY MR. CARPENTER:

Q. I show you what's been marked for

identification as Plaintiff's Exhibit 9. That's Revenue Ruling 96-4. Are you familiar with that revenue ruling?

A. Yes.

Q. Okay. Can you tell we what the subject of that ruling is?

A. Concerns the sale of radioactive isotopes by nuclear pharmacies to hospitals.

Q. Okay. And what was the determination of that revenue ruling?

A. States that the sale of radioactive isotopes by nuclear pharmacies to hospitals are exempt from the sale and uses tax per Code Section 12-36-2120(28)(a).

Q. Okay. Are you aware that radioisotopes can be both diagnostic and therapeutic?

A. I believe that it has been. I'm aware of that.

Q. Yes.

A. I think discussion has come up on that before.

Q. Okay. And does this change your opinion about the taxability of radioisotopes?

A. No. I think this is --

Q. Okay.

A. -- still applicable to them as long as, again, the nuclear pharmacies are still required to sell it by prescription because that was the issue here.

Q. Yes. Thank you. Okay. Let's see. Moving right along. We're going to talk a little bit about the Food and Drug Administration, if we can. And we are on an accelerated path now.

Are you familiar with the Food and Drug Administration?

A. I know they're an agency of the federal government.

Q. Okay. Have you ever reviewed the FDA regulations related to the requirement for a prescription to sell a medical device?

A. I don't recall one way or the other.

Q. Okay. There is an FDA expert who has been associated in this case and the FDA expert says that it is the Food and Drug Administration that determines whether or not a prosthetic device requires a prescription. Are you familiar with that portion of the FDA regulations or that requirement by the FDA?

A. No.

Q. Okay. So you have no information on the

Food and Drug Administration's oversight of prosthetic devices?

A. No. Like I said, I don't recall reviewing anything on that, so don't have any information on that.

Q. Okay. If the Food and Drug Administration expert says that it is the Food and Drug Administration that determines when a prescription -- when a device requires a prescription, would you have any reason to doubt that?

A. Well, I don't know whether I would doubt it. I don't know whether it would be in the correct context with the South Carolina exemption or not.

Q. I understand. Okay. Does the South Carolina Department of Revenue determine when a prosthetic device requires a prescription?

A. No, we would not determine that. We would just make determination whether it's -- from the information we have, whether it does or not; but trying -- but we don't make the determination whether it has -- whether it's something that requires a prescription. That's done by other agencies.

Q. Who, Mr. McCormack, makes that

determination?

A. Well, I think you said it was the FDA.

Q. Okay.

A. But that's your opinion.

MS. GEER: That's your opinion.

BY MR. CARPENTER:

Q. I'm sorry. It is the opinion of the expert of the Food and Drug Administration, not my opinion. Since the Department of Revenue does not make that determination, as you have said, and you have at least acknowledged that the Food and Drug Administration may be the entity that makes that determination and if the prosthetic devices in this case all require a prescription as determined by the Food and Drug Administration, would those prosthetic devices be sold by prescription under the South Carolina Sales and Use Tax Statute?

A. In my opinion, no.

Q. And why would that be?

A. Well, in the same way that when you're in the hospital and the doctor comes and visits you while you're lying in bed and he determines that you need certain medicine and he writes on your chart that you need this medicine.

Q. Uh-huh.

SIGNATURE OF DEPONENT (CONTINUED)

PAGE	LINE	CHANGE	REASON

6/6/2013

JOHN McCORMACK Date

I, Wanda K. Cecil, Notary Public for the State of South Carolina at Large, do hereby certify that the deponent was advised of his or her right to read and sign said deposition both verbally and in writing. If the deponent fails to execute and return foregoing Signature of Deponent pages within the thirty (30) days allowed pursuant to the rules of Civil Procedure, the original transcript may be filed with the court.

WANDA K. CECIL NOTARY PUBLIC SOUTH CAROLINA

Wanda K. Cecil

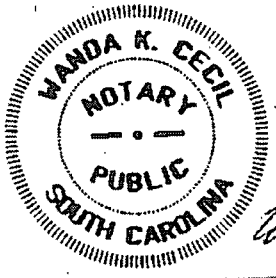
Wanda K. Cecil, CSR
My Commission expires
December 28, 2016

CERTIFICATE OF REPORTER

I, Wanda K. Cecil, Certified Court Reporter and Notary Public for the State of South Carolina at Large, do hereby certify that the foregoing transcript is a true, accurate, and complete record.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof.

Witness my hand, I have hereunto affixed my official seal this 20th day of May, 2013, at Columbia, Richland County, South Carolina.



Wanda K. Cecil
Certified Court Reporter
Notary Public
My Commission expires
December 28, 2016

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

CAREALLIANCE HEALTH SERVICES d/b/a ROPER ST. FRANCIS HEALTHCARE,	)	CIVIL ACTION NO: 12-ALJ-17-0405-CC
Petitioner,	)	
vs.	)	
SOUTH CAROLINA DEPARTMENT OF REVENUE,	)	
Defendant.	)	

* * * * * * * * * * * * * * * * * *

DEPOSITION OF: JOHN MCCROSSON, M.D.

DATE TAKEN: Thursday, April 25, 2013

TIME: 3:15 p.m.

PLACE: Roper St. Francis Healthcare
125 Doughty Street, Suite 720
Charleston, South Carolina

REPORTED BY: EVE WILBANKS
Registered Professional Reporter, Certified LiveNote Reporter and Notary Public

* * * * * * * * * * * * * * * * * *

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ALSO PRESENT: BRITT C. DOBBINS

Electronically signed by Eve Wilbanks (101-177-349-6970) 0d95a6e3-60fe-41e1-bf25-82cc9fbe72da

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** Exhibit Nos. 3, 10, 11, 13 and 14 were not entered.

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Q. Is there any reason you feel you will not be able to testify fully and accurately today?

A. No.

Q. Did you meet with Mr. Carpenter or any of the other lawyers involved with this case before coming to this deposition today?

A. Yes.

Q. And during that meeting, did you prepare for this deposition?

A. Yes.

Q. How did you prepare?

A. Just by thinking about what we would be discussing today as far as what happens in the operating room. I just feel like I'm here to shed light on our processes.

Q. Did you review any documents during your preparation?

A. Yes. I reviewed the posting slip that I use for surgeries, an invoice of implants after surgery, one or two other documents, maybe. Oh, the boxes that the implants come in. Maybe one or two other things, but I can't think.

Q. So to talk about you a little bit, what type of doctor are you?

A. Orthopaedic surgeon.

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Q. Could you write yourself a prescription for something?

A. Yes. I actually could write you one, but I would have to make a chart and establish that we had some kind of -- I wouldn't do that in this situation. But as long as I establish a physician/patient relationship and document that in a chart, I can prescribe most things to most people, but I cannot prescribe certain controlled substances to family members or inappropriate relationships, where it would be foggy whether I had a proper therapeutic relationship.

Q. Can you give me an example or a couple of examples of things that you have written prescriptions for?

A. Yes. Most commonly, pain medication after surgery, antibiotics. Those are, by far, the most common prescriptions I write.

Q. Now, you're going to have bear with me through these questions because I might not understand your answers.

A. Okay.

Q. How do you know what you need to write a prescription for and what you don't need to write a prescription for? Is there a book that tells

and they might do something crazy with it.

Q. So would you say -- using a glucose meter, for example, or blood glucose meter, that's something that would be different from a prosthetic device that you use during your surgeries?

A. Yes.

Q. To your knowledge, if a patient wanted to purchase parts for a knee replacement on their own, could they?

A. I don't think they can.

Q. Why do you think that they can't?

A. It says on the box "by prescription only." I think the FDA requires you to have a prescription in order to use or prescribe the device.

Q. So if you wrote a prescription and gave it to a patient to take to Zimmer, do you think they could then purchase the device?

A. I don't think so. I wouldn't do that. Looking back at your former exhibit, 47, "Issued for a legitimate medical purpose," I'm not saying that every time I order a prosthetic it falls under prescription drug order. But certainly that line of thinking, if it's not for a legitimate

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medical purpose, I wouldn't write the prescription. I don't know if it could be done, but I don't think I would be behaving properly if I did it.

Q. Could you purchase the device from the manufacturer?

A. I don't think so.

Q. But you don't know for sure if you could or couldn't?

A. That's right.

Q. You've never tried to --

A. That's right.

Q. Do you know if you would need a prescription for you to purchase it yourself?

A. A prescription is required to purchase it no matter what. But I don't know if simply writing a prescription entitles you to be able to purchase if, if that answers your question.

Q. How do you know that a prescription is required for you to purchase it?

A. Because it says it right on the box.

Q. So Zimmer requires you to give them a prescription before you can purchase the device?

A. Yes.

Q. But you don't have any records of those

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were in your private practice -- back in 2000, I think you said you started?

A. Right.

Q. Was that your first job out of medical school?

A. After fellowship, yes. So you're really employed as a resident and fellow too. So this whole six years I had a job, and it was my first time out in real practice.

Q. So when you were in private practice, who was your employer?

A. The corporation known as Orthopaedic Specialists of Charleston that I became a partner of two years later.

Q. So they paid you? That's where you got your paychecks?

A. Right.

Q. When you were in private practice, did you ever administer anything in your office that would be considered by prescription only?

A. Yes.

Q. Like what?

A. Like injections, knee joint injections, cortisone or Viscosupplementation, artifical joint fluid. Those come to mind. Braces -- knee

braces.

Q. Did you have those on-site in inventory?

A. The cortisone and local anesthetic we did. The artificial joint fluid I did not. I wrote a prescription and the patient would go get it filled and bring it back, because we lost money if we kept inventory. And braces, we had -- DonJoy handled our durable medical equipment. So it was in our office, but we did not own the inventory or profit from it.

Q. You said you kept an inventory of the cortisone shots --

A. Yes.

Q. -- or I guess the fluid that would go in the --

A. Right, right.

Q. How did you get those? Do you know how they were purchased?

A. No. All I know is the medical assistants just took inventory and did monthly orders or something like that. But I don't know what was involved with doing that. I don't remember ever signing anything as part of that.

Q. Do you know where they ordered them from?

ever know exactly what I need until bone cuts are made and I'm about to stick it in.

Q. So he looks at your plan and he says, I'm going to need to pull boxes A, B, C and D, and brings those?

A. Right.

Q. And you may need one of those boxes?

A. That's right.

Q. And he can tell from looking at it that you may need that?

A. He probably is pretty good at that. But I never rely on him to do it. So I feel that I always communicate what I need to him and never leave that up to him.

Q. And again, going back to the emergency situation, when there's no vendor in the room, you said that you still call out the oral prescription?

A. Yeah, absolutely.

Q. Who do you call it out to?

A. The RN. The RN is always in charge of that whole process. The vendor just is the one that is best at knowing where he has it in his pile. But the RN is the one that that order is going through every time.

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Q. The RN being the same person that you referred to as the circulating nurse?

A. That's right. And they're always in the room.

Q. Is there anything that you've testified to today that you feel you would like to clarify or further explain?

A. No.

MS. ACQUAVIVA: Then I don't have any further questions.

MR. CARPENTER: I have just one question.

CROSS-EXAMINATION

BY MR. CARPENTER:

Q. Dr. McCrosson, I show you what has been marked for identification as I guess Deposition Exhibit No. 1 and Deposition Exhibit No. 16. And I ask you -- you've already testified with regard to these documents, but would you consider these documents to constitute a work order -- a work authorization or an order for the items that will be used in a procedure?

A. Yes.

MR. CARPENTER: No further questions.

REDIRECT EXAMINATION

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C E R T I F I C A T E

STATE OF SOUTH CAROLINA:

COUNTY OF CHARLESTON:

I, EVE WILBANKS, Registered Professional Reporter and Notary Public, State of South Carolina at Large, certify that I was authorized to and did stenographically report the foregoing deposition; and that the transcript is a true record of the testimony given by the witness.

I further certify that I am not a relative, employee, attorney or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

WITNESS MY HAND AND OFFICIAL SEAL this 26th day of April, 2013, in the City of Charleston, County of Charleston, State of South Carolina.

Eve Wilbanks
Registered Professional Reporter
and Notary Public

My commission expires:
December 16, 2014

Electronically signed by Eve Wilbanks (101-177-349-6970)

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STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a Roper St. Francis Healthcare,	)	CIVIL ACTION NO: 12-ALJ-17-0405-CC
Plaintiff,	)	
vs.	)	
SOUTH CAROLINA DEPARTMENT OF REVENUE,	)	
Defendant.	)	

* * * * * * * * * * * * * * * * *

VIDEOTAPED DEPOSITION OF:	JOHN MCCROSSON, M.D.
DATE TAKEN:	June 13, 2013
TIME:	4:02 p.m.
PLACE:	Roper St. Francis 125 Doughty Street Charleston, SC
REPORTED BY:	DENISE LAUDER Registered Professional Reporter and Notary Public

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(Petitioner's Exhibit Number 5 retained by Counsel.)

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Hospital.

MR. MARINELLI: Adam Marinelli representing the South Carolina Department of Revenue.

MS. ACQUAVIVA: And Lauren Acquaviva also representing the Department of Revenue.

THE VIDEOGRAPHER: Please swear in the witness.

JOHN MCCROSSON, M.D.,

being first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. CARPENTER:

Q. Would you state your full name for the record?

A. John Joseph McCrosson.

Q. Okay. Dr. McCrosson, by whom are you employed?

A. Roper St. Francis Physician Partners.

Q. And are you a physician?

A. Yes.

Q. Okay. And what is your area of specialization?

A. Orthopedic surgery, hip and knee replacements.

Q. Can you describe what you do in that

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area of specialization?

A. I replace hip and knees, that's 90 percent of my practice.

Q. Okay. Are you board certified in this area or any area?

A. Board certified in orthopedic surgery. There's no special certification beyond that for hip and knee replacement.

Q. Okay. Tell us about your educational background.

A. I went to college at Emory University in Atlanta, then medical school and residency at the Medical University of South Carolina here in Charleston, and a one-year fellowship in adult reconstructive surgery in New York City, Insall Scott Kelly Institute.

Q. How long have you been employed by Roper St. Francis?

A. Since 2007, so five and a half or six years.

Q. Approximately, how many of the nip -- heat -- knee and hip surgeries do you perform during a week, month, year?

A. I usually perform about 12 per week, 40 to 50, sometimes more, in a month, and over 500 a

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hospital, tells them which implants that we want to have available and it goes from there.

Q. With regard to the implants, do you discuss the type of implant with the patient? In other words, do you and the patient come to some kind of joint decision on that or how do you make that decision?

A. Yes. Some patients want to know more details than others, but in every exam room we have models of the implants that we use. Most patients have already looked at those models. Usually while we're talking to them about the surgery, we're showing them the model. Some patients are interested in the specifics of if it's metal, plastic, ceramic, who made it, and at that point we talk about what would be the best option for them.

And of course I have my go-to favorite implants that I'm most accustomed to using that I get good results with. That's generally what I use. I usually explain to the patient, if that's appropriate for them, that that's why I will be using it, because it works well for me. And I hope that answers your question.

Q. Yeah, but at the end of the day, who makes that decision, is it you or the patient?

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A. I make the decision for the implant.

Q. Okay. When you make a decision to treat a patient with a specific device, how do you then identify that device and order that device?

A. I start with that preop posting slip. If it's the standard stuff, I just put, right total knee, and I have the standard things. There's always -- the supplier, the Zimmer representative that I work with, is in the operating room every time I operate. And that information is communicated, by the way, to him.

He knows the types of procedures for -- on any given date so that he'll have -- he'll bring the implant assortment that we'll need to make it through the day. Because if we do eight surgeries in a day, he needs to have multiple in case several patients all require the same size, et cetera.

Q. Let's go back to -- to right after we've met with the patient and you've made a determination that the patient is a candidate for hip or knee replacement. Now you're going to order the device. Do you -- how do you communicate that and with whom do you communicate at that time?

A. I communicate that with Pam usually or Jeanine, one of my two medical assistants.

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distributor doesn't want to have all of his thousands of dollars of inventory sitting down here not getting used. So there's constant communication between the distributor and my local rep.

Q. Do you have an inventory of these devices that you use in your surgeries?

A. No, I do not. The Zimmer rep holds and has all of that. It's just something that stays within the hands of Zimmer until I use it.

Q. All right. When do you communicate with the manufacturer's representative with regard to the items?

A. First communication is when we schedule the surgery. So we're usually scheduled maybe two months out. So we give him the heads-up that early on. And then a week before, he goes over all of the surgeries for the following week again, and he actually comes in and looks at the X-ray plan, on all the hip replacements at least. Because the X-rays are more important for determining what implants we'll use in that case.

Usually I've already drawn on them with software what type of device and particular sizes we'll probably use. And he makes notes based on

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what I've already put on the preoperative plan, asks me any questions that he has.

Then on the day of surgery, when we're -- we may communicate more before we make the incision if we still are needing to discuss what we might use, but otherwise, we're just verifying that he has everything we had already planned available, and then make the incision, make the bone cut, start doing the preparation.

We don't know what size we're going to use until we prepare the bone for the implant. All the planning we do ahead of time just gets it narrowed down to a range; but in my mind, the order occurs -- you know, we're building up to it all along, but the order occurs when the bone is prepared, I've put in trial implants that we have available for every patient, and then I take those trial implants out and I say, now open these things, and I name the sizes. And, to me, that's the -- that's when the prescription is occurring.

Q. Okay. And who do you name that to?

A. I name that to the Zimmer rep who then opens the devices and gives them to the circulating nurse. We have a circulating nurse who is a registered nurse in every surgery. I think that's

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maybe a state law, but it's always the case. So that RN is the one that's authorized or licensed to be able to deliver the implant to me. The Zimmer rep cannot give that to me.

Q. Right. So these come to you directly from the manufacturer?

A. Essentially, yeah. With the Zimmer rep being the manufacturer's last -- last hand.

(Petitioner's Exhibit 1, Copy of Pre-Op Planning Checklist, was marked for identification.)

BY MR. CARPENTER:

Q. Okay. Dr. McCrosson, I show you what has been marked for identification as Plaintiff's Exhibit 1. Do you recognize that document?

A. Yes. This is a document I created to assist with my pre-op planning.

Q. Okay. Who completes that document?

A. My physician's assistants, me, and that's it. And my medical assistant will sometimes write some more notes as I'm telling her what to write on it.

Q. Okay. Outside of those persons in your office, does anyone else see this form?

A. The Zimmer rep often sees it. He

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doesn't -- he sees it on unusual cases or at least he is communicated the information on and over the phone in cases where he cannot see it.

Q. Okay.

A. And sometimes I'm using other companies too, so that goes the same for a Stryker rep or Smith & Nephew or another company.

Q. Do you know how or where you file this form or store it in your office? I mean, does it go in the patient's records or anything of that sort?

A. I'm not sure where it goes.

Q. Uh-huh. Is it stored in that form of paper or is it stored as -- electronically, or do you know?

A. I don't know. I know that it is basically re-entered in electronic format into another computer system so that the information is communicated to the operating room. And that is kept within the electronic medical records system of the hospital somehow. I don't know what Pam does with this piece of paper after that.

For special situations, whenever I say, hey, may I see that again and make some changes, she always has it, but I don't know if it's in the

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patient chart or in a file that she keeps on the side.

Q. And once again, what is -- what is the purpose of the form?

A. That is to have -- the purpose of that is to have all of the implants available that we may need when we do the surgery.

Q. Okay.

(Petitioner's Exhibit 2, Copy of schedule page, was marked for identification.)

BY MR. CARPENTER:

Q. Okay. I show you, Dr. McCrosson, what has been marked for identification as Plaintiff's -- Petitioner's Exhibit Number 2, and ask if you recognize that document.

A. Yes.

Q. Can you tell us what it is?

A. This is a page from Pam's surgery scheduling calendar, schedule book.

Q. Okay. What kind of information do you have on there?

A. The patient names are crossed out, and then underneath each crossed-out patient name is a -- an abbreviation of a procedure. For example, on

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the top left it says, RT for right, THA for total hip arthroplasty. Arthroplasty is a fancy word for replacement. And then it says near there 7:30. And this is saying that the start time for that surgery is scheduled for 7:30 in the morning. And up above that it says Dr. T. That means Dr. Thompson is going to be my assistant that day in that room.

And then the ones that are directly underneath that are more procedures for a particular operating room for that day and the times that they are scheduled to go. The column over to the right is a second operating room on that day and the procedures that are listed to go in that room.

Q. Okay. And did you indicate that the manufacturer's representative may at times see this form?

A. Yes.

Q. Okay. Who else may see this form?

A. The physician assistants look at it too. I have two physician assistants and they also are interested in it for planning their day. Oftentimes one of them is in each room. Dr. Thompson is the one that helps when one of them is

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sick or out. So usually it's a physician assistant in each room.

Q. And the two forms, Plaintiff's 1 and 2, are -- can they -- can those forms be described as your work authorizations?

A. Absolutely.

MR. MARINELLI: Objection; leading. I don't know if we let him answer it at this point or if you just ask it a different way; I don't know.

BY MR. CARPENTER:

Q. Okay. Do these forms memorialize the information with regard to patients and procedures that you are conducting during a period of time?

MR. MARINELLI: Objection; leading.

MR. CARPENTER: You can still answer.

THE WITNESS: Yes.

BY MR. CARPENTER:

Q. You've described the information that is on the form -- summarized on the form. And this information is -- I don't know, is it used by your staff for -- what is it used by your staff for?

A. To schedule surgeries while we're in the office. The first step is -- in the situation where I walk out of the exam room and tell Pam, okay, this patient would like to schedule a total

knee; then when she goes in to talk to them and start the process, giving them the book about -- with more information, et cetera, she comes in with a schedule book and says, when would you like to schedule it? And they say, oh, I don't know, as soon as I can. And then she sees when the next available is.

Or they may say, I want to do it during Christmas break. So she starts -- and this helps her keep track of how many surgeries we have on a given day. I usually operate on Monday and Tuesday. So she just starts scheduling patients that way. And then as we get closer to the date, then the physician assistants and the manufacturer rep look at it more to start making sure that all the labs that are coming back for -- in the case of the physician assistants, those labs we ordered two weeks before, they're starting to make sure that they've reviewed all of that, reviewed that preoperative clearance letter from the primary care doctor.

And then if there are any discrepancies or concerns with that information, they forward that to me and say, we have an issue here, what do you want to do about it? Can we still do surgery,

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et cetera.

Q. Okay.

A. So this book starts that whole process. And then there are times when someone -- for example, today a patient for next week went to visit her daughter and her daughter's cat attacked her and scratched her leg all up, so now we have to cancel her surgery for next week. So then we have to cross her off. And then we have a waiting list and Pam calls them and says, hey, there's an opening for next week if you want to come.

Q. Do you or your staff prepare any other documents in preparation for or subsequent to surgery?

A. We do a preoperative history and physical as part of the hospital chart. We take the -- a lot of the information from our last office evaluation and then we update that with the -- anything that's changed up until the day of the patients's admission.

The other paperwork involves lab results, preoperative clearance, and we talked about there's a sheet that the physician assistants check off that says that -- where they check off that they have the X-rays ready for surgery day,

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all of these things are completed. And my office probably has a few more pieces of paper that they use to help make sure they get all the work done so that when the patient arrives, everything is smooth, but, you know, I can answer in detail --

Q. Yeah. I think you've done that.

On the day of surgery, who makes the final decision on what prosthetic device is implanted in the patient?

A. I do.

Q. And how do you convey that decision to people in the room?

A. Verbally.

Q. Okay.

A. Because by then I've already established which brand I'm going to use. And it may have changed already during the surgery, but I would change that verbally; if I say, well, the Zimmer is not working out, let's use the Stryker Restoration, the Stryker guy is there in that situation already because I knew that was a possibility, then we use that. And then after we find out what size of that we need, we say, open the 32.

Q. Is the decision to use a specific kind

of device memorialized by your staff in any way?

A. Yes. The circulating nurse, the registered nurse, enters the bar code numbers into the computer system; and also takes the stickers from the implant boxes, they usually have stickers on those, and places them in the chart and also in a log that the hospital keeps of all the implants -- joint replacement implants. So sometimes we can access those when the computer system is down to see what size this patient has, if we're in an emergency situation and I'm going to operate on that extremity again.

And then in my operative report I also dictate the sizes, in the discharge summary from the patient when they leave the hospital, we also includes the sizes. So there are several times the brand, size, the -- of the device is memorialized. Also on the brief operative report after surgery that we complete, besides the one that we dictate for the final chart.

Q. Are Plaintiff's 1 and 2 -- or Petitioner's 1 and 2, are they -- do they constitute memorialization of the procedure that you actually completed?

MR. MARINELLI: Objection; leading.

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THE WITNESS: They're preparation. They're preparation, getting ready for the prescription to occur. If we did not have these planning steps, we would never get to the point where I could order it and it would be there.

BY MR. CARPENTER:

Q. Okay. That's fine. The procedure that you have described and that's memorialized in the documents before you, is this the procedure that you follow on a regular basis in terms of the way that you -- that you intake and document what has been done with your patients?

A. Yes. To do the volume of work we do, it has to be very mechanized.

Q. Right. And do you know if -- if the procedures that you follow are procedures that are generally followed by other orthopedic surgeons at Roper St. Francis?

MR. MARINELLI: Objection; leading and calls for speculation.

MR. CARPENTER: If he knows.

MR. MARINELLI: I'm just making my objection.

MR. CARPENTER: Yeah. Okay.

THE WITNESS: Yes.

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available by prescription only or -- or not.

Q. Right.

A. But we still can write the prescriptions for the others, but you can obtain them without a prescription. When an item is prescription only or an activity is prescription only, when something's been deemed prescription only by the powers that I have to listen to, they can only obtained by a prescription.

Q. Okay. Are these -- going back to Plaintiff's 1 and 2, are those documents part of your memorialization of the order for the devices?

A. You could say so. Certainly, it's not in itself memorializing it because if the patient's cancelled, you know, the order never occurred, but this is part of the planning of the work that we're going to do. But the kicker, to me, is, I am ordering the device when I call out the sizes in the room. It's still not ordered when I say, I think it's between a 54 and a 56, Thomas. Not ordered. Not prescribed; nothing's been prescribed.

I've done a bunch of work maybe to get ready for it, but when I say, 56, 12, 32, that is a prescription. I mean, it's like any other

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prescription that I do. I mean, I feel like it's very similar to a lot of things that I do.

Q. Right. Are you familiar with a chart order?

A. Yes.

Q. Once again, in your world, what is a chart order?

A. A chart order is an order on a hospital chart, that I either write in the chart or a registered nurse writes in the chart, that is a prescription to perform a certain activity or administer a certain treatment, medication, et cetera.

Q. And do you issue chart orders?

A. Yes, every day.

Q. Okay. During the course of your treatment of a patient?

A. That's right.

Q. And is the chart order otherwise memorialized in your records?

A. Yes.

Q. All right. Let's go to the surgery and what happens during the course of surgery. When you make a determination that you're going to perform surgery on an individual, do you make a

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MR. CARPENTER: Thank you. And -- just go crazy.

(Petitioner's Exhibit 5, Box, was marked for identification.)

BY MR. CARPENTER:

Q. Dr. McCrosson, I show you what has been marked for identification Petitioner's 5, and ask you if you are familiar with that item.

A. Yes.

Q. Okay. Can you tell us what it is?

A. It's a box that holds one implantable device of a -- part of a knee replacement.

Q. Okay. And on what occasion do you see that -- that item?

A. Every Monday and Tuesday. Except Christmas and holidays.

Q. And what's occurring when you see that item?

A. Yeah. This is -- right after I call out the sizes, the Zimmer rep picks this up off the cart where he has potential likely sizes and pulls off the wrapper which are hermetically sealed, he begins to open it, and then the inside part is finished opening by the nurses and the nurse hands it to the sterile field.

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Q. And you would use that in the treatment of the patient that's in the operating room?

A. That's right. The circulating nurse gives it to the scrub nurse, or tech, that's another hospital staff member that is assisting me in surgery, sterile. That's why they're called scrubbed. And then that nurse sometimes may apply some cement to it or get it ready for me and then hands it to me and I put it in the patient.

So from the time it's out of the box and in the patient is just, you know, less than a minute oftentimes.

Q. I call your attention to the writing on the box. Can you tell us if there's any descriptive information on the box that -- that is related to Plaintiff's 5 and 6?

A. Yes. There's an RX only on the box.

Q. And what does that tell you?

A. It's a prescription only device.

MS. GEER: Did you say Exhibits 5 and 6?

MR. CARPENTER: I did say 5 and 6. 4 and -- yeah, that was 5. This is 5? I'm sorry, Exhibits 3 and --

THE WITNESS: Somehow I knew what you

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were saying.

MR. CARPENTER: Three and 4 come before 5.

BY MR. CARPENTER:

Q. And this is the type of prosthetic device that is used routinely in your practice?

A. Yes.

Q. Okay. Do you know if that device can be sold without a prescription?

MR. MARINELLI: Objection; leading and calling for a legal conclusion.

MR. CARPENTER: Do you know?

THE WITNESS: It sure seems like it cannot be. It says prescription only, so I think it would be illegal if it were sold otherwise.

MR. CARPENTER: Okay. We're going to take a break for about five minutes.

THE VIDEOGRAPHER: Off the record at 4:46.

(A recess transpired.)

THE VIDEOGRAPHER: On the record at 4:55.

BY MR. CARPENTER:

Q. Dr. McCrosson, I just have one -- one additional question.

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A. Okay.

Q. Do you issue an order for a knee and hip device on every occasion when you make that -- when you implant one in a patient?

A. Yes.

MR. MARINELLI: Objection; leading.

THE WITNESS: Yes.

MR. CARPENTER: Thank you. That's all I have.

THE VIDEOGRAPHER: Okay. Anyone else have any questions?

MS. ACQUAVIVA: We have cross-examination.

THE VIDEOGRAPHER: Do you want me to go off?

MS. ACQUAVIVA: You don't have to. I made copies, one of everything, for all of you.

CROSS-EXAMINATION

BY MS. ACQUAVIVA:

Q. Ready? Dr. McCrosson, this might get a little tedious, but bear with me. I'm going to briefly go over some of your testimony. When your patients that you're going to operate on go to the hospital, they're admitted to the hospital?

A. That's right.

Q. So they are patients of the hospital, right?

A. Right.

Q. Okay. And then by the time you get to the operating room -- you have two operating rooms going at once, correct?

A. Right.

Q. By the time you get there, the patient is already under anesthesia?

A. Yes.

Q. And they're ready for you to operate on them?

A. Right.

Q. And you call out to the vendor and the circulating nurse what device you need?

A. That's right.

Q. And then it goes to the circulating nurse who opens it, correct?

A. Correct.

Q. And she hands it to the sterile nurse?

A. Right.

Q. And then the sterile nurse hands it to you?

A. Right.

Q. And it's immediately implanted into the

patient?

A. Right.

Q. Okay. And according to your testimony, when you call out the device that you need, that is what constitutes the prescription?

A. To me, that's the -- without that, there's no prescription. There are other things that may be considered building up to it or part of the prescription, but that is the kicker. That's when I feel that I'm making the prescription.

Q. And you testified that your definition of a prescription is a doctor's order?

A. That's right.

Q. Okay. I'm going to hand you what has been marked for identification as Defendant's Exhibit 1. Could you identify where that document comes from for the record? I highlighted it for you to make it a little easier.

A. I was about to say, New York, Toronto, London, but it's Random House, Webster's College Dictionary.

Q. And can you turn to the second page and identify the definition, what has been highlighted -- just what -- the word that is being defined, not the actual definition?

haven't said that what I'm saying is wrong. You're just saying that a chart order is not a prescription. Yeah, I guess I said a chart order is a prescription, but what I'm getting at is, I'm not saying that what I do in the operating room is a chart order and only a chart order. So I -- we haven't gone through the step where we're saying what I do in the operating room is not a prescription. So that's the part that I would have said no to.

But you are correct, the State of South Carolina says differently than me. They say and that -- and then I bow my knee to that, so I was wrong according to the State of South Carolina when I said a chart order is a prescription.

Q. Okay.

MS. ACQUAVIVA: Can we go off the record for one minute?

THE VIDEOGRAPHER: Off the record at 5:18.

(A recess transpired.)

THE VIDEOGRAPHER: On the record at 5:24.

THE WITNESS: Am I allowed to answer more on the last question?

And I would like you to read what she testified to starting from line 9 on page 14 through line 13, for starters.

A. Question: Okay. Is the requisition sheet the only document that Zimmer receives from the hospital?

Answer: No.

Question: What other documents do they receive.

Answer: We receive a purchase order.

Q. Thank you. And then I'm going to ask you to read starting from line 25 on the bottom of page 14 through line 2 on page 15. And that was 25 on the bottom and 1 and 2 on the next page.

A. Question: And is that the only other document that the hospital passes onto Zimmer.

Answer: Yes.

Q. Okay. Thank you. So according to Zimmer and what you just read, the only two documents they receive from the hospital are a requisition sheet and a purchase order, correct?

A. That's what she receives in her corporate office at Zimmer, but other people on the way are receiving other things.

Q. And you don't think that a prescription

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would have to go to the corporate office to be kept in records if the FDA required that a prescription be -- a prosthetic device be sold by prescription?

A. If they don't have one, then it's not required, but the device is being sold by prescription, as far as we all believe, and until someone interprets the law differently and says that we're violating it, we're going to continue to do this. But it says prescription only, we give them a prescription, no one has told us we're doing wrong. And they don't have a prescription up in -- up there, so I guess no one's saying that they have to have that piece of paper that's fitting the definition that you all would like.

Q. All right. And one last time, what is the prescription that you're giving Zimmer?

A. It's a -- it starts off in the office when we start to authorize the work that Zimmer is going to perform for us. When I start to -- tell Zimmer that this date we're going to do this surgery and that we need to have these implants here, the authorization to work is already beginning.

The wheels are turning, but it is not finalized until I put it in the patient. Even when

A. A written instruction by a physician for the preparation and administration of a medicine.

Q. What is the -- what is the first prescription there? What is the first definition? I'm sorry, we're not looking at the same thing. Mine didn't come out. Is Mosby a separate --

MS. ACQUAVIVA: Yes.

MR. CARPENTER: Oh, that's a separate -- this didn't come through.

MS. GEER: Yeah. That somehow got messed up in copying.

MR. CARPENTER: Yeah. I thought that was the same thing.

BY MR. CARPENTER:

Q. Which exhibit is Mosby?

A. That is 9.

Q. Number 9.

MS. A: That was the last one prior to the last dictionary definition.

BY MR. CARPENTER:

Q. Okay. So Mosby's number 9. Can you look at number 9?

A. Yes.

Q. What is the preferred definition of

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prescription in Mosby?

A. Is it the one that's page 1520 at the top?

Q. That's correct.

A. Prescription, an order for medication, therapy or therapeutic device given by a properly authorized person which ultimately goes to a person properly authorized to dispense or perform the order.

Q. Do you know what I mean when I say the preferred definition?

A. Usually the first one.

Q. Okay. And that, what you just read, is the first one; is that correct?

A. Correct.

Q. Okay. Let's go to the Merriam-Webster Medical Desk Dictionary. Was that number 7?

A. Yes.

Q. Under the definition of prescription, can you give us the second definition under prescription there?

A. Number 2, a prescribed remedy.

Q. Okay. And I'm just going to trouble you with one other. Number 4, the American Heritage College Dictionary?

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A. Okay.

Q. Give me the preferred definition of prescription under this one.

A. One A, the act of establishing official rules, laws, or directions.

Q. Okay. Now, in a -- under a number of different headings Ms. Acquaviva asked you to read the definition that was second or third in terms of preference out of that dictionary; did she not?

A. It may have been.

Q. Yeah. And what you've just read is the preferred definition -- or the three that I've given you here were the first definition in those dictionaries?

A. That's right.

Q. Okay. One more, under The World Book, Number 3. Can you read the preferred definition there?

A. The act of prescribing.

Q. Okay. And the written direction is, in terms of order of preference, what number?

A. Number 3.

Q. So the written direction is the third preferred definition of prescription; is it not?

A. Right. Then -- you know, it says the

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act of prescribing, but you can see the definition of prescribe up above there. And the first one is, to lay down as a rule to be followed, order, direct.

Q. Okay. Let's look again at Defendant's Number 13. And can you describe where this -- this definition comes from? I'm sorry.

A. Which one is 13?

Q. That's the Code of Federal Regulations, Title 21, Food and Drugs.

A. Yeah. 13 -- Exhibit 13 is Code of Federal Regulations, Chapter -- or Title 21, Food and Drugs, Chapter II, Drug Enforcement Administration, Department of Justice, Part 1300, Definitions. And it says, 1300.01, Definitions relating to controlled substances.

Q. Okay. Now, do you know what this provision is describing or regulating?

A. Yes.

Q. What is it?

A. It's regulating class one, two and three drugs, probably. They're talking about the strongest medicines that you can prescribe, that are strictly monitored by the Drug Enforcement Agency, starting with ananabolic steroids, they

CERTIFICATE OF REPORTER

I, Carol Denise Lauder, Registered Professional Reporter and Notary Public for the State of South Carolina at Large, do hereby certify that the foregoing transcript is a true, accurate, and complete record.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof.

Witness my hand, I have hereunto affixed my official seal this 16th day of June, 2013 at Charleston, Charleston County, South Carolina.

Carol Denise Lauder
Registered Professional Reporter, CP
My Commission expires August 2, 2017

Electronically signed by Denise Lauder (301-268-293-2597) b2d71412-c841-4d90-be9e-1ca5a647e7d1

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

CARE ALLIANCE D/B/A ROPER ST. FRANCIS MEDICAL HEALTH CARE, INC., Petitioner, vs. SOUTH CAROLINA DEPARTMENT OF REVENUE, Respondent.	DOCKET NO. 12-ALJ-17-0405-CC

* *

DEPOSITION OF: M. DAUD NAWABI, M.D.

DATE TAKEN: Friday, June 14, 2013

TIME: 10:00 a.m.

PLACE: 125 Doughty Street
Suite 720
Charleston, SC

REPORTED BY: TERI L. SAMPSON, RPR,
Notary Public and Certified
Live Note Reporter

* *

POST OFFICE BOX 21784
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I N D E X

WITNESS: M. DAUD NAWABI, M.D.

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EXHIBITS:

Defendant's Exhibit	Description	Page
1	Highlights of Prescribing Information, Gamunex-C	14
2	21 U.S.C.A. 321 (West)	21

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S T I P U L A T I O N S

It is hereby stipulated and agreed by and between the parties hereto, through their respective counsel, that the reading and signing of the transcript is waived by the Deponent.

Electronically signed by Teri Sampson (401-251-957-7637) 0dc4827a-97c1-4f91-86d7-cc0b2c0b49cc

Where are you currently employed?

A I'm employed with Lowcountry Hematology & Oncology, and that is owned by Roper St. Francis.

Q And what do you do there?

A I'm a hematologist and oncologist.

Q How did you become a hematologist?

A I did a residency -- a residency and a fellowship training in hematology and oncology.

Q Give me your brief educational background.

A I after high school went to college at Washington University in St. Louis and then came here two years later, in 1988, and started medical school at the Medical University of South Carolina, which I finished in 1992.

Q And then was it your first job at this --

A No. And then from there, I started training. I did three years of surgery/urology training and then came back to Charleston, did three years of internal medicine residency. And after I finished that, I did three years of hematology and oncology subspecialty training, finished in 2001.

Q Give us a brief kind of description of what a hematologist does in his day-to-day job.

A A hematologist is a physician who manages blood disorders and cancers -- that would include

various cancer organizations, national cancer organizations.

Q Okay. And in those treatment plans, is the prescription of medicines included?

A Yes.

Q And what type of medicines do you typically prescribe your patients with cancer?

A We usually use chemotherapy and the supportive medications for chemotherapies.

Q Okay. And when you are -- is your office within Roper's buildings, or is this an off-site outpatient facility?

A These are off-site outpatient facilities.

Q Okay. And it's owned wholly entirely by Roper St. Francis?

A The practices are owned.

Q Okay.

A The properties are leased.

Q Okay. What type of medical supplies do you keep on site at your doctor's office?

A We keep chemotherapeutics, we keep the support drugs necessary, we keep pumps, I.V. bags, whatever is necessary to administer chemotherapy that we administer in the office. We keep, you know, other equipment, gloves, tongue depressors, gauze, the usual

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stuff.

Q Back up for a minute. You said chemotherapeutics, and what was the second one?

A The support drugs.

Q And what would that those entail?

A The support drugs would be things like fluids to hydrate a patient, normal saline, they would include some steroids, they would include medicines to control nausea and vomiting. They might include medicines to help sedate a patient.

Q Are most of those considered controlled substances?

A No. Most of those are not controlled substances.

Q Could I buy them at a drugstore without a prescription?

A No.

Q Okay. So they are controlled to some level?

A Well, yes, but controlled substances generally refer to narcotics.

Q Narcotics, okay. But these are drugs that a layperson couldn't just purchase on the street?

A That's correct.

Q Okay. Only doctors can buy these items, correct?

Q Do you keep some form of immunoglobulins in your office?

A Not regularly.

Q Okay. Has your attorney told you that globulins of that nature are pretty much the lion's share of the blood derivatives at issue in this case?

A Yes.

Q Are you familiar with those types of drugs?

A Yes.

Q Can you testify adequately to those drugs today?

A I believe so.

Q Okay, good. Going back briefly to the other prescription drugs that you keep in inventory, when your office makes purchases to stock those inventories, say they're on sale and you want to buy a big bulk of them like you said earlier, what type of information do you provide, does your office provide to the vendor?

A I think that in order to establish a relationship with a vendor, we've already provided them with our license numbers, our credit, our address and the normal stuff necessary in order to purchase those drugs.

Q So is it all online? Is it just a computer system that you log on and buy what you need, or is

it --

A I believe so.

Q Okay.

A Yeah. I don't think that there's -- you can call them, but I believe that it can be ordered, I think you can also set up your storage device to automatically order. There are some things that we -- you know, that keeps an inventory and when we -- when the machine knows that we've used a certain amount, it automatically places an order for certain things.

Q So you don't even have to be involved in the process at that point, it just comes in the mail?

A We set where the -- we set what our stock should be and we can change that.

Q Okay. But when you're stocking inventory drugs that you need for any given patient, you don't provide any sort of patient-specific data to the vendor, do you?

A No.

Q Okay. Let talk about Gamunex or globulins in general, really. As you understand it, what are those drugs made of, what are they?

A So immunoglobulins are pooled immunoglobulins. Immunoglobulins are proteins that are found in the blood that are created by plasma cells.

C E R T I F I C A T E

STATE OF SOUTH CAROLINA:

COUNTY OF BERKELEY:

I, TERI L. SAMPSON, Registered Professional Reporter, Notary Public and Certified Live Note Reporter, State of South Carolina at Large, certify that I was authorized to and did stenographically report the foregoing deposition; and that the transcript is a true record of the testimony given by the witness.

I further certify that I am not a relative, employee, attorney or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

WITNESS MY HAND AND OFFICIAL SEAL this 16th day of June, 2013, in the Town of Goose Creek, County of Berkeley, State of South Carolina.

Teri L. Sampson, RPR,
Notary Public and Certified
Live Note Reporter
My commission expires:

Electronically signed by Teri Sampson (401-251-957-7637)
0dc4827a-97c1-4f91-86d7-cc0b2c0b49cc

STATE OF SOUTH CAROLINA

ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a Roper St. Francis Healthcare, Petitioner, vs. South Carolina Department of Revenue, Respondent.	Civil Action No. 12-ALJ-17-0405-CC

Washington, D.C.

Wednesday, May 1, 2013

Deposition of:

MARY KATHERINE PENDERGAST

called for oral examination by counsel for Respondent, pursuant to notice, at the office of Nelson Mullins Riley & Scarborough, 101 Constitution Avenue, Northwest, Washington, D.C., before Blaire G. Benefield, FPR, of Capital Reporting Company, a Notary Public in and for the District of Columbia, beginning at 1:03 p.m., when were present on behalf of the respective parties:

A P P E A R A N C E S

On behalf of Petitioner (telephonically):

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A P P E A R A N C E S (cont'd.)

On behalf of Respondent (telephonically):

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C O N T E N T S

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1	South Carolina Pharmacy Practice Act	5
2	Document ROPER_00029	5
3	Purchase Order, ROPER_00034	5
4	Internet printout, Frequently Asked Questions about Home Use Devices	5
5	Internet printout, FDA's Role in Regulating Medical Devices	5
6	Letter dated 02/27/06 from the Food and Drug Administration to Zimmer Trabecular Metal Technology Incorporated	5
7	21 C.F.R. 801.109, Prescription Devices	5
8	Excerpt from Deposition of Scott Ferguson	5
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(* Exhibits retained by Counsel for Petitioner.)

Q Now, the item at issue in that letter seems to be classified as regulatory class II?

A Yes.

Q Can you tell me what that means?

A All right. When Congress passed the Medical Device Amendments in the 1970s -- in '76, there were already on the market thousands of medical devices, so it instructed the FDA to, quote/unquote, classify all of the devices that were then on the market into one of three classes: Class I, which means that only general controls are necessary for the sale of the product; class II, which requires more standards and information before it can be sold; and then class III, which generally requires a PMA.

So most of the things that you think about when you go to the drugstore and you're looking at medical devices, many of them are in class I, such as Band-Aids where the main thing is they have to be clean and sterile. Some are class II. But you can't buy something over-the-counter if it's class III.

So this is a class II medical device, and it's being permitted onto the market through a 510(k)

signed by the practitioner," and it goes on to explain "for a legitimate medical purpose."

So this is -- this is similar to federal law, although federal law doesn't require a signature. You know, it could be purely electronic or purely oral or written.

Q So in your mind as a federal regulator, any kind of correspondence from a doctor, whether it be out of his mouth or in writing, in any format whatsoever, that's what you consider a prescription?

A Yes. It has to be memorialized somehow. And a hospital has to keep a record of it -- of the medical devices used in the hospital by prescription, but it can be oral, written, or electronic.

Q Would you look at Exhibit 2 for me?

A Okay.

Q And Exhibits 3 and 9 and 10?

A Okay. Just let me line these up here, please.

Q Sure.

A Okay. I have them all lined up.

Q Okay. Before we get to these individual

A Yes. Using the industry standards, it's got a physician's name on it, and a hospital.

Q So in your mind, selling it to a doctor is the same thing as a sale by prescription?

A Well, a doctor -- well, I mean, yes, if you think it about, because it's the doctor who is making the decision. A prescription is a memorialization of a decision made by a doctor.

Q Okay. Go back to Exhibit 7 for me, please.

A Okay. Just a second. Okay.

Q If selling it to a physician is the same thing as a sale by prescription, why would there be the distinction then in subsection (a)(2) for it to be sold only to or on the order of?

A Well, I mean, it's very practical. If you're a -- if you are handing a device to a doctor because the doctor has asked you to sell the doctor the device, that is an implicit -- the sale is an implicit order saying, give me this. And so you only need a prescription or other order if it isn't being sold directly to the doctor because then you have to memorialize that that's what the doctor is asking for,

is prescribing, is wanting.

Q Do prescriptions require patient data?

A Do they require patient data? Only --

Q Let's take the heart valve, for example. In your mind, if they order hundreds of heart valves to keep in inventory, do you still consider that a prescription even though they are not meant for any particular patient yet?

A Yes, because at the end of the day there's got to be a prescription and it's got to be kept in a little box or file at the hospital.

Q And so if South Carolina law dictates that a prescription have very specific patient information, would that change your mind?

A Well, it's hard to describe. I mean, from a federal perspective, it doesn't quite matter what South Carolina says about a prescription.

Q Well, I think a South Carolina judge would not like to hear that.

A Well, I know, but -- I'm sorry, but like the FDA, you've got regulations about what pharmacies can compound and you've probably been reading all of this

CERTIFICATE OF NOTARY PUBLIC

I, BLAIRE G. BENEFIELD, FPR, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was taken by me in stenotypy and thereafter reduced to typewriting under my direction; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.



Blaire Benefield

BLAIRE G. BENEFIELD
Notary Public in and for the
Commonwealth of Virginia

My commission expires:
January 31, 2016
Notary Registration No.: 7530333

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a Roper/St. Francis Medical Healthcare, Inc., Petitioner, vs. South Carolina Department of Revenue, Respondent.	Docket No. 12-ALJ-17-0405-CC **RESPONDENT'S FIRST MOTION FOR A CONTINUANCE**

COMES NOW the South Carolina Department of Revenue (Department), by and through the undersigned counsel, and respectfully requests this Court for a continuance in the above-referenced case, which is scheduled for trial beginning on July 8, 2013. This Motion is a first request for Continuance, is made pursuant to ALC Rule 19(B), and is made upon the basis that the parties have not yet completed discovery in this case.

The present matter involves sales and use tax on various medical items purchased by the Petitioner and requires testimony from various medical professionals. The Petitioner has named three medical doctors as witnesses thus far, all of whom have extremely busy schedules and were difficult to line up for depositions. Because the witnesses are unavailable for trial, the Department also consented to the use of video depositions at trial, requiring two sessions for each witness. Currently, only two of those witnesses have been deposed and videotaped for testimony. The Department still has to depose the third witness, both for discovery purposes and for use at trial. Additionally, all three of the video depositions have to be reviewed and edited for trial.

Furthermore, the Department has sought testimony from the U.S. Food and Drug Administration which has taken longer to procure than anticipated. The Federal regulations concerning subpoenas dictate a certain bureaucratic process, and the delay has been unavoidable. As trial is set to begin in less than three weeks, the Department does not anticipate that discovery can be completed in time for adequate preparation without undue prejudice. The Petitioner has been consulted concerning this motion, but has neither consented nor objected to date.

WHEREFORE, the matter at bar before this Court represents a tax controversy of serious implications of both State policy and monetary resources, and the discovery stage has not yet been completed, Department moves for a first continuance of this matter, of both the deadline for dispositive motions and trial of at least ninety (90) days from the original hearing date of July 8, 2013.

Respectfully submitted,

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Columbia, South Carolina
June 20, 2013

STATE OF SOUTH CAROLINA

ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a Roper St. Francis Healthcare, Petitioner, vs. South Carolina Department of Revenue, Respondent.	)	Civil Action No. 12-ALJ-17-0405-CC **MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT OF SAME**

COMES NOW, PETITIONER, AND MOVES THIS HONORABLE COURT FOR SUMMARY JUDGMENT AND SHOWS THE FOLLOWING:

1. There is no material issue of fact in this matter;

2. Petitioner is entitled to judgment as a matter of law on all matters at issue; and

3. Petitioner is entitled to a full refund of all sales and use tax paid on items at issue in this case.

MATTERS AT ISSUE

I. Whether the sale of the orthopedic and cardiac prosthetic devices at issue to hospitals upon the order of a physician is a "sale by prescription" as that term is used in the sales tax exemption statute at S.C. Code §12-36-2120 (28) and whether the devices replace a missing part of the body as required by S.C. Code Reg. § 117-332 such that these devices are exempted from sales and use tax.

II. Whether the sale of blood derivatives is a sale of medical services as that term is used in the Revised Anatomical Gift Act as adopted in South Carolina and therefore excluded from the imposition of sales and use tax.

STATEMENT OF THE UNDISPUTED FACTS

I. Facts Related to the Prosthetic Devices at Issue

A. Purchasing Practices regarding all Prosthetic Devices at Issue

The prosthetic devices at issue in this case include (1) orthopedic devices such as artificial hips, knees and shoulders (the "Orthopedic Devices")[1]; (2) orthopedic trauma devices such as plates, pins, nails and screws (the "Trauma Devices"); (3) cardiac devices such as implantable cardioverter defibrillators ("ICDs") and pace makers (the "Cardiac Devices") (collectively the "Prescription Prosthetic Devices"). The Prescription Prosthetic Devices are referred to as "prescription only" devices because they require a prescription for their sale and purchase. See Ex. A, Affidavit of Mary K. Pendergast ("Pendergast Aff.") at ¶6(e) and (f); Ex. B, Affidavit of Charles Trescott Ferguson ("Ferguson Aff.") at ¶2.

As set forth in the affidavit of Mr. Ferguson, Petitioner's materials handling manager, Petitioner purchases all of these devices only upon the prescription or order of physicians who are authorized to use such devices in their practices. Ex. B, Ferguson Aff. at ¶3(b). The hospital does not own any inventory of Orthopedic or Cardiac Devices; however, it does purchase and maintain an inventory of Trauma Devices for use on patients treated in the hospital as these items are needed on an emergency basis. Id. at ¶3(c). Even these Trauma

[1] This claim also involves some mastectomy reconstruction implants and other tissue and muscle implants. Although formal stipulations have not yet been entered by the parties, it is Petitioner's understanding that the evidence regarding the Orthopedic Devices will apply to these other devices as well as they are ordered and used in the same manner and also replace missing body parts and that if Petitioner obtains a favorable ruling on the Orthopedic Devices, that ruling will apply to these items as well.

Devices kept in inventory, however, are ordered only upon the order or prescription of a physician. Id. The hospital is required to maintain and/or provide sufficient documentation to the hospital accrediting agency and to the FDA to document the proper purchase practices for prescription only devices. Id. at ¶3(a) and (d).

Petitioner is, and was during the time periods at issue, in full compliance with the FDA mandates that (a) all sales be made by or on the order of a physician, and (b) all physicians' orders be properly memorialized. Id. at ¶3(e). The hospital has not been held in violation of laws or regulations of the state, federal government or the hospital accrediting agency with regard to the purchase or documentation of prescription prosthetic devices during the past ten years, if not longer. Id. at 3(f).

B. Ordering Practices regarding Orthopedic Devices

Dr. John McCrosson is a board certified orthopedic surgeon who is authorized to implant orthopedic hips and knees into his patients who require hip and knee joint replacements. Deposition of John McCrosson, M.D. ("McCrosson Dep.") at 7:19- 8:6 and 12:12-15.[2] He testified that these devices are prescription devices and can only be sold by prescription. Id. at 34:5-9 and 40:6-42:15. He stated that he issues an oral order for the orthopedic prosthetic devices he implants during surgery, which is when he finally determines exactly what size and type of device the patient needs. Id. at 25:7-24. He testified that his order for the orthopedic device is a prescription as required by law. Id. at 28:22- 29:11. This prescription is then memorialized in writing in a number of ways, including, in the hospital's computer system, on stickers on the boxes of the implants used, in the patient's chart, in a hospital log and in the operative report. Id. at 25:25- 26:20.

[2] The relevant portions of Dr. McCrosson's deposition are attached hereto as Ex. C.

C. Ordering Practices regarding Cardiac Devices

Dr. Brett Baker is a board certified cardiologist who specializes in the field of cardiac electrophysiology, and he is authorized to implant ICDs and pace makers into his patients who require them. Deposition of Brett M. Baker, M.D. ("Baker Dep.") at 7:10-8:12.[3] He testified that the Cardiac Devices are prescription devices and may only be sold by prescription. Id. at 12:10-15. He stated that he issues an oral order for the Cardiac Devices he implants during surgery, which is when he finally determines exactly what device, including the components and leads, the patient needs. Id. at 16:5- 17:12. He considers this oral order to be a prescription. Id. at 44:2-8. This prescription is then memorialized in writing at the conclusion of the surgery via a detailed report that is kept in Dr. Baker's office as well as placed in the patient's medical records and sent to other physicians who are involved in the patient's care. Id. at 17:13- 18:7.

D. Replacement of a Missing Part of the Body by the Prescription Prosthetic Devices

Both the Orthopedic and Cardiac Devices replace a missing part of the body of the patient into whom these devices are implanted. More specifically, for example, Dr. McCrosson testified that a patient receiving a knee replacement will always be missing cartilage. McCrosson Dep. at 36:4-13. Additionally, he testified that during surgery, he would remove more of that patient's joint to accommodate the prosthetic knee replacement. Id. at 36:10-18. The Orthopedic Devices replace the missing cartilage and joint. Id. at 36:4-18.

[3] The relevant portions of Dr. Baker's deposition are attached hereto as Ex. D.

Similarly, Dr. Baker testified that the Cardiac Devices replace a missing part of the body of the patient into whom these devices are implanted. He explained that in patients who are experiencing some type of heart irregularity, the cause is most commonly that some portion of the heart's electrical system has degenerated over time and that portions of the heart tissue responsible for conduction of electrical signals to the heart have "died off." Baker Dep. at 9:17- 10:21 and 11:4-14. The Cardiac Device replaces this missing cardiac tissue and restores the normal heart rhythm. Id.[4]

II. Facts Related to the Blood Derivatives at Issue

Whole blood is composed of four components: red blood cells, white blood cells, platelets and plasma. Deposition of M. Daud Nawabi, M.D. ("Nawabi Dep.") at 7:23- 8:5.[5] Whole blood is not commonly administered to patients; rather, it is typically separated into its component parts such that only the component needed by a patient can be used. See id. at 9:16-23. After the four component parts are separated, the platelets and red blood cells are then processed (which can include being screened for infectious diseases, typing, re-suspending in a buffer solution, and adding a preservative to maintain the stability of the product) and stored. Id. at 10:19- 11:7 and 25:23- 26:16. The plasma, which is a liquid comprised of proteins, water, salts and buffers) is then further separated, which primarily involves separating or precipitating out the blood proteins. Id. at 8:6-12; 10:13-18; 11:8-11. The blood proteins, which include, *inter alia,* immunoglobulins and albumin (see id. at 10:13-18), are then processed in a similar way to the red blood cells and platelets (i.e. which can include

[4] Dr. Baker testified that there are situations where a patient is born with a genetic defect of the heart cells (and thus the cells are defective versus missing), but this represents less than 1% of his patients. Baker Dep. at 11:15- 12:1.

[5] The relevant portions of Dr. Nawabi's deposition are attached hereto as Ex. E.

screening for infectious diseases, re-suspending in a buffer and adding a preservative). Id. at 11:8-12:4 and 18:20-25. A buffer is simply a liquid replacement for the liquid portion of plasma and is typically a solution made of water and salts. Id. at 21:16- 22:5. Nothing in the processing of the red blood cells, the platelets or the blood proteins extracted from the plasma in any way alters, modifies or changes their nature in any way. Id. at 12:7-22. The blood proteins are not synthetic, artificial or pharmaceutical. Id. at 12:23- 13:3. They are not manufactured but rather are created by the human body. Id. at 17:17-24.

Petitioner purchases certain products derived from whole blood for use in its patients. The blood products at issue include the following: Gamunex, Octagam, Plasbumin, Albutein, Buminate, Flexbumin, Alburx and Albuminar. Gamunex (which comprises the bulk of the purchases at issue in this case) and Octagam are both human immunoglobulin proteins, while the remaining products are albumin proteins, both of which, as previously discussed, are extracted from the plasma in whole blood. Ex. E, Nawabi Dep. at 8:13- 9:12 and 10:13-18.

Whether whole blood and products derived from whole blood are subject to sales and use tax in South Carolina has been a subject of discussion within the South Carolina Department of Revenue (the "Department") for a period in excess of twenty years. To date, no definitive revenue regulation or policy statement has been issued by the Department to inform the public or even the Department's own employees of the Department's policy regarding these items. Ex. F, Deposition of John P. McCormack ("McCormack Dep.") at 47:1- 59:18. As a result, Department employees continue to express confusion as to whether any or all blood or blood products or their derivatives are subject to tax. Ex. G, Deposition of Christine Buddin ("Buddin Dep.") at 28:1- 25 and 32:10- 34:25 and 37:19 –40:5. This may have resulted in some hospitals paying the tax on purchases of whole blood and its derivatives

while others have not. The Department concedes that it does not currently tax whole blood, red blood cells, platelets or plasma (see e.g. Ex. G, Buddin Dep. at 34:12-25), but there appears to be no basis for it to distinguish blood proteins derived from plasma from the aforementioned blood products.

SUMMARY JUDGMENT STANDARD

Pursuant to Rule 56 of the South Carolina Rules of Civil Procedure, summary judgment is appropriate where there is "no genuine issue as to any material fact," and the moving party shows that it is entitled to judgment as a matter of law. The moving party has the burden to establish that, based on the pleadings, affidavits and discovery on file, it is entitled to judgment as a matter of law. Bovain v. Canal Ins., 383 S.C. 100, 678 S.E.2d 422, 424 (2009); Bravis v. Dunbar, 316 S.C. 263, 449 S.E.2d 495, 496 (Ct. App. 1994). Petitioner will show that there is no genuine issue as to any material fact in this case and that it is entitled to judgment as a matter of law.

DISCUSSION OF APPLICABLE LAW

I. Petitioner Purchased the Subject Prosthetic Devices, which Replace Missing Parts of the Body, Upon the Orders of Physicians, and, therefore, these Purchases are Exempt from Sales and Use Tax.

South Carolina sales and use tax law defines the sale of prescription prosthetic devices to hospitals as taxable retail sales. See S.C. Code Ann. § 12-36-110 (stating that the hospital is deemed to be the consumer or user of the devices). However, the law also provides an exemption for sales of prescription medicines and prosthetic devices when the sale is made "by prescription." S.C. Code Ann. § 12-36-2120 (28). The South Carolina tax code does not define the term "prescription," but a tax code regulation does define the term "prosthetic device" to include "an artificial device used to replace a missing part of the body. . . ." S.C.

Code Reg. § 117-332. In addition, Revenue Ruling #11-3 provides that in order to qualify as a "sale by prescription," (a) the device must be of a type that requires a prescription; (b) the sale must require a prescription; and (c) the device must actually be sold by prescription. S.C. Rev. Ruling #11-3 at p. 8. The sales tax exemption statute does not elaborate further on the term "sold by prescription" and beyond the four requirements above, no case law, statute or regulation controls the exact facts of the issues in this case. Therefore, this is a case of first impression for the courts of South Carolina on this issue.[6] As will be discussed below, Petitioner meets all four requirements set forth above and qualifies for the sales tax exemption for the purchase of prescription prosthetic devices sold by prescription.

A. Rules of Statutory Construction

When interpreting a statute, the sole function of the Court is to determine and give effect to the intent of the legislature. Hodges v. Rainey, 341 S.C 79, 85, 533 S.E.2d 578, 581 (2000). The starting point in doing so should always be the text of the statute itself. Id. (holding that "[w]hat a legislature says in the text of a statute is considered the best evidence of the legislative intent or will"); Wigfall v. Tideland Utilities, Inc., 354 S.C. 100, 580 S.E.2d 100 (2003). In interpreting the text, the plain meaning rule requires that "words must be given their

[6] Upon information and belief, SCDOR may argue that Home Medical Systems, Inc, v. South Carolina Department of Revenue, 382 S. C. 556, 677 S. E. 2d 582 (2009) is controlling and applicable to this matter, but Petitioner asserts that it is neither controlling nor applicable. The Home Medical case involved sales of continuous positive airway pressure and bi-level positive airway pressure devices, ventilator devices, nasal intermittent positive pressure ventilation devices, nebulizer devices, and enteral nutritional formulas. It also involved a Certificate of Medical Necessity ("CMN"), a standard form used by Medicare and Medicaid. None of the devices in Home Medical were surgically implanted into the body of the patient nor did the devices replace a missing part of the body as the testimony in this case establishes. Neither these devices nor the CMN form are at issue in the instant case and, therefore, the factual and legal conclusions drawn from the issues in Home Medical are not applicable to the facts in this case.

plain and ordinary meaning without resort to subtle or forced construction to limit or expand that statute's operation." State v. Leopard, 349 S.C. 467, 471, 563 S.E.2d 342, 344 (Ct. App. 2002). As discussed more fully below, Petitioner submits that the sales tax exemption statute at issue is not ambiguous and that the Court should simply interpret it in accordance with the clear and plain meaning of the language and statutorily defined terms therein.

B. The Sales Transactions at Issue Meet the Four Requirements to Be Exempt from Sales and Use Tax.

1. The Devices at Issue Are of a Type that Require a Prescription.

Although the parties have not entered into formal stipulations, it is Petitioner's understanding that the Department does not contest that the prosthetic devices at issue are prescription devices. The relevant FDA regulations provide as such, and the physician witnesses in this case have testified that the prosthetic devices at issue are prescription devices. See e.g. Ex. C, McCrosson Dep. at 40:6-42:15; Ex. D Baker Dep. at 12:10-15.

2. The Sales Transactions at Issue Require a Prescription.

The Food, Drug and Cosmetics Act of 1976, under the authority of the Commerce Clause, empowers the Secretary of the Federal Department of Health and Human Development to require by regulation that a device be restricted to sale, distribution or use:

(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or,

(B) upon such other conditions as the Secretary may prescribe in such regulation.

21 U.S.C. § 360j (e)(1).[7]

[7] Under S.C. Code Ann. 19-3-150, this Court may take judicial notice of foreign law, which could be

The Secretary has exercised the authority above in 21 CFR § 801.109, which provides, *inter alia*, that:

> A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act, if all of the following conditions are met:
>
> (a) The device is:
> (1) (ii) In the possession of a practitioner, such as a physician, . . .licensed by law to use or order the use of such device; and
> (2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

21 CFR § 801.109; see also Ex. A, Pendergast Aff. at ¶ 6(e). A sale to a hospital, like the sale to any other consumer, "requires" the order of a physician to avoid harm to the public, which is not allowed to purchase or possess these types of devices. 21 CFR § 801.109; Ex. A, Pendergast Aff. at ¶ 6(f). Hospitals that purchase such devices without the lawful prescription or order of a physician are subject to prosecution under federal law for "misbranding" of prescription devices. 21 U.S.C. §352; Ex. A, Pendergast Aff. at ¶ 6(g).

The FDA is the only agency of government, federal or state, with legal authority to regulate the labeling, distribution, and restrictions regarding the use of prosthetic devices implanted in human beings. 21 U.S.C. §360j(e)(1); see also Ex. A, Pendergast Aff. at ¶ 6(a). The State of South Carolina has no authority to modify, limit or expand restrictions placed on prosthetic devices implanted into human beings without specific authority from the FDA. See

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interpreted to include federal statutes and regulations being applied to a case pending in state court.

21 C.F.R. §808; see also Ex. A, Pendergast Aff. at ¶ 6(b). FDA regulations provide an appeal process for states to request exemptions from such restrictions. 21 CFR §808; Ex. A, Pendergast Aff. at ¶ 6(c). Twenty-two states and the District of Columbia have requested and received such exemptions. 21 CFR §808 and 21 C.F.R. §801.109; Ex. A, Pendergast Aff. at ¶ 6(d). South Carolina is not one of these entities. 21 C.F.R. §801.109; Ex. A, Pendergast Aff. at ¶ 6(d).

In this case, the Prescription Prosthetic Devices are all devices regulated by the FDA because they present a "potentiality for harmful effect in their use that justifies their limitation to sale only to those with special training or experience in their use. See 21 CFR § 801.109. FDA regulations require that they be purchased only upon the order or prescription of a physician who is licensed to use the particular device. Id.; Ex. A, Pendergast Aff. at ¶ 6(f). If Petitioner purchased, or the relevant manufacturers sold, the Prescription Prosthetic Devices without an order or prescription, such transactions would violate the law. 21 U.S.C. §352; Ex. A, Pendergast Aff. at ¶ 6(g). Thus, the sales transactions at issue all require a prescription.

3. The Devices at Issue Were, In Fact, Sold by Prescription.

The physicians in this case have testified that they issue an oral order to the manufacturer's representative for the Cardiac and Orthopedic Devices in the operating room at the time of the procedure when the specific type of device needed by their patients becomes known to them. See Ex. C, McCrosson Dep. at 25:7-24; Ex. D, Baker Dep. at 16:5- 17:12. The physicians have further testified that these oral orders constitute their prescriptions. Ex. C, McCrosson Dep. at 28:22- 29:11; Ex. D, Baker Dep. at 44:2-8. The physicians then

memorialize the orders in writing. Ex. C, McCrosson Dep. at 25:25- 26:20; Ex. D, Baker Dep. at 17:13- 18:7. In addition, Petitioner also purchases the Trauma Devices upon the orders of physicians. Ex. B, Ferguson Aff. at ¶3(c).

As previously stated, federal law requires that these prescription prosthetic devices be sold on the order or prescription of a physician. 21 CFR § 801.109; see also Ex. A, Pendergast Aff. at ¶ 6(e). The order of a physician, a term used in federal and state law interchangeably with the term "prescription", fulfills the requirement under the sales tax exemption statute that the devices actually be sold by prescription. See S.C. Code Ann. §40-43-30 (defining a "medical order" as "a lawful order of a practitioner which may or may not include a prescription drug order" and defining "prescription drug order" as "a lawful order from a practitioner for a drug or device").

4. The Prosthetic Devices at Issue Replace a "Missing Part of the Body."

Dr. McCrosson testified that the Orthopedic Devices are artificial devices that "replace a missing part of the body," and Dr. Baker provided similar testimony as to the Cardiac Devices. More specifically, Dr. McCrosson testified that an artificial knee, shoulder, or hip replaces missing cartilage in the joint(s) of the patient and any portion of the joint removed during surgery. Ex. C, McCrosson Dep. at 36:4-18. Similarly, Dr. Baker testified that the ICDs and pace makers that he implants into the body of his patients replace missing cardiac tissue, which conducts electrical signals to the heart, that has died off over the life of the patient, and the devices replace the tissue and restore the normal heart rhythm. Ex. D, Baker Dep. at 9:17- 10:21 and 11:4-14. The testimony of these witnesses is uncontested.

II. The Sale of Blood and Products Derived from Blood is a Sale of a Service Excluded from the Sales and Use Tax Statute.

A. South Carolina Law is Clear that Blood is a Sale of a Service that is Excluded from the Sales and Use Tax.

The sales and use tax statute imposes tax on a variety of transactions in South Carolina. See S.C. Code §12-36-910. These transactions are comprised of sales of tangible personal property and certain specifically enumerated services, which are collectively defined as sales of "tangible personal property." Id. Blood and products derived from blood are not specifically listed as taxable in the portion of the sales tax statute that defines a retail sale and imposes sales tax. S.C. Code Ann. §12-36-60 defines tangible personal property and is a catch-all provision designed to impose a tax on a large volume of transactions that are not otherwise exempted from the statute. Sales of services, on the other hand, are generally not taxed. See S.C. Code Reg. 117-308. See also S.C. Rev. Ruling 93-4 (addressing treatment of professional, personal and other services and discussing use of the "true object test" to determine if a sale is a sale of tangible personal property or a service); S.C. Code Ann. §12-36-60 (providing that some services are specifically subjected to tax as sales of tangible personal property, such as communications services, even though no tangible personal property changes hands).

The Revised Uniform Anatomical Gift Act ("RUAGA"), S.C. Code Ann. § 44-43-10, defines the sale of blood and its products or derivatives as the sale of a "medical service" and excludes these transactions from consideration as sales of a "commodity" for commercial purposes:

> The implied warranties of merchantability and fitness shall not be applicable to a contract for the sale, procurement, processing, distribution or use of human tissue such as corneas, bones, organs whole blood plasma, blood products or blood derivatives. Such human tissues, whole blood, plasma, blood products or blood

> derivatives shall not be considered commodities subject to sale or barter and the transplanting, injection, transfusion or other transfer of such substances into the human body shall be considered a medical service.

S.C. Code Ann. § 44-43-10. Based upon the language in this statute, the South Carolina Supreme Court has held that ". . .the legislature did not intend for blood [and other human products] to be classified as a product. Furthermore, this construction is consistent with the underlying purpose of the blood shield statute . . . to facilitate a readily available supply of blood by limiting liability to defects resulting from negligence." Samson v. Greenville Hospital System, 297 S.C. 409, 377 S. E. 2d 311 (1989). The Court's ruling in this case was necessary because strict liability in tort applies only to sales of products (i.e. tangible personal property) and not to services. By finding that the Legislature intended that the sale of blood was and should be treated as a sale of a service and not subjected to strict liability in tort, the Court affirmed the public policy of the Legislature to characterize this transaction as the sale of a service for commercial purposes. See also Deloach v. Whitney, 275 S. C. 543, 273 S. E. 2d 768 (1981).

Sales of blood and products derived from blood, and other human harvested products are clearly sales of medical services. The "true object" of the purchaser is to obtain the treatment of a licensed physician and not the tangible blood, blood product or blood derivative. As a result, under a sales and use tax analysis, the sale of a medical service not otherwise identified as taxable as a sale at retail or as an exception to the general rule that services are not taxable, would be excluded from the sales and use tax as such a sale does not constitute a retail transaction as defined in the sales tax statute. The sales tax statutes impose a tax on the sale of tangible personal property, which do not include sales of services unless specifically enumerated. Sales of blood products or derivatives are not specifically enumerated.

Accordingly, whole blood and products derived from blood are sales of medical services that are not specifically included among taxable transactions in the sales and use tax statute and, thus, such sales are not subject to tax in South Carolina.

B. Whether Sales of Blood and Products Derived from Blood are Subject to Sales and Use Tax is Not a Settled Issue within the South Carolina Department of Revenue.

Internal communication within the South Carolina Department of Revenue indicates that there has been considerable discussion among members of the Department concerning whether sales of products derived from blood are subject to tax. There is some indication that at various times, hospitals in some areas of the state were paying the tax while others were not. See Ex. H, Email Correspondence, Bates-stamped 000048-000068.

Disturbingly these documents do not indicate that the leadership of the Department has responded to the questions raised by auditors and field supervisors and the public itself. There is no objective indication that the Department has informed the taxpaying public, its auditors, supervisors, revenue agents or the Legislature of its policy in regard to the taxation of these products. Moreover, the Department does not currently tax whole blood, red blood cells, platelets or plasma. See Ex. G, Buddin Dep. at 34:12-25. As Dr. Nawabi made clear in his testimony, there is no medical basis on which to distinguish some items derived from blood as less "human" than others. Nothing in the processing of the red blood cells, the platelets or the blood proteins extracted from the plasma in any way alters, modifies or changes their nature in any way. Ex. E, Nawabi Dep. at 12:7-22. The blood proteins are not synthetic, artificial or pharmaceutical. Id. at 12:23- 13:3. They are not manufactured but rather are created by the human body. Id. at 17:17-24. Finally, if the Department is unsure of whether these transactions are subject to tax, it should resolve such uncertainties in the taxpayer's favor.

C. Unreported Opinions of the Former South Carolina Tax Commission that have not been Formally Adopted by the Department of Revenue, nor Memorialized in a Revenue Ruling or Regulation, are Due No Deference by this Court.

Upon information and belief, the Department of Revenue may seek to rely upon an unreported, unadopted, and otherwise unacknowledged opinion from 1992 wherein the former Tax Commission found that sales of blood products were not subject to sales tax, but in unrelated dicta, opined that sales of blood were sales of tangible personal property. See Commission Decision 92-26.

In this decision, the former Tax Commission rejected the position of its own legal staff and determined that sales of blood were sales of tangible personal property. The Commission then determined that the sales were also sales of medicine. However, it finally determined that because blood could be purchased without a physician's prescription and stored, the purchases of blood were subject to the sales and use tax. This decision is not mentioned in any publication of the South Carolina Department of Revenue available to the public or to its employees. See Ex. G, Buddin Dep. and 48:9- 49:8. The decision is contradictory on its face because the taxpayer who was held to be subject to the tax received a tax refund in the final paragraph of the decision. Moreover, the decision is factually incorrect, as Dr. Nawabi pointed out when he testified that sales of blood "require" the order of a physician. See Ex. E, Nawabi Dep. at 13:4-20. Because this decision is unreported, has not been formally adopted by the Department of Revenue, nor memorialized in a revenue ruling or regulation, is contradictory and cased on inaccurate facts, this decision is due no deference by this Court.

CONCLUSION

The Petitioner has demonstrated:

A. That the State of South Carolina has established, by statute and regulation, four requisites to qualify for the prosthetic devices sold by prescription exemption from sales and use tax in S.C. Code Ann. §12-36-2120 (28), and Petitioner meets all four requirements as follows.

1. The sale of prosthetic devices at issue in this case is regulated by the FDA, which has designated all devices at issue in this case as devices that require a prescription to be sold to avoid harm to the inexperience and untrained public.

2. The sale to a hospital, like the sale to any other consumer, "requires" a prescription or order of a physician to avoid harm to the public, which is not allowed to purchase or possess these types of devices.

3. A prescription or order of a licensed physician qualified to use the devices in his practice was actually used in the sales transactions at issue according to the testimony of the physician witnesses in this case.

4. The uncontested factual testimony of the physician witnesses describes the cardiac tissue and cartilage that is missing, which was the basis for the determination by the physician that the device was required to replace the missing tissue or cartilege.

B. The Sale of Blood and Products Derived from Blood is a Sale of a Service Excluded from the Sales and Use Tax Statute because:

1. The South Carolina Legislature has evidenced an intent that sales of blood, products derived from blood and human products be characterized as sales of a *service* and not sales of a *product* for commercial purposes. As such, sales of the items listed in the RUAGA are clearly services that are not specifically identified for tax purposes in the sales tax statute nor identified as constituting a retail sale.

2. Evidence indicates that the Department of Revenue is uncertain about the taxability of these transactions and has published no statement to the general public or even its own employees that would clarify its position. Its confusion should not inure to the detriment of this taxpayer by paying tax on transactions that even the Department cannot say with certainty are within their authority to tax.

3. Finally, the Department should not be allowed to rely upon an unreported, unacknowledged decision of the former Tax Commission to resolve an issue of this significance. Sales of blood and products derived from blood are sales of services not specifically included within the taxing statute and are therefore non-taxable.

Petitioner having carried its burden requests summary judgment based on the pleadings, testimony and evidence of record in this case.

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By: _____

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Attorneys for CareAlliance Health Services d/b/a Roper St. Francis Healthcare

Charleston, South Carolina
August 26, 2013

CERTIFICATE OF SERVICE

I, the undersigned Administrative Assistant of the law offices of Nelson Mullins Riley & Scarborough LLP, attorneys for CareAlliance Health Services d/b/a Roper St. Francis Healthcare, do hereby certify that I have served all counsel in this action with a copy of the pleading(s) hereinbelow specified by mailing a copy of the same by United States Mail, postage prepaid, to the following address(es):

Pleadings:

Counsel Served:

Adam N. Marinelli
Lauren Acquaviva
Counsel for Litigation
Office of General Counsel for Litigation
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Donna Horn
Administrative Assistant

August 26, 2013

STATE OF SOUTH CAROLINA

ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a Roper St. Francis Healthcare, Petitioner, vs. South Carolina Department of Revenue, Respondent.	)	Civil Action No. 12-ALJ-17-0405-CC **AFFIDAVIT OF MARY K. PENDERGAST IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT**

I, Mary K. Pendergast, being first duly sworn, state as follows:

1. I am a former Deputy Commissioner and Senior Advisor to the Commissioner of the Federal Food and Drug Administration ("FDA") of the Department of Health and Human Services, a position that I held from December 1990 through December 1997.

2. Prior to this position, I served as an attorney in the office of General Counsel and as Associate Chief Counsel for Enforcement of the Office of General Counsel of the FDA from July 1979 though December 1997.

3. Since leaving the FDA I have provided regulatory guidance on FDA matters to companies, universities and other entities.

4. In these capacities I have developed specific knowledge of the law and regulations regarding jurisdiction, statutory authority, and scope of enforcement authority of the FDA.

5. In preparation for testifying as an expert witness in this case, I have reviewed certain federal and state laws, regulations and guidances in order to be able to respond to questions regarding the prosthetic devices at issue in this case.

EXHIBIT A

6. Based upon this review and the knowledge and experience developed in my education and experience with the FDA over more than thirty years, I state as follows:

(a) The FDA is the only agency of government, federal or state, with legal authority to regulate the labeling, distribution, and restrictions regarding the use of prosthetic devices implanted in human beings.

(b) The State of South Carolina has no authority to modify, limit or expand restrictions placed on prosthetic devices implanted into human beings without specific authority from the FDA.

(c) FDA regulations provide an appeal process for states to request exemptions from such restrictions.

(d) Twenty–two states and the District of Columbia have requested and received such exemptions. South Carolina is not one of these entities.

(e) Prosthetic devices that can cause harm in their use are restricted by FDA regulations to sale only by "prescription or other order" of a physician licensed to use such devices in their medical practice.

(f) Hospitals can only purchase such restricted prosthetic devices upon the lawful "prescription or other order" of a physician licensed to use such devices in their medical practice.

(g) Hospital that purchase such devices and manufacturers/suppliers that sell such devices without the lawful prescription or order of a physician are subject to prosecution under federal law for "misbranding" of prescription devices.

7. Federal statutes and regulations upon which these conclusions are drawn are attached hereto as **Exhibit 1** and include the following:

(a) 21 USC §331 (Prohibited Acts and Penalties)

(b) 21 USC §360 j(e)(1) (General Provisions regarding control of devices intended for human use)

(c) 21 USC §360k (State and Local Requirements regarding devices)

(d) 21 CFR §801.109 (Prescription Devices)

(e) 21 CFR §801.110 (Labeling Exemption from adequate directions for use for prescription devices)

(f) 21 CFR §808 (explanation of how States may seek exemptions and listing of States with exemptions)

FURTHER AFFIANT SAYETH NOT.

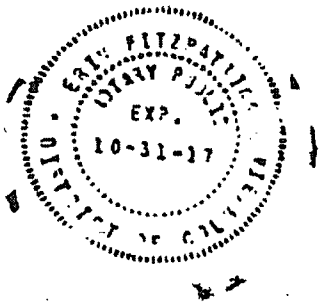
Mary Pendergast

Mary K. Pendergast

SWORN to and subscribed before me
this 23 day of August, 2013

(L.S.)

Notary Public for the District of Columbia
My commission expires 10/31/2017



STATE OF SOUTH CAROLINA

ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a Roper St. Francis Healthcare, Petitioner, vs. South Carolina Department of Revenue, Respondent.	)	Civil Action No. 12-ALJ-17-0405-CC **AFFIDAVIT OF CHARLES TRESCOTT FERGUSON IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT**

I, Scott Ferguson, being first duly sworn, state as follows:

1. I am the Director of Material Services for Roper St. Francis Healthcare, Inc., the Petitioner in the above litigation.

2. In this capacity, I have personal knowledge of Petitioner's business practices regarding the purchase of prescription orthopedic prosthetic devices (such as hip, knee and shoulder joint implants) (the "Orthopedic Devices"); prescription trauma prosthetic devices (such as plates, pins, nails and screws) (the "Trauma Devices"); and prescription cardiac prosthetic devices (such as pacemakers and implantable cardioverter defibrillators ("ICDs") (the "Cardiac Devices") (collectively, the "Prescription Prosthetic Devices"). I also have knowledge regarding the application of state and federal laws related to the requirements for the sale and purchase of the Prescription Prosthetic Devices.

3. Based upon my personal knowledge of the purchasing practices of the hospital and my personal knowledge and understanding of the application of state and federal laws to these practices, I state as follows:

(a) The Federal Food and Drug Administration ("FDA") requires the hospital to (1) purchase all of the Prescription Prosthetic Devices

EXHIBIT B

on the order or prescription of a physician, and (2) memorialize all such orders or prescriptions.

(b) All purchases by the hospital of Prescription Prosthetic Devices implanted in patients of the hospital are made by the hospital only upon the prescription or order of a physician authorized to use such devices in his or her practice.

(c) The hospital does not own any inventory of Orthopedic or Cardiac Devices; however, it does purchase and maintain a limited inventory of Trauma Devices for use on patients treated in the hospital, as these items are needed on an emergency basis. Even these Devices kept in inventory, however, are purchased by the hospital only upon the order or prescription of a physician.

(d) In addition to the FDA, the hospital's accrediting agency requires the hospital to maintain and/or provide sufficient documentation to the agency to document the proper purchase practices for prescription only devices.

(e) The hospital is, and was during the time periods at issue, in full compliance with the FDA mandates related to the hospital's purchase of Prescription Prosthetic Devices that (a) all sales be made by or on the order of a physician, and (b) all physicians' orders be properly memorialized.

(f) The hospital has not been held in violation of laws or regulations of the state, federal government or the hospital accrediting agency with regard to the purchase or documentation of prescription prosthetic devices during my ten years as materials manager.

FURTHER AFFIANT SAYETH NOT.

Charles Trescott Ferguson

SWORN to and subscribed before me
this 30th day of August, 2013

(L.S.)

Notary Public for South Carolina
My commission expires May 19, 2016

FRIEDA S. WYNN NOTARY PUBLIC SOUTH CAROLINA

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a Roper St. Francis Healthoare,	) CIVIL ACTION NO:) 12-ALJ-17-0405-CC
Plaintiff,	)
vs.	)
SOUTH CAROLINA DEPARTMENT OF REVENUE,	)
Defendant.	)

* * * * * * * * * * * * * * * * *

VIDEOTAPED DEPOSITION OF:	JOHN MCCROSSON, M.D.
DATE TAKEN:	June 13, 2013
TIME:	4:02 p.m.
PLACE:	Roper St. Francis 125 Doughty Street Charleston, SC
REPORTED BY:	DENISE LAUDER Registered Professional Reporter and Notary Public

* * * * * * * * * * * * * * * * *

POST OFFICE BOX 21784

CHARLESTON, SOUTH CAROLINA 29413-1784

EXHIBIT C

Electronically signed by Denise Lauder (301-268-293-2597)

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(DFT. EXH. 11, Copy of definition, was marked for identification.)
(DFT. EXH. 12, Copy of definition, was marked for identification.)
(DFT. EXH. 13, Copy of definition, was marked for identification.)
(DFT. EXH. 14, Copy of definition, was marked for identification.)
THE VIDEOGRAPHER: The date today is June 13, 2013, the time is 4:02. This is the video deposition of Dr. John McCrosson in the matter of CareAlliance Health Services d/b/a Roper St. Francis Healthcare vs. South Carolina Department of Revenue, the State of South Carolina Administrative Court, Civil Action Number 12 ALJ 17 0405 CC.
This deposition is being held at Roper Hospital located at 125 Doughty Street in Charleston, South Carolina.
Will Counsel please identify themselves for the record?
MR. CARPENTER: I'm Raymond P. Carpenter representing CareAlliance doing business as Roper St. Francis Hospital.
MS. GEER: Bryson Geer also representing CareAlliance doing business as Roper

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Hospital.
MR. MARINELLI: Adam Marinelli representing the South Carolina Department of Revenue.
MS. ACQUAVIVA: And Lauren Acquaviva also representing the Department of Revenue.
THE VIDEOGRAPHER: Please swear in the witness.
JOHN MCCROSSON, M.D.,
being first duly sworn, testified as follows:
DIRECT EXAMINATION
BY MR. CARPENTER:
Q. Would you state your full name for the record?
A. John Joseph McCrosson.
Q. Okay. Dr. McCrosson, by whom are you employed?
A. Roper St. Francis Physician Partners.
Q. And are you a physician?
A. Yes.
Q. Okay. And what is your area of specialization?
A. Orthopedic surgery, hip and knee replacements.
Q. Can you describe what you do in that

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area of specialization?
A. I replace hip and knees, that's 90 percent of my practice.
Q. Okay. Are you board certified in this area or any area?
A. Board certified in orthopedic surgery. There's no special certification beyond that for hip and knee replacement.
Q. Okay. Tell us about your educational background.
A. I went to college at Emory University in Atlanta, then medical school and residency at the Medical University of South Carolina here in Charleston, and a one-year fellowship in adult reconstructive surgery in New York City, Insall Scott Kelly Institute.
Q. How long have you been employed by Roper St. Francis?
A. Since 2007, so five and a half or six years.
Q. Approximately, how many of the nip -- heat -- knee and hip surgeries do you perform during a week, month, year?
A. I usually perform about 12 per week, 40 to 50, sometimes more, in a month, and over 500 a

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year for the last few years. And I've been in practice since 2000, I've just been employed since 2007. Before that I was in private practice.
Q. I see. Doctor, I'm going to ask you a series of questions with regard to the nature of your practice, how you order prosthetic devices, things of that sort, what happens in your office during that process. Let's begin by talking about when a patient presents themselves for knee or hip replacement. Can you describe the procedure that you follow in your office to determine the course of treatment for that parent?
A. Yes. I examine the patient, along with my physician assistant, and we do a history, physical, review X-rays, sometimes MRIs, CAT scans, other types of radiologic studies, sometimes other lab tests. Oftentimes we are seeing patients that have previously seen orthopedic surgeons or other doctors that refer the patient to us. We review that prior medical record and any correspondence from those doctors.
And then once we determine that the patient probably is a good candidate for joint replacement surgery, we talk to the patient about that, or any other treatment options that may be

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appropriate for that patient. Then at that point I walk out of the exam room, tell my medical assistant -- there are two actually that are out there -- that the patient is a candidate for whatever procedure it is, and fill out a preoperative planning sheet.

For 90 percent of the patients, that's all the same type of thing. We're saying it's a right knee, left knee, hip, et cetera, revision, et cetera. And 90 percent of the time it's the standard types of implants that I want to have available for the operation that I always use on a customary basis, and to the out-of-the-ordinary situation, I mark that on the sheet, including if the surgery may take longer than usual, for scheduling purposes, and give that sheet to my medical assistant.

She then goes into the room, gives the patient a book that is published here in the hospital about hip or knee replacement, tells them to go to the joint replacement class. I have a video in my office where I'm giving more frequently answered -- frequently asked questions answers, et cetera, for more information for the patient.

Pam then -- after giving them the book,

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telling them about the class, how to watch the videos online or on DVD, then instructs the patient on what they need to do prior to surgery. She tells them to avoid certain injections that may affect their immune system prior to surgery, what medicines to stop, and tells them that they'll get another call from a preop nurse from the hospital two weeks prior to surgery about doing routine preoperative labs and, again, going over medications and maybe stopping more medications.

She tells the patients that they need to have a preoperative clearance from their primary care doctor so that we're not missing anything medical; being specialized in hip and knee replacement, we want to make sure we get a letter from their primary doctor and sometimes a cardiologist or other specialist, depending on the situation.

And, finally, she tells the patient to take some antibiotics prior to surgery, apply some in their nose and to do an antibiotic bath several days prior to surgery. She then does a posting slip for the operating room where she takes what I did on my piece of paper, puts it into a computer format so she can electronically send it to the

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hospital, tells them which implants that we want to have available and it goes from there.

Q. With regard to the implants, do you discuss the type of implant with the patient? In other words, do you and the patient come to some kind of joint decision on that or how do you make that decision?

A. Yes. Some patients want to know more details than others, but in every exam room we have models of the implants that we use. Most patients have already looked at those models. Usually while we're talking to them about the surgery, we're showing them the model. Some patients are interested in the specifics of if it's metal, plastic, ceramic, who made it, and at that point we talk about what would be the best option for them.

And of course I have my go-to favorite implants that I'm most accustomed to using that I get good results with. That's generally what I use. I usually explain to the patient, if that's appropriate for them, that that's why I will be using it, because it works well for me. And I hope that answers your question.

Q. Yeah, but at the end of the day, who makes that decision, is it you or the patient?

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A. I make the decision for the implant.

Q. Okay. When you make a decision to treat a patient with a specific device, how do you then identify that device and order that device?

A. I start with that preop posting slip. If it's the standard stuff, I just put, right total knee, and I have the standard things. There's always -- the supplier, the Zimmer representative that I work with, is in the operating room every time I operate. And that information is communicated, by the way, to him.

He knows the types of procedures for -- on any given date so that he'll have -- he'll bring the implant assortment that we'll need to make it through the day. Because if we do right surgeries in a day, he needs to have multiple in case several patients all require the same size, et cetera.

Q. Let's go back to -- to right after we've met with the patient and you've made a determination that the patient is a candidate for hip or knee replacement. Now you're going to order the device. Do you -- how do you communicate that and with whom do you communicate at that time?

A. I communicate that with Pam usually or Jeanine, one of my two medical assistants.

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sick or out. So usually it's a physician assistant in each room.

Q. And the two forms, Plaintiff's 1 and 2, are -- can they -- can those forms be described as your work authorizations?

A. Absolutely.

MR. MARINELLI: Objection; leading. I don't know if we let him answer it at this point or if you just ask it a different way; I don't know.

BY MR. CARPENTER:

Q. Okay. Do these forms memorialize the information with regard to patients and procedures that you are conducting during a period of time?

MR. MARINELLI: Objection; leading.

MR. CARPENTER: You can still answer.

THE WITNESS: Yes.

BY MR. CARPENTER:

Q. You've described the information that is on the form -- summarized on the form. And this information is -- I don't know, is it used by your staff for -- what is it used by your staff for?

A. To schedule surgeries while we're in the office. The first step is -- in the situation where I walk out of the exam room and tell Pam, okay, this patient would like to schedule a total

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knee; then when she goes in to talk to them and start the process, giving them the book about -- with more information, et cetera, she comes in with a schedule book and says, when would you like to schedule it? And they say, oh, I don't know, as soon as I can. And then she sees when the next available is.

Or they may say, I want to do it during Christmas break. So she starts -- and this helps her keep track of how many surgeries we have on a given day. I usually operate on Monday and Tuesday. So she just starts scheduling patients that way. And then as we get closer to the date, then the physician assistants and the manufacturer rep look at it more to start making sure that all the labs that are coming back for -- in the case of the physician assistants, those labs we ordered two weeks before, they're starting to make sure that they've reviewed all of that, reviewed that preoperative clearance letter from the primary care doctor.

And then if there are any discrepancies or concerns with that information, they forward that to me and say, we have an issue here, what do you want to do about it? Can we still do surgery,

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et cetera.

Q. Okay.

A. So this book starts that whole process. And then there are times when someone -- for example, today a patient for next week went to visit her daughter and her daughter's cat attacked her and scratched her leg all up, so now we have to cancel her surgery for next week. So then we have to cross her off. And then we have a waiting list and Pam calls them and says, hey, there's an opening for next week if you want to come.

Q. Do you or your staff prepare any other documents in preparation for or subsequent to surgery?

A. We do a preoperative history and physical as part of the hospital chart. We take the -- a lot of the information from our last office evaluation and then we update that with the -- anything that's changed up until the day of the patient's admission.

The other paperwork involves lab results, preoperative clearance, and we talked about there's a sheet that the physician assistants check off that says that -- where they check off that they have the X-rays ready for surgery day,

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all of these things are completed. And my office probably has a few more pieces of paper that they use to help make sure they get all the work done so that when the patient arrives, everything is smooth, but, you know, I can answer in detail --

Q. Yeah. I think you've done that.

On the day of surgery, who makes the final decision on what prosthetic device is implanted in the patient?

A. I do.

Q. And how do you convey that decision to people in the room?

A. Verbally.

Q. Okay.

A. Because by then I've already established which brand I'm going to use. And it may have changed already during the surgery, but I would change that verbally; if I say, well, the Zimmer is not working out, let's use the Stryker Restoration, the Stryker guy is there in that situation already because I knew that was a possibility, then we use that. And then after we find out what size of that we need, we say, open the 32.

Q. Is the decision to use a specific kind

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of device memorialized by your staff in any way?
A. Yes. The circulating nurse, the registered nurse, enters the bar code numbers into the computer system; and also takes the stickers from the implant boxes, they usually have stickers on those, and places them in the chart and also in a log that the hospital keeps of all the implants -- joint replacement implants. So sometimes we can access those when the computer system is down to see what size this patient has, if we're in an emergency situation and I'm going to operate on that extremity again.
And then in my operative report I also dictate the sizes, in the discharge summary from the patient when they leave the hospital, we also includes the sizes. So there are several times the brand, size, the -- of the device is memorialized. Also on the brief operative report after surgery that we complete, besides the one that we dictate for the final chart.
Q. Are Plaintiff's 1 and 2 -- or Petitioner's 1 and 2, are they -- do they constitute memorialization of the procedure that you actually completed?
MR. MARINELLI: Objection; leading.

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THE WITNESS: They're preparation. They're preparation, getting ready for the prescription to occur. If we did not have these planning steps, we would never get to the point where I could order it and it would be there.
BY MR. CARPENTER:
Q. Okay. That's fine. The procedure that you have described and that's memorialized in the documents before you, is this the procedure that you follow on a regular basis in terms of the way that you -- that you intake and document what has been done with your patients?
A. Yes. To do the volume of work we do, it has to be very mechanized.
Q. Right. And do you know if -- if the procedures that you follow are procedures that are generally followed by other orthopedic surgeons at Roper St. Francis?
MR. MARINELLI: Objection; leading and calls for speculation.
MR. CARPENTER: If he knows.
MR. MARINELLI: I'm just making my objection.
MR. CARPENTER: Yeah. Okay.
THE WITNESS: Yes.

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BY MR. CARPENTER:
Q. If you know. Yeah. Okay.
A. I think the way that we do it is very standard. I think sometimes people do it without having this sheet that I created, et cetera, but everyone has a schedule book and everyone communicates with their rep. Everyone orders the prosthesis in the same way after they've done the trials. They say what sizes that they need every place, you know -- in every operating room I've been, you know, all around the United States.
Q. Okay. Are you in your practice audited by any state or federal agency for compliance with state and federal laws?
A. Yes.
Q. Okay. Has any agency that has audited your procedures in any way found those procedures to be deficient in the documentation of your orders for prosthetic devices?
A. No.
Q. And that's all I need on that.
Are you familiar with the term prescription?
A. Yes.
Q. Okay. What is a prescription as far as

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you are -- your understanding?
A. An order by a medical professional, a doctor or a licensed physician assistant; they can also do some prescribing. But to simplify, it's a doctor's order.
Q. Okay. Do you then in ordering prescription devices give a prescription for those devices?
A. Yes.
Q. And how do you do that?
A. By saying what the prescription is.
Q. As an orthopedic surgeon, are you licensed to order an implant, orthopedic devices, in the patients that you treat?
A. Yes.
Q. By whom are you licensed -- so licensed?
A. The State of South Carolina Board of Medical Examiners.
Q. Okay. Can medical -- can the -- can the hip and knee replacement devices that you order be ordered by your patients?
A. No.
Q. Have you ever had occasion to write a prescription for a patient to take to a drugstore

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available by prescription only or -- or not.
Q. Right.
A. But we still can write the prescriptions for the others, but you can obtain them without a prescription. When an item is prescription only or an activity is prescription only, when something's been deemed prescription only by the powers that I have to listen to, they can only obtained by a prescription.
Q. Okay. Are these -- going back to Plaintiff's 1 and 2, are those documents part of your memorialization of the order for the devices?
A. You could say so. Certainly, it's not in itself memorializing it because if the patient's cancelled, you know, the order never occurred, but this is part of the planning of the work that we're going to do. But the kicker, to me, is, I am ordering the device when I call out the sizes in the room. It's still not ordered when I say, I think it's between a 54 and a 56, Thomas. Not ordered. Not prescribed; nothing's been prescribed.
I've done a bunch of work maybe to get ready for it, but when I say, 56, 12, 32, that is a prescription. I mean, it's like any other

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prescription that I do. I mean, I feel like it's very similar to a lot of things that I do.
Q. Right. Are you familiar with a chart order?
A. Yes.
Q. Once again, in your world, what is a chart order?
A. A chart order is an order on a hospital chart, that I either write in the chart or a registered nurse writes in the chart, that is a prescription to perform a certain activity or administer a certain treatment, medication, et cetera.
Q. And do you issue chart orders?
A. Yes, every day.
Q. Okay. During the course of your treatment of a patient?
A. That's right.
Q. And is the chart order otherwise memorialized in your records?
A. Yes.
Q. All right. Let's go to the surgery and what happens during the course of surgery. When you make a determination that you're going to perform surgery on an individual, do you make a

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determination that a portion of the body is -- is missing in that process?
A. Yes.
Q. Okay. What -- with regard to knee surgery, what portion of the body would be missing?
A. There's always cartilage missing. I never replace a knee that I don't at least think has missing articular cartilage. So missing part of the joint.
Q. And during surgery, do you -- is there any part of the body removed during surgery?
A. Yes. Then we remove more of the joint to accommodate the thickness of the implant. Engineering the implants require that the -- that they be a certain thickness so they don't break, et cetera. So most of the time we have to remove even more in order to implant the knee or hip replacement.
Q. Okay.
MR. CARPENTER: That's just the second page.
MS. GEER: Did you divide them up? All right. So this is 1 and 2, so you can put that as an exhibit.
(Petitioner's Exhibit 3, Copy of

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invoice, was marked for identification.)
BY MR. CARPENTER:
Q. Dr. McCrosson, I show you what's been marked for identification as Plaintiff's -- I'm sorry, Petitioner's Exhibit 3.
MS. GEER: Can I switch out with you?
BY MR. CARPENTER:
Q. I call your attention to the products and the descriptions of the items that are listed on the invoice, and ask if you are familiar with those items.
A. Yes. Those are knee replacement implants.
Q. Are they the type of implants that you use in your surgeries?
A. Yes.
Q. Look at the date of the invoice, if you would.
A. Yes.
Q. And the date of surgery on the invoice.
A. Yes.
Q. Does that tell you anything about the process, or your process, in terms of how you go about treating your patients and ordering devices,

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or what does it tell you?
A. Well, on the day of surgery, after I called out the sizes that I want to use, the -- not only did the nurse put that in the computer, but the Zimmer rep put it into his iPad so that he could charge the hospital. And surgery in this case was December 17, 2007, and the Zimmer rep sent a bill to Roper Hospital two days later -- one day later, on December 18th, 2007, for the devices that we had used the day before.
Q. Okay. So the document shows that the surgery occurred prior to the date of the invoice?
A. That's correct.
Q. And are you listed as the doctor on this invoice who performed the surgery?
A. Yes.
Q. Okay. Let's go to 4.
(Petitioner's Exhibit 4, Copy of letter, was marked for identification.)
BY MR. CARPENTER:
Q. Dr. McCrosson, I show you what has been marked for identification as Petitioner's Exhibit 4. And I'll tell you that it's a FDA premarket approval letter to a manufacturer. Once again I call your attention to the description of

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the item in this letter and ask you if you're familiar with that item.
A. Yes. It says the Zimmer NexGen LPS knee.
Q. Is it related to the same item in the previous exhibit?
A. Yes.
Q. All right.
A. That's a similar model, same manufacturer.
Q. And just for purposes of the record, would you read in the second paragraph just the first and second lines of that -- of that document?
A. The sale, distribution, and use of this device are restricted to prescription use, in accordance with 21 CFR 801 19, within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act.
Q. What does that tell you as far as your practice is concerned?
MR. MARINELLI: Objection; calls for a legal conclusion.
THE WITNESS: It tells me that this device can be only sold or distributed by prescription.

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MR. CARPENTER: Thank you. And -- just go crazy.
(Petitioner's Exhibit 5, Box, was marked for identification.)
BY MR. CARPENTER:
Q. Dr. McCrosson, I show you what has been marked for identification Petitioner's 5, and ask you if you are familiar with that item.
A. Yes.
Q. Okay. Can you tell us what it is?
A. It's a box that holds one implantable device of a -- part of a knee replacement.
Q. Okay. And on what occasion do you see that -- that item?
A. Every Monday and Tuesday. Except Christmas and holidays.
Q. And what's occurring when you see that item?
A. Yeah. This is -- right after I call out the sizes, the Zimmer rep picks this up off the cart where he has potential likely sizes and pulls off the wrapper which are hermetically sealed, he begins to open it, and then the inside part is finished opening by the nurses and the nurse hands it to the sterile field.

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Q. And you would use that in the treatment of the patient that's in the operating room?
A. That's right. The circulating nurse gives it to the scrub nurse, or tech, that's another hospital staff member that is assisting me in surgery, sterile. That's why they're called scrubbed. And then that nurse sometimes may apply some cement to it or get it ready for me and then hands it to me and I put it in the patient.
So from the time it's out of the box and in the patient is just, you know, less than a minute oftentimes.
Q. I call your attention to the writing on the box. Can you tell us if there's any descriptive information on the box that -- that is related to Plaintiff's 5 and 6?
A. Yes. There's an RX only on the box.
Q. And what does that tell you?
A. It's a prescription only device.
MS. GEER: Did you say Exhibits 5 and 6?
MR. CARPENTER: I did say 5 and 6. 4 and -- yeah, that was 5. This is 5? I'm sorry, Exhibits 3 and --
THE WITNESS: Somehow I knew what you

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were saying.
MR. CARPENTER: Three and 4 come before 5.
BY MR. CARPENTER:
Q. And this is the type of prosthetic device that is used routinely in your practice?
A. Yes.
Q. Okay. Do you know if that device can be sold without a prescription?
MR. MARINELLI: Objection; leading and calling for a legal conclusion.
MR. CARPENTER: Do you know?
THE WITNESS: It sure seems like it cannot be. It says prescription only, so I think it would be illegal if it were sold otherwise.
MR. CARPENTER: Okay. We're going to take a break for about five minutes.
THE VIDEOGRAPHER: Off the record at 4:46.
(A recess transpired.)
THE VIDEOGRAPHER: On the record at 4:55.
BY MR. CARPENTER:
Q. Dr. McCrosson, I just have one -- one additional question.

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A. Okay.
Q. Do you issue an order for a knee and hip device on every occasion when you make that -- when you implant one in a patient?
A. Yes.
MR. MARINELLI: Objection; leading.
THE WITNESS: Yes.
MR. CARPENTER: Thank you. That's all I have.
THE VIDEOGRAPHER: Okay. Anyone else have any questions?
MS. ACQUAVIVA: We have cross-examination.
THE VIDEOGRAPHER: Do you want me to go off?
MS. ACQUAVIVA: You don't have to. I made copies, one of everything, for all of you.
CROSS-EXAMINATION
BY MS. ACQUAVIVA:
Q. Ready? Dr. McCrosson, this might get a little tedious, but bear with me. I'm going to briefly go over some of your testimony. When your patients that you're going to operate on go to the hospital, they're admitted to the hospital?
A. That's right.

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Q. So they are patients of the hospital, right?
A. Right.
Q. Okay. And then by the time you get to the operating room -- you have two operating rooms going at once, correct?
A. Right.
Q. By the time you get there, the patient is already under anesthesia?
A. Yes.
Q. And they're ready for you to operate on them?
A. Right.
Q. And you call out to the vendor and the circulating nurse what device you need?
A. That's right.
Q. And then it goes to the circulating nurse who opens it, correct?
A. Correct.
Q. And she hands it to the sterile nurse?
A. Right.
Q. And then the sterile nurse hands it to you?
A. Right.
Q. And it's immediately implanted into the

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patient?
A. Right.
Q. Okay. And according to your testimony, when you call out the device that you need, that is what constitutes the prescription?
A. To me, that's the -- without that, there's no prescription. There are other things that may be considered building up to it or part of the prescription, but that is the kicker. That's when I feel that I'm making the prescription.
Q. And you testified that your definition of a prescription is a doctor's order?
A. That's right.
Q. Okay. I'm going to hand you what has been marked for identification as Defendant's Exhibit 1. Could you identify where that document comes from for the record? I highlighted it for you to make it a little easier.
A. I was about to say, New York, Toronto, London, but it's Random House, Webster's College Dictionary.
Q. And can you turn to the second page and identify the definition, what has been highlighted -- just what -- the word that is being defined, not the actual definition?

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA

CareAlliance Health Services d/b/a Roper St. Francis Healthcare, Plaintiff, vs. South Carolina Department of Revenue, Defendant.	) CIVIL ACTION NO: 12-ALJ-17-0405-CC

* * * * * * * * * * * * * * * * * * *

VIDEOTAPED DEPOSITION OF:	BRETT M. BAKER, M.D.
DATE TAKEN:	July 2, 2013
TIME:	2:43 p.m.
PLACE:	Roper St. Francis 125 Doughty Street Charleston, SC
REPORTED BY:	DENISE LAUDER Registered Professional Reporter and Notary Public

* * * * * * * * * * * * * * * * * * *

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CHARLESTON, SOUTH CAROLINA 29413-1784

EXHIBIT D

BY MR. CARPENTER:

Q. Dr. Baker, would you state your full name for the record, please?

A. Brett Matthew Baker.

Q. Okay. And, Dr. Baker, are you a physician?

A. Yes.

Q. And by whom are you currently employed?

A. Carolina Arrythmia Consultants, P.A.

Q. Do you have a medical specialty?

A. Cardiac electrophysiology.

Q. Okay. And can you describe what that specialty is?

A. It is the specialty of -- it's a subspecialty of cardiology that involves management of heart rhythm disorders.

Q. Okay. And are you board certified in that area?

A. Yes.

Q. Okay. Do you use prosthetic devices in your practice?

A. Yes.

Q. Okay. What types of devices do you use to treat your cus -- your clients -- your patients?

A. Right. So we use devices that

basically essentially are present to manage an irregularity or insufficiency with regard to heart rhythm and heart electrical function.

Q. Okay. And what types of devices would that be?

A. We use a variety of different pacemakers and defibrillators.

Q. And over your career, approximately how many procedures or surgeries have you performed with regard to these items?

A. Right. Probably somewhere in the neighborhood of 3 to 4,000.

Q. Can you describe what a pacemaker does?

A. So a pacemaker is designed to essentially replace the function of natural tissue that is -- so basically a pacemaker is there to maintain heart rhythm. So if a person has a normal heart rhythm, then a pacemaker basically is there to -- when a patient has a situation where their heart rhythm is excessively slow, the pacemaker remedies that situation.

Q. Okay. And what about a -- an ICD? Would you explain what an ICD is?

A. Right. So an ICD is a pacemaker plus. So it has the features of a pacemaker, plus it has

additional features that can maintain the rhythm in situations where patients develop excessively fast heart rates. The device can also correct issues that are related to loss of components of the conduction system that can result in congestive heart failure.

Q. Okay. And how do you determine among your patients when they would need one of these devices?

A. We typically evaluate the patient by doing a history and physical and then reviewing the information that we have regarding test results, EKGs, imaging studies, and then essentially we -- we discuss a patient's symptoms with them, and -- and upon that evaluation we make a recommendation for a device if indicated.

Q. Okay. If the patient has heart irregularities, what -- what would be the cause of that?

A. The most common cause is that the heart's electrical system -- some component of the heart's electrical system has basically degenerated and portions have died off. So they've lost an area -- portion of tissue of the heart's electrical system that leads to the rhythm abnormality that

would be treated with the device.

Q. And describe again, what has happened to the heart tissue when -- on your examination when you find that the tissue has died off, as you -- as you described it?

A. So, for example, in this situation with a pacemaker, there are a variety of parts of the heart's electrical system that serve the function of creating the initial cardiac impulse and then transmitting it from the upper chambers to the lower chambers and coordinating the timing of contraction of the lower chambers. The -- we can see an excessive slowing of the heart rate. In some cases patients can present with loss of consciousness or full cardiac arrest, no heart rate. And then basically insertion of the device restores the heart rhythm by essentially replacing that lost area of tissue.

Q. Okay. And pacemakers and ICDs replace the lost tissue?

A. Yes.

Q. Do --

MR. MARINELLI: Objection; leading.

BY MR. CARPENTER:

Q. Could you tell us what an ICD stands

for? What is that --

A. So it's implantable cardioverter defibrillator.

Q. Okay. And do pacemakers -- I'm sorry. Is there such a thing as a biological pacemaker?

A. They're under development currently, so they're essentially a research tool, but the concept is that -- that cells -- essentially, artifical cells could be inserted that would replace cells that are lost in the cardiac conduction system, the cardiac electrical system.

Q. But in current practice, what devices take that -- take that place?

A. The pacemakers and defibrillators do.

Q. Okay. Are there cases where you would implant a pacemaker or ICD where no part of the body is missing?

A. There are situations where patients are born with -- with a defect, a genetic abnormality of their heart cells. Typically, it involves the way that those cells handle elements such as potassium and sodium. And that's a small subset of the patients that we deal with.

Q. Okay. What percentage?

A. I would say it represents less than 1

percent.

Q. Okay. Are you familiar with the boxes in which these devices come that you implant into the patients?

A. I've seen them, certainly.

Q. Do they have anything on them that indicates that they are prescription only?

MS. ACQUAVIVA: Objection; leading.

BY MR. CARPENTER:

Q. Do they have anything on them that indicates that they are restricted?

A. They do have a designation for -- they have RX only.

Q. And what does that RX only mean?

A. Prescription.

Q. Okay. When you are discussing -- when you meet with your patient that has presented himself to you and you are discussing the need for one of these devices, who determines what device you will implant into the patient? Who makes that decision?

A. Well, I -- I discuss the situation with the patient and it's a joint decision between myself and the patient, but, ultimately, I make the decision in terms of the hardware I guess you could

Q. Okay. Is mostly your communication with the manufacturer or the manufacturer's representative oral communication?

A. Yes.

Q. Okay. Do you -- at what point do you give a definitive order to the manufacturer's representative for the devices that you're going to implant?

A. So when we're doing the procedure, basically we'll actually order the specific component, typically by its model number, as we move through each phase of the procedure. So, for example, it's very common for me to start with a lead that goes in the ventricle. And I'll ask for a specific lead size and model number.

And then we'll go to a different chamber, the atrium perhaps, and then the -- and then the generator's usually the last component, but it's at that point that we determine specifically what we're going to use.

Q. Are you communicating with the manufacturer's representative during that process?

A. Yes.

Q. And how are you communicating with him?

A. Just verbally.

Q. Okay. And how does he deliver to you the device that you -- or the device and its components that you implant into the patient?

A. It will be essentially taken out of that. So usually we'll -- we'll know with some level of likelihood what we're going to use and he'll bring those into the room. He may have to, you know, go back out and pull something else out of the bag depending on how what we've selected works or what we -- you know, if there's a change in the game plan based on information we get during the course of the process.

Q. Okay. At the conclusion of the operation how do you memorialize what devices you have used in the process?

A. So we do a detailed report right at the time that we're finished, detailing model numbers, serial numbers, location in the heart, electrical measurements that we obtained as a result of testing during the procedure. And then, again, that's all in a report that goes in the medical record that I sign off on.

Q. Okay. Do you have any idea what happens to those records, where they're kept in your office or in the hospital?

A. In terms of my report?
Q. Yes.
A. Okay. So one is sent to my office, one stays in the medical record. I typically will send a copy of it to other physicians that are involved in the patient's care. I know those things for a fact.
Q. Okay.
A. Beyond that, I -- that would be what I know.
Q. And it's part of your normal business practice to prepare such documents after each procedure?
A. I have to. I'm obligated to --
Q. Okay.
A. -- as part of my privileges at the hospital.
Q. Okay. And it's in the normal course of your practice to do that?
MR. MARINELLI: Objection; leading.
THE WITNESS: If I didn't prepare reports, then I would not be allowed to practice at the hospital.
BY MR. CARPENTER:
Q. Okay. Is your practice audited for

A. Uh-huh.

Q. And do you consider that to be a prescription?

A. Well, I mean, yes. I'm picking a very specific, you know, piece of equipment for an individual based on what I know about them and what I'm observing during that whole process, so I would say, yes.

Q. And in that situation, who would you be prescribing the pacemaker or ICD or lead to?

A. Well, it's the patient who gets it, so...

Q. Okay. And who purchases this equipment?

A. Well, I think ultimately the patient pays for it. There's an interaction, I mean, between the hospital and the manufacturer, but that's not part of the process I'm involved in.

Q. Okay. But the transaction at issue in this case is between the manufacturer and the hospital, correct?

A. I assume so, yes.

Q. Okay. And those invoices are to the hospital, correct?

A. It appears so. Again, first time I've

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

CARE ALLIANCE D/B/A ROPER ST. FRANCIS MEDICAL HEALTH CARE, INC., Petitioner, vs. SOUTH CAROLINA DEPARTMENT OF REVENUE, Respondent.	DOCKET NO. 12-ALJ-17-0405-CC

* *

VIDEOTAPED DEPOSITION OF:	M. DAUD NAWABI, M.D.
DATE TAKEN:	Friday, June 14, 2013
TIME:	10:42 a.m.
PLACE:	125 Doughty Street Suite 720 Charleston, SC
REPORTED BY:	TERI L. SAMPSON, RPR, Notary Public and Certified Live Note Reporter

* *

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CHARLESTON, SOUTH CAROLINA 29413-1784

Electronically signed by Teri Sampson (401-261-957-7637)

EXHIBIT E

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STIPULATIONS

It is hereby stipulated and agreed by and between the parties hereto, through their respective counsel, that the reading and signing of the transcript is waived by the Deponent.

CHARLESTON, SOUTH CAROLINA, FRIDAY, JUNE 14, 2013
10:42 A.M.
PROCEEDINGS

VIDEOGRAPHER: The date today is June 14th, 2013. The time is 10:42. This is the video deposition of Dr. Daud Nawabi in the matter of Care Alliance Health Services d/b/a Roper St. Francis Health Care, versus South Carolina Department of Revenue, State of South Carolina Administrative Law Court, Civil Action No. 12-ALJ-17-0405-CC.

This deposition is being held at Roper Hospital located at 125 Doughty Street in Charleston, South Carolina.

Counsel identify themselves for the record.

MS. GEER: Bryson Geer on behalf of Care Alliance doing business as Roper St. Francis Health Care.

MR. CARPENTER: And Ray Carpenter on behalf of Care Alliance.

MR. MARINELLI: Adam Marinelli on behalf of the DOR.

MS. ACQUAVIVA: And Lauren Acquaviva on behalf of the Department of Revenue.

VIDEOGRAPHER: Please swear in the witness.

WHEREUPON,
M. DAUD NAWABI, M.D.,
being first duly sworn, testified as follows:

EXAMINATION

BY MS. GEER:

Q You're starting with me this time.
A Okay.
Q Dr. Nawabi, could you please state your full name for the record?
A Mohammad Daud Nawabi.
Q And are you a physician?
A I am.
Q What is your specialty?
A Hematology and oncology.
Q And could you please give us a brief description of the specialty, what do you do?
A I treat, diagnose, and manage patients with cancer and blood disorders.
Q And are you licensed by the State of South Carolina to practice medicine?
A I am.
Q And who are you currently employed by?
A Lowcountry Hematology & Oncology.
Q And can you tell us about your educational

background?
A After graduating high school, I went to Washington University and graduated with a bachelor's in biology, moved to Charleston, South Carolina, and after two years of research, completed four years of medical school at the Medical University of South Carolina in 1992.
Q And what did you do after your residency?
A After my residency, I started a practice in hematology and oncology.
Q Okay. Did you do any fellowships?
A I -- after -- after medicine residency, I completed a three-year fellowship in hematology and oncology.
Q And so you started your own practice. Where was that?
A Initially, it was in Mt. Pleasant. We now have three location, one in Mt. Pleasant, one in North Charleston at Trident Hospital, and one in West Ashley at St. Francis Hospital.
Q Is that Roper St. Francis?
A At Roper St. Francis Hospital.
Q Okay.
(Plaintiff's Exhibit 1 marked.)
BY MS. GEER:

Q I've handed you what's been marked as Plaintiff's Exhibit 1. Can you identify that document for us?
A This is my CV.
Q Okay. And is this fairly current?
A It appears to be relatively current.
MR. MARINELLI: Not to interrupt, but do you want to start marking them at the last number you left off on yesterday? Because I think you've already got a 1.
MS. GEER: Yes. Where did we leave off yesterday?
MS. ACQUAVIVA: I believe the last one was 5, so you would be at No. 6.
MS. GEER: Okay. Do you mind changing it to Plaintiff's Exhibit 6.
(Discussion off the written record.)
(Plaintiff's Exhibit 6 marked.)
A (Continuing) I noticed one discrepancy, that my board certification in internal medicine has expired and was not renewed, so I'm just board certified in medical oncology.
Q Okay. All right. I want to ask you some basic questions about the blood first. What is whole blood made of?

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A Whole blood is made of cellular elements that -- and plasma.
Q Okay. And what are the cellular elements?
A The cellular elements include red blood cells, white blood cells, and platelets.
Q Okay. And can you tell us about the plasma? What is it?
A The plasma is a liquid in which there are proteins and buffers dissolved or suspended within it.
Q Okay. What is the liquid part made of?
A It's a water base and then there are salts, buffers, proteins.
Q All right. And I will represent to you that two of the items at issue in this case are Gammaex ad Octagam. Do you know what those items are?
A Those are immunoglobulins.
Q Okay. And what is an immunoglobulin?
A Immunoglobulins are proteins that are produced by a human being and are used to provide passive immunity to an individual. They're antibodies, they're produced by plasma cells --
Q Okay.
A -- which are a subtype of white blood cell.
Q So are these the proteins you were talking about earlier when you said what was in the plasma?

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A These are some of the proteins in the plasma. There are others.
Q Okay. All right. I'm going to give you another list of items that I will represent to you are at issue in this case. Plasbumin, Albutein, Buminate, Flexbumin, AlbuRx, and Albumunar. Are you familiar with those items?
A I am.
Q And what are they?
A They are forms of albumin.
Q And what is albumin?
A Albumin is another plasma protein.
Q Okay.
A And it is the most abundant of the plasma proteins.
Q All right. When a person donates blood, is it typical for that whole blood to be used in another patient?
A No.
Q And what commonly -- what is more typical?
A More typically, blood is separated into its parts. There are usable parts and then there are other parts that are not usable and discarded. So...
Q All right. So can you -- you identified the component parts for us earlier. Can you separate out

Page 10

all of those different component parts?
A You can. Generally what happens is that the initial separation is to separate the cellular elements from the plasma.
Q And the cellular elements were?
A The white blood cells, the red blood cells, and the platelets.
Q Okay.
A Of those cellular elements, the platelets and the red blood cells are usable, so they are then processed and stored --
Q Okay.
A -- for use. And then there's the plasma, which can then also be separated into its component parts.
Q Okay. And some of its component parts are?
A The coagulation factors, cryoprecipitates, the immunoglobulins, albumins.
Q Okay. And you talked about that there is some processing that is done. Is there some processing done as to all of these parts?
A Yes.
Q Okay. And can you just give us a couple of examples of things that are done?
A So with the red blood cells, they are usually

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washed and they are then typed so that one understands the source that they came from, the ABO typing, the Rh factor is then identified. They are then resuspended into a buffer. There -- there's usually a preservative added in order to maintain the stability of the product.
Platelets go -- undergo a similar process. The plasma, because the proteins are suspended within the plasma, the proteins need to be precipitated from the plasma, and there are a number of different ways that that can be done.
Usually we use -- or usually what is done is cold ethanol fractionation, which is a -- an older method of chemically separating it. And then there are obviously variations based on that in order to -- again, in order to -- the goal is to achieve purity and to maintain the integrity of the product and not alter it.
Q Okay. So talking about the blood protein specifically, they're separate -- did you say that they are separated from the plasma, the blood proteins?
A The proteins that are suspended in the plasma are separated from the plasma.
Q Okay. And then they are -- what -- what is done with them next?

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A They are then also -- they're purified and then they may be buffered or they may be lyophilized, or freeze-dried, into a powder form, depending on what the particular protein is.
Q Okay.
A And then they're packaged for use.
Q Okay. Is there anything -- let me go back to -- to more general, not just the blood proteins. Is there anything in the processing of any of these cellular components or the blood proteins that in any way alters, modifies, or changes the nature of the blood components in any way?
A The goal is to not change, alter, or modify, as that would then likely have an adverse implication on the function.
Q Okay. And so same question, specifically as to the blood proteins, is there anything in the processing of the blood proteins that alters, modifies, or changes their nature in any way?
A No.
Q Okay.
A The goal is not to do that.
Q So are the blood proteins at issue here, are they synthetic or artificial in any way?
A No.

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Q Okay. Would you consider them to be a pharmaceutical?
A No.
Q All right. I have a few questions about blood banks and pharmacies. Who can order blood from the blood bank at Roper?
A A prescribing licensed physician.
Q Okay. And where is blood stored at Roper?
A At the blood bank.
Q Not in the pharmacy?
A Not in the pharmacy.
Q So could a pharmacist order blood without a doctor's order?
A Order to store for commercial use, no.
Q Okay. And who can order the blood proteins at issue here for Roper?
A Physicians can order the blood proteins. I suppose the pharmacists can order them to stock them for sale, for use, but they can't order them to be administered to a patient.
Q Okay. And if these blood proteins at issue are -- are kept in the pharmacy, does that make them become nonhuman?
A Where you store them doesn't change the -- the source of where they came from.

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Q Okay. Have you heard the terms blood product, blood derivative, or plasma derivative?
A I've heard the term.
Q Okay. Are these medical terms?
A I don't think they're medical terms.
Q What do they mean to you?
A They sort of -- I think that they -- they're used for lay terms or commercial for commercial use to determine how they're sold or where they're stored.
Q Okay. In your practice, do you ever use these terms in describing the blood proteins at issue, or how do you refer to them in your practice?
A Yeah, we refer to them by the specific products. We don't -- we don't tell our nurses that we're going to be transfusing blood products or blood derivatives. We may tell a patient that these things fall under the general umbrella of blood products so -- so that they can understand, but the -- usually patients are smart enough to know that red blood cells are red blood cells and white blood cells are white blood cells, so --
Q Right.
A -- we can usually educate them.
Q And would anything that is described as a plasma derivative also be a blood derivative?

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A Plasma comes from blood, so any plasma derivative is a blood derivative.
Q Okay.
(Discussion off the written record.)
MS. GEER: I don't have any further questions.
EXAMINATION
BY MR. MARINELLI:
Q Dr. Nawabi --
A Sir.
Q -- how long have you been in private practice?
A Since 2001.
Q And you said you've opened three offices in this area?
A My practice has three offices, that's correct.
Q Okay. And in your deposition, you testified to the fact that your offices keep on site various sundries and medical supplies, including prescription drugs, correct?
A That's correct.
Q And who did you testify to earlier as to who does the purchasing for these types of products?
A I testified to you.

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Q Touche. Who in your office purchases these items?
A Our -- under our direction, our pharmacy tech would order these agents.
Q And in some instances, did you say you have an automated stocking system that -- that alerts the vendor to provide you with these products?
A There are some -- there are some items that are automated.
Q And are those items prescription items?
A Yes.
Q Okay
A Some of them are.
Q Is it safe to assume that when these purchases are made by either your pharmacy tech or this automated system, that patient-specific data is not provided to the vendor?
A That's true.
Q Okay. What gives you the -- the power or the legal ability to purchase items that I could not, such as prescription drugs?
A I'm a licensed physician, so I --
Q So by the very nature of your medical license, you now have the ability to purchase items that a person without that license cannot, correct?

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A I think that there are others, like physician's assistants, nurse practitioners, who are allowed to also purchase and -- or, rather, at least prescribe these medications in -- in certain circumstances, but I'm not clear as to all the legalities of that.
Q But as far as you're concerned, if you were to, say, be inspected by some sort of federal or state agency that regulates these types of products, that you have the power to legally possess and purchase these products?
A That's correct.
Q And that's irregardless of the fact that a specific patient was in mind when you purchased those, correct?
A That's correct.
Q Okay. Now, to the drugs at issue in this case, Gammex and the various albumins, describe again, as far as you understand, because I know you're not a chemist, how these products are manufactured.
A So they're not manufactured. They're -- God has manufactured them.
Q Okay.
A Your body has manufactured them. You are -- people are donating whole blood, and from that whole

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blood, these products are then separated. As to the exact details of the separation process, I am no expert at that, but the -- the basic process is -- the initial process is the first thing to do is to separate the plasma from the whole blood.
In the plasma are these proteins, like immunoglobulin and albumin, and generally, there is a process called cold ethanol separation or fractionation that would then separate -- cause these product -- cause these proteins to precipitate out of solution and you would then separate them.
Q What is the goal or goals of that process?
A The goals of that process is to obtain a purified intact protein so that it maintains function.
Q When you say "purified," purified from -- from what?
A Purified from the other proteins, so that when you're purifying immunoglobulin, it's not contaminated by other proteins.
Q Is there any sort of sterilization process?
A There's a pasturization.
Q Describe that for me.
A I think that it's -- it's pasturized and the purpose of that is to -- to eliminate infectious disease, Hepatitis A, B, C, and HIV.

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Q Okay. I'm going to hand you --
MR. MARINELLI: We need to mark this now. Will you start at 15 for me.
(Defendant's Exhibit 15 marked.)
BY MR. MARINELLI:
Q It's been pre-marked as Defendant's Exhibit 15. Could you identify that document for me?
A This looks like the package insert for Gammex.
Q Okay. And have you ever used Gammex in your practice?
A We've used immunoglobulins in our practice. I couldn't tell you exactly whether it's Gammex, although I would have to believe that it is since --
Q This is --
A -- this is a common...
Q Okay. Turn to page 14 for me. The third paragraph, could you read the first five words of it?
A "The capacity of the manufacturing process to remove and/or" --
Q That's fine. You can stop there. So obviously, the company that makes this product believes that it has gone through some sort of manufacturing process, correct?
A I don't know what they believe. This is the

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word they've chosen to use.
Q Okay. It's safe to say that you can't take these protein strains directly from the human body and put them into someone else, correct? You have to put it through this sort of process?
A Right. The proteins are suspended in the blood.
Q Okay. And throughout this process, are the proteins subjected to anything artificial or synthetic?
A The proteins themselves are not artificial or synthetic. They go through a process, and so, for instance, if you pour them into a glass container, the glass container is synthetic and artificial.
Q Okay. Would ethanol be found in the human body?
A I think that you can find ethanol under certain circumstances in the human body, but not under normal circumstances.
Q Is the cold ethanol they use in the fractionation process --
A No, that's not found in the human body.
Q It's not a human product, okay.
A No.
Q Is caprylate a human --
A No, it's not.

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Q Okay. And how is caprylate used in this manufacturing process?
A I don't know.
Q Okay. What is caprylate?
A It says here that it is some sort of plant product. I assume that it's used in -- as part of the purification or separation process.
Q And what is the buffer solution they use in these products?
A The buffer, I don't see where the buffer is mentioned.
Q It doesn't have to be specific to Gammunex, but in general --
A Oh, what is a buffer?
Q Yeah.
A A buffer is the -- the solution that the protein is then suspended in so that it is -- so that it is -- it maintains its viability and its -- its -- its structure. It's a -- it's a substitute for the plasma.
Q Okay. And is the buffer an artificial substance?
A The buffer is created. It's a -- it's a water based, it has water, it has salts, it has other things to -- to cause it to buffer. It's not -- it's

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created, it's not -- so I don't know if that's artificial or not. I mean, water --
Q Safe to say it wasn't created by God?
A Well, it was created -- all things are created by God.
Q Debatable, but we're not going to have a religious discussion today.
Is the company that produces these types of products, the companies, rather, they are the ones that created the buffers that they mix with these proteins, correct?
A Well, you really can't create water, but you can make the buffer from water.
Q They mix the solutions?
A Yeah, they mix the solutions. There you go.
Q Arguing semantics at this point, but the only part of Gammunex that has been taken from a human body, is it safe to assume that that would be the protein strains that came from plasma?
A That's right.
Q Okay.
MR. MARINELLI: All right, let's..
(Defendant's Exhibit 16 marked.)
BY MR. MARINELLI:
Q I'm handing you what's been pre-marked as

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Defendant's Exhibit No. 16. Try to identify that document for the record, please.
A It says, "21 U.S.C.A. 321 (West)."
Q Okay. Seems to be a federal code section. And the first portion of this code section, what do you -- what does it indicate to you? What does it appear to be?
A It appears to be a definition of the word "drug."
Q Okay. And subsection B, could you read that out loud for the record?
A B?
Q Under G1, B.
A G1 and B, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals."
Q And in your mind, does Gammunex and drugs of that nature fit within that definition?
A Yes.
Q I want to hand to you what's been pre-marked as Defendant's Exhibit 17 in just a moment.
(Defendant's Exhibit 17 marked.)
MR. MARINELLI: Thank you.
BY MR. MARINELLI:
Q Could you identify that document for the

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record?
A It says, "Code of Laws of South Carolina, 1976 Annotated, Adulterated, Misbranded, or New Drugs and Devices."
Q And could you read the definition --
MS. GEER: I'm sorry. Do we have a copy of that?
MR. MARINELLI: I'm sorry, we don't.
MS. GEER: Okay.
MR. MARINELLI: Do you want to stop and make copies?
MS. GEER: I would love to.
VIDEOGRAPHER: Off the record at 11:05.
(Brief recess taken.)
VIDEOGRAPHER: On the record at 11:08.
BY MR. MARINELLI:
Q Dr. Nawabi, could you identify this document for the record, Defendant's Exhibit 17?
A This is -- it says, "Code of Laws of South Carolina, 1976 annotated, Title 39, Trade and Commerce, Chapter 23, Adulterated, Misbranded, or New Drugs and Devices, Code 1976, 39-23-20, 39-23-20, Definitions" --
Q That's okay. Thank you. Under subsection B1, and under that, subsection B, is that identical to the definition you testified to earlier?

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A It appears to be.
Q And does -- in your mind, does Gammunex and drugs of that nature fit within that definition?
MS. GEER: Object to the form of the question as calling for a legal conclusion.
A (Continuing) Gammunex -- immunoglobulin seems to fall under this definition.
Q Okay.
MR. MARINELLI: Thank you, Dr. Nawabi. No further questions.
A (Continuing) You're welcome.
MS. GEER: Can we take about a five-minute break?
MR. MARINELLI: Sure.
VIDEOGRAPHER: Off the record at 11:09.
(Brief recess taken.)
VIDEOGRAPHER: On the record at 11:16.
FURTHER EXAMINATION
BY MS GEER:
Q Dr. Nawabi, I just have a few questions for you.
A Okay.
Q So you've testified during your cross that -- about the processing of the blood proteins and I want to ask you a few questions about the processing of the

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red blood cells. Do those also go through a screening process and a purification process to make sure infectious diseases are removed?
A Yes, or that they're identified.
Q Okay. And do those need preservatives to be added sometimes?
A Sometimes.
Q Do they need anti-coagulants to be added?
A Yes, sometimes.
Q Do they need to be placed in a buffer or liquid?
A Yes.
Q What type of liquid are red blood cells placed in?
A They're usually placed in a saline based citrate buffer.
Q And you were shown two definitions of drug by Mr. Marinelli. And I believe part B was identical, so I'm just going to read one of them. "Articles intended for" – this is the definition of drug, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." Would whole blood qualify as a drug under that definition?
A It would.

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Q Would a donated heart organ qualify under that definition?
A It would.
Q Bone?
A Yes.
Q Corneas?
A Uh-huh (affirmative).
Q Okay.
MS. GEER: That's all the questions I have.
MR. MARINELLI: Nothing further.
VIDEOGRAPHER: This concludes the deposition of Dr. Daud Nawabi. We're off the record at 11:17, Tape No. 1.
(Deposition concluded at 11:17 a.m.)

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CERTIFICATE
STATE OF SOUTH CAROLINA:
COUNTY OF BERKELEY.
I, TERI L. SAMPSON, Registered Professional Reporter, Notary Public and Certified Live Note Reporter, State of South Carolina at Large, certify that I was authorized to and did stenographically report the foregoing deposition; and that the transcript is a true record of the testimony given by the witness.
I further certify that I am not a relative, employee, attorney or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.
WITNESS MY HAND AND OFFICIAL SEAL this 16th day of June, 2013, in the Town of Goose Creek, County of Berkeley, State of South Carolina.

Teri L. Sampson, RPR,
Notary Public and Certified
Live Note Reporter
My commission expires:

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STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

CAREALLIANCE HEALTH SERVICES
D/B/A ROPER/ST. FRANCIS MEDICAL
HEALTHCARE, INC.,

Petitioner,

vs. DOCKET NO. 12-ALJ-17-0405-CC

SOUTH CAROLINA DEPARTMENT OF REVENUE,

Respondent.

DEPOSITION OF: JOHN P. McCORMACK

DATE: May 8, 2013

TIME: 9:31 A.M.

COPY

LOCATION: Offices of South Carolina
Department of Revenue
300A Outlet Pointe Boulevard
Columbia, SC

TAKEN BY: Counsel for the Petitioner

REPORTED BY: WANDA K. CECIL
Certified Court Reporter

A. WILLIAM ROBERTS, JR., & ASSOCIATES

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EXHIBIT F

Q. Do you know what a blood product is?
A. I have a guess of what it might – things it might include, but I, you know. . .
Q. Okay. And I have already asked whether there was an official definition of that term and you indicated that there was not; but 92-26 is clearly about blood products, is it not?
A. It states blood products, yes.
Q. Yes. And even though there's a discussion of whole blood, it's not really about whole blood, is it?
A. Well, it states – the final conclusion, as you said, talks about blood products.
Q. Tell me how the department uses this decision. What do you draw from it and what, in terms of policy, have you developed as a position by the department based upon Commission Decision 92-26?
A. Well, I think the 92-26 is determining that, again, that 43 – give you the right number here, that 44-43-10 is not controlling and that the definition of tangible personal property in 12-36-60 is controlling. So that's the first thing. Then I think with the – which I believe were subsequent to this.
Then with the Associated Medical case

and with the more recent Home Medical case, that the issue here is whether they were sold by prescription, assuming that we're not dealing with things that are used to treat cancer, leukemia, lymphoma, and those – specifically ones that would qualify. You know, that that might be another issue. But as far as sold by prescription, that it has to be something that requires a prescription, it – excuse me, the prescription medicine, requires a prescription and is actually sold by prescription.
Q. Okay.
A. And I think the department's position with respect to this case deals with the issues that hospitals do not need a prescription in order to purchase blood products, you know, in order to do that because hospitals are considered the user or consumer under the statute, under the Sales Tax Statute of anything that they buy, medicines, drugs or equipment, and that they are – that based on those two cases that the determination in this particular issue that we're dealing with here today is that, you know, they were not sold by prescription and – or a prescription that was required under the provisions of the Home Medical case and the Associated Medical case.

Q. Is blood subject to tax in South Carolina?
A. I think the department stated its position under department determination that it would be unless it's used to treat certain diseases.
Q. Is blood being taxed now in South Carolina?
A. That would be an issue, you know. As I think I mentioned earlier, that the department/audit division had made a determination as far as not taxing certain levels of blood and blood – I don't know whether you call it products or not, but certain levels and taxing other levels of it and that – and, obviously, it's been taxed because you're claiming a refund here. So I mean, there's a little bit of issues there.
Q. Well, my question was, do you know if hospitals in the State of South Carolina are paying sales tax on their purchases of blood, whole blood?
A. Whole blood? I don't know whether your issue deals with blood or blood products.
Q. No. I'm just asking the question, do you know of your knowledge whether hospitals in South Carolina are paying sales tax or use tax on their purchases of whole blood?

A. I could not say one way or the other because I don't deal with the hospitals, but –
Q. Okay. You don't know?
A. I don't know other than – unless part of this refund deals with it. That would be the only way I would know.
Q. Okay. Do you know if hospitals are paying tax on blood products in South Carolina?
A. Again, because you're claiming a refund in this case, that would be an issue there, you know, on some hospitals. Now, whether all hospitals are is another issue.
Q. So you don't know of your own personal knowledge or your own professional knowledge whether hospitals in South Carolina are paying sales tax or use tax on blood products?
A. All I can answer is with respect to whatever this – the refund case in this case because I don't audit hospitals and I don't deal with them.
Q. The issue in this case is blood derivatives, what has been described as blood derivatives. And do you know of your own knowledge whether or not hospitals in South Carolina are paying sales tax or use tax on their purchases of

blood derivatives?
A. Obviously, in this case, one did. Whether others are, I don't know.
Q. Is it the policy of the State of South Carolina to tax sales of whole blood?
A. I believe that the policy, you know, as far as derivatives here, I think that's set forth. I think the same policy would probably apply there. Now, whether there's been an official policy issued on that, the closest thing you've got is this department determination.
Q. You are the head of policy; is that correct?
A. Yes.
Q. Okay. Is the policy of the State of South Carolina to tax whole blood purchases by hospitals?
A. What do you mean by policy?
Q. Is it the official position promulgated by yourself and by the director of the department that hospitals are liable for the sales and use tax on their purchases of blood and that sellers of blood are required to collect the tax from the hospitals to whom they sell the blood?
A. Well, there's been no official policy

document, no revenue ruling on that issue specifically. Now, whether -- and there has been this issue here dealing with derivatives. And whether there has been issues dealing with how to handle this under audit as a result of this refund claim or anything else, any other results, you know, I don't know.
Q. So Mr. McCormack, what you're saying is there is no policy?
A. There's no official advisory opinion on blood, whole blood or blood products or blood derivatives.
Q. And you are not aware whether or not hospitals are actually paying tax on their purchases of whole blood in the State of South Carolina?
A. Since I don't audit the hospitals and have not been involved in discussing anything about hospital, other than this one dealing with this issue, I can't say one way or the other.
Q. In your discussions and deliberations within the department with regard to this audit, is there a proposal at hand from anywhere in the department that you need to issue an administrative notice or other public notice with regard to the department's position on the taxation of blood?

A. Not that I'm aware of discussing on that. As we've mentioned earlier, usually when there's cases going on, we're not issuing any advisory opinions until those cases are resolved. So since this case is going on, we would not issue an advisory opinion until it's resolved.
Q. Is the commissioner -- I'm sorry, the director of the department aware of the position of the department with regard to the taxation of blood?
A. That I can't say one way or the other. I have not discussed that with the new director.
Q. You don't know one way or the other if he is aware?
A. I just don't know one way or the other because I don't know whether litigation has discussed that.
Q. You have never discussed it with him?
A. No, not the -- not this new director, no.
Q. Did you discuss it with any of the old directors?
A. The issue probably came up when the issue first arose with the director at the time. I believe it was Ray Stevens and so probably had some initial discussions with him, but I don't recall the

specifics of them right now.
Q. And Mr. Stevens did not instruct you to issue any kind of administrative notice to the public with regard to the position of the department?
A. Not that I recall, no. I mean, because again the refund --
Q. But --
A. The refund issue had come in and so, again, we don't issue advisory -- formal advisory opinions when there's matters going on like that.
Q. 92-26 was a commission decision in 1992; is that correct?
A. Yes.
Q. Okay. And since 1992, no policy statement has been issued discussing 92-26, has it?
A. Not that I'm aware of; no.
Q. Do you know if the legislature is aware of Commission Decision 92-26 and the position of the Department of Revenue with regard to this case?
A. I could not tell you one way or the other. I don't -- I try to keep up with the legislation that they're proposing, but I can't tell you whether they've proposed anything in recent years. I just don't recall one way or the other, so

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a Roper St. Francis Healthcare, Plaintiff,	)	CIVIL ACTION NO: 12-ALJ-17-0405-CC
vs.	)	
SOUTH CAROLINA DEPARTMENT OF REVENUE, Defendant.	)	

* * * * * * * * * * * * * * * * * *

DEPOSITION OF: CHRISTINE BUDDIN

DATE TAKEN: March 28, 2013

TIME: 12:55 p.m.

PLACE: Nelson Mullins Riley & Scarborough, LLP
151 Meeting Street
Charleston, SC 29401

REPORTED BY: DENISE LAUDER
Registered Professional Reporter and Notary Public

* * * * * * * * * * * * * * * * * *

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EXHIBIT G

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Q. But this is Revenue Ruling 96-4, which is issued by the South Carolina Department of Revenue; is it not?
A. In my opinion, the purpose of this Revenue ruling is to say that radioisotopes may only be sold by prescription and so they were exempt.
Q. Okay. And that is the position of the South Carolina Department of Revenue?
A. Yes.
Q. Okay. That's all I have on that.
I want to -- one or two more questions on that. If a hospital or a taxpayer is in possession of radiopharmaceuticals without a prescription, do you know if that's a violation of law or regulation that is in any way actionable?
A. I do not know.
Q. Okay. You don't make any kind of determination whether or not a taxpayer has violated either Department of Pharmacy regulations or other criminal statutes in the possession of radiopharmaceuticals or other prescription medicines, or do you?
MR. MARINELLI: Objection to the form.
THE WITNESS: No.

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BY MR. CARPENTER:
Q. You don't make that determination?
A. No.
Q. Okay. But it was your determination that the radiopharmaceuticals were exempt under 96.4 and under the exemption statute in the sales and tax use law?
A. Yes.
Q. Okay.
(PLF. EXH. 3, Copy of invoice, was marked for identification.)
BY MR. CARPENTER:
Q. Ms. Buddin, I show you what has been marked for identification as Plaintiff's Exhibit 3, and ask you if you recognize that document.
A. I assume it's an invoice that I reviewed as part of the audit -- or refund.
Q. It's a purchase by -- from -- by Biomet. And do you know what your determination was with regard to the items on that invoice?
A. By looking at the description and seeing that it is rib cartilage, I exempted it.
Q. Can you tell us on what basis you exempted that?
A. On the basis that it was a body part.

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Q. Okay. And body parts are exempt from sales and use tax?
A. Administratively, it's been the audit's -- audit department's position that we have not taxed body parts.
Q. Okay. And what is the authority for that, for the administrative position of the Department of Revenue?
A. I asked the question and they said this is the way it's been done.
Q. Of whom did you ask the question?
A. I asked the -- my audit supervisor as well as the district audit manager.
Q. And what was their response?
A. Administratively, in the past, audit has taken -- the audit department has taken the stance we do not tax body parts.
Q. Okay. But they didn't cite you a statute or --
A. No.
Q. -- a regulation or anything?
A. No.
Q. Could they possibly have been talking about the Anatomical Gift Act?
A. Possibly.

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Q. I'm going to ask you to look at -- I think we need the Anatomical Gift Act. I'm going to ask you to take a look at Section 4443-10 of the South Carolina Code, and ask you if you would just read that provision out loud for us, if you would.
A. The implied warranties of merchantability and fitness are not applicable to the contract for the sale, procurement, processing, distribution, or use of human tissues, including, but not limited to, corneas, bones or organs, whole blood, plasma, blood products, or blood derivatives. Human tissue, whole blood, plasma, blood products, and blood derivatives must not be considered commodities subject to sale or barter, and the transplanting, injecting, transfusing or other transfer of these substances into the human body are considered a medical service.
Q. Okay. Now, would you go back to Exhibit 1.4, page 2, and read your --
A. Reason For Refund Denied -- Denied or Allowed, which one do you --
Q. Allowed portion, please.
A. Reason For Refund Allowed. Code Section 4443-10 reads -- what I just read. The invoices provided by the taxpayer were reviewed in

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detail and it was determined that all invoices for the purchase of human tissue and rib cartilage and therefore exempt. These invoices were accrued as a use tax by the taxpayer.

Q. Okay. I'm not clear. Did your supervisors cite that particular provision to you as the reason for exempting the rib cartilage?

A. Did they cite this?

Q. Did they tell you that was the authority -- that was the basis for their administrative decision -- their administrative position?

A. I don't recall them saying what their basis was. Again, what I remember them saying is, audit has not taxed body parts.

Q. Okay. But you cited that provision?

A. But I am familiar with 4443-10, yes.

Q. And you cited it in your determination?

A. That is correct.

(PLF. EXH. 4, Copy of invoice, was marked for identification.)

BY MR. CARPENTER:

Q. Go ahead. If you're refreshing yourself with regard to that invoice, that's precisely what I would like for you to do.

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A. Okay.

Q. Okay. I show you what's been marked for identification as Plaintiff's Exhibit Number 4, and ask if you would tell me what that invoice is.

A. It's called Humate.

Q. Okay. Is the purchase of Humate by Roper St. Francis Hospital, the taxpayer in this case?

A. Yes, it is made to Roper, a purchase by Roper.

Q. And would you tell me what your disposition was with regard to the purchase on that invoice?

A. Well, I had to find it to see, because I honestly could not remember if it was taxable or not, but according to my spreadsheet, I said that it was exempt because it is made -- it is human plasma.

Q. Okay. And how did you make that determination that it was human plasma?

A. I went to drugs.com and read about Humate.

Q. Okay. Is there an administrative finding or a Revenue ruling or anything of that sort issued by the Department of Revenue that would help you in making this determination?

A. Not that I know of.

Q. Okay. And would you have discussed this determination with your supervisors in the same manner that you discussed your other -- your other decisions on taxability?

A. Yes, I assume so. I don't recall if I specifically discussed this one particular drug, but...

Q. Okay. And once again, from your determination, why did you exempt Humate?

A. Again, I can't recall specifically what it said on drugs.com, but I'm assuming it was human -- mostly human plasma.

Q. Okay. And --

A. And it looks like it's sold like in a liquid form, in a vial.

Q. Okay. And would this have been pretty much in the same line as the previous exhibits that you looked at, where you determined -- where you used the Anatomical Gift Act as at least a part of your determination of taxability?

A. Yes.

(PLF. EXH. 5, Copy of chart, was marked for identification.)

Page 33

BY MR. CARPENTER:

Q. Now, Ms. Buddin, I show you what's been marked for identification as Plaintiff's Exhibit 5. Can you describe what that is?

A. It appears to be a chart that was put together, from what I was told, years ago to provide guidance to the auditors as to the -- what we would hold taxable or exempt.

Q. Do you know who put it together?

A. I don't remember the man's name, and I don't believe he works for us anymore.

Q. Who told you that somebody put it together?

A. I first saw this document when I was a part of another hospital audit within two years of when I was employed, and it was given to me by another auditor in our office.

Q. And not by your supervisor?

A. No.

Q. Okay. Would it be fair to say that this is a chart that lists whole blood at the top and it lists four subcategories of blood and three subcategories of plasma?

A. Yes.

Q. Okay. Now, on this chart, Plaintiff's

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Page 34

Exhibit 5, there is written -- handwritten the term, exempt, next to whole blood. The term, exempt, is also written next to the four divisions of whole blood. And then at the bottom there's a term written in that says, taxable, under the three subdivisions of plasma. Is that an accurate description of Plaintiff's Exhibit 5?

A. Yes.

Q. Do you know who wrote those notes on the paper?

A. No.

Q. Okay. What -- what do those notes tell you with regard to your -- the taxability or non-taxability of blood and its divisions as you -- as you move down?

A. Whole blood is exempt.

Q. Okay.

A. Red blood cells, white blood cells, platelets and plasma are exempt. Albumin, globulin, and fibrinogen are taxable.

Q. And you have used this in other audits of hospitals and health care systems, the information on this Plaintiff's Exhibit 5?

A. I used it previously in one other hospital audit.

Page 35

Q. In one other audit. Okay. And you got it from another auditor, so other auditors are using it; is that correct?

A. The auditor I got it from no longer works for us, but at the time he was the auditor in charge of the audit I was working assisting with.

Q. Do you mind telling us who that is?

A. Who?

Q. The auditor that is no longer working for you.

A. Jack Thames.

Q. Jack?

A. Jack Thames, T-H-A-M-E-S.

Q. Okay. Thank you.

It is the policy of the Department of Revenue to not tax whole blood; is that right?

MR. MARINELLI: Object to the form.

THE WITNESS: Yes.

BY MR. CARPENTER:

Q. Okay. Is this document the authority for that policy, as far as you know?

A. I don't know if it's the authority. Again, it's just the guidance that the Department of Revenue or the audit division has taken as to how we were going to handle these purchases if they were found in audits.

Page 36

Q. Okay. Do you know if this is included in any regulation that was issued by the Department of Revenue?

A. I don't know.

Q. Is it issued in any other administrative notice that goes out to taxpayers in South Carolina to inform them of the position of the Department?

A. I don't know.

Q. Is it in any statute that was adopted by the Legislature, that you know of?

A. I don't know.

Q. Okay. Does it appear in the Anatomical Gift Act?

A. No.

Q. Okay. Are there other instructional charts, graphs or pieces of paper like this that are used by auditors to determine if these items are subject to sales tax?

A. I don't know. This is the only one that I recall.

Q. Okay. And this was not part of any manual or other document when you received it? Did you receive it just as a single piece of paper?

Page 37

A. I had it as a single piece of paper from the auditor from years ago.

Q. Okay. Has it ever been a subject of a training course that you had as a member of the Department of Revenue?

A. No.

Q. Okay. We are going to go through one more and then take a short break. Plaintiff's Exhibit 6.

(PLF. EXH. 6, Copy of invoice, was marked for identification.)

BY MR. CARPENTER:

Q. Ms. Buddin, I show you what has been marked for identification as Plaintiff's Exhibit Number 6, and ask you if you recognize that document.

A. I assume it's one of the invoices I reviewed as part of the refund.

Q. Okay. Can you look at your determination and tell me what your determination was with regard to the purchase on Plaintiff's Exhibit 6?

A. The product is called Gamunex and I held it as taxable.

Q. Okay. Can you tell me why you held

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this purchase to be taxable?
A. Upon researching what the drug was, it was determined that there was some human protein and then it was a manufactured product. It took other tangible stuff and it made a new product.
Q. Okay. And based upon that, you determined that it was subject to sales tax?
A. It fell within the guidelines of the taxable line almost in that -- that exhibit. It wasn't whole blood and it wasn't plasma, red blood cells, white blood cells, or platelets.
Q. But your decision with regard to Gamunex in Plaintiff's Exhibit 6 was based upon your use of the chart which is Plaintiff's Exhibit 5?
A. I based it upon the decision that it really was a manufactured product. It was not whole blood, plasma, white blood count, or red blood count, or platelets.
Q. Can you tell me where in the tax code those types of product are subjected to sales tax?
A. No, I can't.
Q. Do you know what a blood derivative is?
A. No, I don't.
Q. Do you know what a blood product is?

Page 39

A. Not specifically, no.
Q. And you have some idea what whole blood is, I'm sure.
A. Yes.
Q. Okay. How does a -- how does the blood derivatives, blood products, how do they differ from whole blood as far as -- as far as you would determine in making your decisions on taxability?
A. The blood products, again, are -- appear to be manufactured products. They take a portion of a blood product or a blood protein and they add additional material to it, and the end result is a totally different product. Some of the products that we looked at ended up being a powder form and came in a package.
Q. Okay.
A. So it's totally different than what was taken out of the body. It was a manufactured product.
Q. Is there a regulation or an administrative notice or something of that sort issued by the Department that makes the differentiation that you have just made between whole blood and blood products and blood derivatives?

Page 40

A. Not that I'm aware of.
Q. Okay. So when you made that distinction, is this something that you discussed with your supervisors?
A. Yes.
Q. Okay. And do all auditors in South Carolina make that distinction?
A. I don't know.
Q. Okay. But your supervisors are aware of the fact that you make it and you -- you base your decisions on taxability on the research that you just described to me from the website that you mentioned?
A. On this particular drug, yes.
Q. Okay. Do you know what fractionated plasma products are?
A. No.
Q. I'm going to show you Commission Decision 92.26, and ask you if you recall -- or what does that -- how does that decision inform your actions with regard to the taxability of blood and blood products? Are you familiar with Commission Decision 92.26?
A. No.
Q. Okay. I believe you cited it in your

Page 41

findings with regard to -- to Gamunex.
A. Where would that be?
Q. I think it's on page 6 and 7, Exhibit 1.2.
A. Okay.
Q. Okay. You did cite that?
A. I did.
Q. Okay. If you recall, what does your -- what is your understanding of the holding of the Commission in Commission Decision 92-26?
A. It recognizes the sale of blood and blood derivatives as tangible personal property subject to sales and use tax.
Q. So Commission Decision 92-26 says blood is subject to sales and use tax?
A. It says the sale of blood is the sale of tangible personal property and that they are medicines.
Q. Okay. Did Commission Decision 92-26 hold the items that were at issue in that case taxable or nontaxable, as far as you recall?
A. Repeat the question.
Q. Did the Commission Decision 92-26 -- and I'll tell you that at issue in that case were blood products.

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From: Tommy Butler
To: DONOVAN, TIM
Date: 9/6/02 10:48AM
Subject: Re: Blood, Plasma...etc

Tim,

We went through a period where we did not tax it based on a 1968 Act #1154 (I have a copy of it) which stated blood, plasma, blood products or blood derivatives were not considered a commodity for sale.

Then Steve Hallman provided us with Commission Decision 92-26 which indicated blood is a sale of tangible personal property but may be exempt as a prescription medicine. Thus, we started taxing blood and its derivatives when purchased by hospitals as the end user.

Then we changed and decided not to tax blood and its derivatives.

So, to answer your question we did not tax it - then for about three years we did tax it and now for the past two to four years we have not taxed it.

I am not sure if this helps, but we have not been consistent in Charleston on this issue.

>>> TIM DONOVAN 09/06/02 09:46AM >>>
I am interested in how each district has been handling the taxability of blood, plasma, etc. Are you taxing blood, plasma, blood derivatives when sold to a hospital?

Any help would be greatly appreciated.

Thanks,
Tim

000048

EXHIBIT H

From: BUDDY CREECH
To: DONOVAN, TIM
Date: 9/6/02 10:35AM
Subject: Re: Blood, Plasma...etc

When B'fort was open, we did the Hilton Head Hospital and were considering taxing the blood, plasma,etc purchases. I believe it was Steve Hallman who came up with a Ferderal code section that prohibted the taxing of sale of blood, etc.

To answer your question, B'fort never taxed these items and I have not seen the issue since coming to Chas. Tommy may be able to address what has happened in Chas.

>>> TIM DONOVAN 09/06/02 09:46AM >>>
I am interested in how each district has been handling the taxability of blood, plasma, etc. Are you taxing blood, plasma, blood derivatives when sold to a hospital?

Any help would be greatly appreciated.

Thanks,
Tim

From: James Watson
To: DONOVAN, TIM
Date: 9/6/02 9:57AM
Subject: Re: Blood, Plasma...etc

Florence has not taxed blood because most blood transactions were conducted by the Red Cross who is considered an instrumentality of the federal government. Plasma, platelets, and other derivatives have not been taxed because the Resource Ring indicated that the DOR had an unwritten policy not to tax body parts and tissues even though there is no exemption for blood and blood derivatives.

>>> TIM DONOVAN 09/06/02 09:46AM >>>
I am interested in how each district has been handling the taxability of blood, plasma, etc. Are you taxing blood, plasma, blood derivatives when sold to a hospital?

Any help would be greatly appreciated.

Thanks,
Tim

000050

Drugs.com

Gamunex

Generic Name: Immune globulin (intravenous) (IGIV) (im MYOON GLOB yoo lin)
Brand Names: *Carimune, Flebogamma, Gammagard, Gammagard S/D, Gammaplex, Gammar-P I.V., Gamunex, Octagam, Polygam S/D, Privigen, Sandoglobulin*

What is Gamunex?

Gamunex (immune globulin) is a sterilized solution made from human plasma. It contains the antibodies to help your body protect itself against infection from various diseases.

Gamunex is used to treat primary immune deficiency conditions. Gamunex is used to treat people with chronic inflammatory demyelinating polyneuropathy (CIDP), primary immunodeficiency (PI), or idiopathic thrombocytopenic purpura (ITP).

Gamunex may also be used for purposes not listed in this medication guide.

Important information about Gamunex

Gamunex can harm your kidneys, and this effect is increased when you also use certain other medicines harmful to the kidneys. Before using Gamunex, tell your doctor about all other medications you use. Many other drugs (including some over-the-counter medicines) can be harmful to the kidneys.

Before using Gamunex, tell your doctor if you have kidney disease, diabetes (especially if you use insulin), a history of stroke or blood clot, heart disease, high blood pressure, a condition called paraproteinemia, or if you are over 65 years old.

To be sure Gamunex is helping your condition and is not causing harmful effects, your blood will need to be tested often. Your kidney function may also need to be tested. Visit your doctor regularly.

Gamunex can cause unusual results with certain blood glucose tests. Tell any doctor who treats you that you are using Gamunex.

Gamunex is made from human plasma (part of the blood) which may contain viruses and other infectious agents. Donated plasma is tested and treated to reduce the risk of it containing infectious agents, but there is still a small possibility it could transmit disease. Talk with your doctor about the risks and benefits of using Gamunex.

Before using Gamunex

You should not use Gamunex if you have ever had an allergic reaction to an immune globulin or if you have immune globulin A (IgA) deficiency with antibody to IgA.

PO Box 125
Columbia, SC 29214
Phone: 803 898-5619
Fax: 803 898-5685

South Carolina Dept of Revenue

Fax

To:	Allison Lanier	From:	Tim Donovan
Fax:	813 329 2320	Date:	October 28, 2003
Phone:	704 344 7784	Pages:	1
Re:	Blood Derivatives	cc:	

☐ Urgent x For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

•Comments:

Whole blood is made up of four components. Red Blood Cells, White Blood Cells, Platelets, and Plasma.

The Department allows an administrative exemption for whole blood, red blood cells, white blood cells, platelets, plasma, and any other organ which can be transplanted from one person to another without being manufactured into a new medicine.

Blood Derivatives are generally produced from source plasma by medical manufactures and therefore considered medicines subject to the sales tax. These include such products such as albumin, globulin, Fibrinogen, and many of the vaccines used today.

If you have any further questions you may contact me (803) 898-5619.

000052

Tim Donovan
South Carolina Dept of Revenue
PO Box 125
Columbia SC 29214

South Carolina Dept of Revenue

Fax

To:	Jack Thames	From:	Tim Donovan
Fax:	843 556-1780	Pages:	6
Phone:		Date:	8/29/2008
Re:	Blood Derivatives	CC:	

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

• Comments:

After review if you want to discuss further let me know and I will give you some background on the reasoning. I will be in meetings this morning but will be available after lunch.

Tim

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State of South Carolina
Department of Revenue
301 Gervais Street, P.O. Box 125, Columbia, South Carolina 29214

April 29, 2003

Roper Hospital Systems
Charleston SC

Dear Sir or Madam:

For conversation on April 29, 2003, the following is a discussion on the Departments position on blood and blood products.

Code Section 12-36-910(A) is the imposition of Sales Tax and states:

> A sales tax, equal to five percent of the gross proceeds of sales, is imposed upon every person engaged or continuing within this State in the business of selling tangible personal property at retail.

Code Section 12-36-110 defines Sale at Retail; Retail Sale as:

> Sale at retail and retail sale mean all sales of tangible personal property except those defined as wholesale sales.

Code Section 12-36-110(c) includes:

> the withdrawal, use or consumption of tangible personal property by anyone who purchases it at wholesale..

Code Section 12-36-60 defines Tangible Personal Property as:

> "Tangible personal property" means personal property which may be seen, weighed, measured, felt, touched, or which is in any other manner perceptible to the senses. It also includes services and intangibles, including communications, laundry and related services, furnishing of accommodations and sales of electricity, the sale or use of which is subject to tax under this chapter and does not include stocks, notes, bonds, mortgages, or other evidences of debt. Tangible personal property does not include the transmission of computer database information by a cooperative service when the database information has been assembled by and for the exclusive use of the members of the cooperative service.

In the issue of determining the taxability of blood products one must first determine if it is considered tangible personal property, then whether or not it is sold at retail, and lastly, if it is considered exempt under statute.

In Commission Decision 92-26 the Department argued that blood was not tangible personal property under the language found in §44-43-10, which states:

> The implied warranties of merchantability and fitness shall not be applicable to a contract for the sale, procurement, processing, distribution or use of human tissues such as corneas, bones or organs, whole blood, plasma, blood products or blood derivatives. Such human tissues, whole blood, plasma, blood products or blood derivatives shall not be considered commodities subject to sale or barter and the transplanting, injection, transfusion or other transfer of such substances into the human body shall be considered a medical service.

The outcome of the Commission Decision 92-26 changed the Department's position as the Commission ruled that "The general rule is that nothing may be read into a statute which is not within the manifest intention of the legislature as gathered from the act itself, and that a statute should not be construed any more broadly or given any greater effect than its terms require. Where the language of the statute is clear in limiting its application to a particular class of cases and leaves no room for doubt as to the intention of the legislature, there is no authority to transcend or add to the statue, which may not be enlarged, stretched, or expanded..." 73 AM.Jur.2d, Statutes, § 198, p. 394. The Commission found that the reliance of §12-36-60 which states "Tangible personal property means personal property which may be seen, weighed, measured, felt, touched, or which is in any other manner perceptible to the senses..." would be a more applicable statute.

Through this Commission Decision the Department's position changed to one of taxable instead of exempt. In an attempt to conform with the Federal prohibition for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce, the Department continued the policy of not taxing whole blood, plasma, red blood cells, white blood cells, platelets, or any human organs such as kidneys, livers, hearts, lungs, pancreas, bone marrow, cornea, eye, or any parts of a human fetus. The Department would continue to tax any blood products and blood derivatives sold as medications at retail.

If you have any further questions concerning the South Carolina Sales and Use Tax statutes, please do not hesitate to contact me at (803) 898-5619.

Yours very truly,

SOUTH CAROLINA DEPT OF REVENUE
OFFICE OF APPEALS

Tim Donovan
Tax Analyst

cc: Jan Crangle
Tommy Butler

PROPOSED LEGISLATION FOR 2003 SESSION

TAX TYPE: Sales and Use

CODE SECTIONS AFFECTED: 12-36-2120

PURPOSE OF THE AMENDMENT: Exempt whole blood, organs, plasma.

EXPLANATION OF THE AMENDMENT: Prior to CD 92-26 the Dept of Revenue did not tax blood, organs, plasma, and blood derivatives due to the ruling of Samson v. Greenville Hospital. This case stated that under Code Section 44-43-10 these products have no implied warranties of merchantability. Under CD 92-26 the Commission rejected the Departments assertion that blood and human tissue did not fall under the definition of tangible personal property, but also found that these products could be considered medicine under Code Section 12-36-2120(28).

In 1997 the Court of Appeals in an unpublished ruling found in favor of the Department in a ruling that stated medicine sold by prescription must be sold by prescription, and that sales of prescription medicines sold to hospitals, doctors, and alike do not meet the exemption.

Therefore, in order to exempt products such as whole blood, organs, and human tissue which is donated from one individual, sold and delivered to hospitals, and transplanted into another individual we must have an exemption from the sales tax .

ADMINISTRATIVE IMPACT: Administrative impact would be minimal.

REVENUE IMPACT: There should be no revenue impact on this exemption. The Department is not currently pursuing the purchases of these products..

SUBMITTED BY: Tim Donovan
DATE: 10/15/2002

APPROVAL:
DATE:

ATTACH DRAFT OF PROPOSED LEGISLATION:

( ) human tissue transplants, which shall be defined to include all human organs, bone, skin, cornea, blood and blood products transplanted from one individual into another recipient individual.

PO Box 125
Columbia, SC 29214
Phone: 803 898-5619
Fax: 803 898-5665

South Carolina Dept of Revenue

Fax

To:	Allison Lanier	From:	Tim Donovan
Fax:	813 329 2320	Date:	October 28, 2003
Phone:	704 344 7784	Pages:	1
Re:	Blood Derivatives	CC:	

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Whole blood is made up of four components. Red Blood Cells, White Blood Cells, Platelets, and Plasma.

The Department allows an administrative exemption for whole blood, red blood cells, white blood cells, platelets, plasma, and any other organ which can be transplanted from one person to another without being manufactured into a new medicine.

Blood Derivatives are generally produced from source plasma by medical manufactures and therefore considered medicines subject to the sales tax. These include such products such as albumin, globulin, Fibrinogen, and many of the vaccines used today.

If you have any further questions you may contact me (803) 898-5619.

000057

From: TIM DONOVAN
To: CLELAND, MEREDITH
Date: 10/18/02 10:34AM
Subject: Blood Legislation

Attached is the proposed legislation document that I had put together for an exemption for blood and related products. I understand that you are contacting the Hospital Association so that they may introduce legislation for an exemption.

As you are aware, legislation was proposed in the past to exempt blood, organs, plasma, and blood derivatives but did not pass. The proposed legislation attached is worded slightly different in that it limits the exemption to those items that are transplanted from one individual to another. This was done because there is some question as to what is considered to be blood derivatives. Should the Hospital Association decide to go with the previously proposed legislation I would suggest that a definition for blood derivative be added.

Currently these items are taxable under the Code, but administratively we have tried to stay away from taxing the blood and human tissue items.

If you need any information on the background of this issue, and why we feel an exemption or clarification is needed, just let me know.

Tim

000058

US Code as of: 01/03/03

Sec. 274e. Prohibition of organ purchases

- (a) Prohibition
  It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.

- (b) Penalties
  Any person who violates subsection (a) of this section shall be fined not more than $50,000 or imprisoned not more than five years, or both.

- (c) Definitions
  For purposes of subsection (a) of this section:
  - (1) The term "human organ" means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human Services by regulation.
  - (2) The term "valuable consideration" does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.
  - (3) The term "interstate commerce" has the meaning prescribed for it by section 321(b) of title 21.

To: Jan Crangle
From: Sandra Long
Fax: 803 898-5685

As promised.

Sandra

000059

From: JOHN SWEARINGEN
To: CRANGLE, JAN
Date: 3/6/03 10:13AM
Subject: Fwd: Audit Supervisor Meeting

fyi

>>> BUDDY CREECH 3/6/2003 9:41:33 AM >>>
Based on audit supervisors' responses, I have prioritized the agenda topics for the proposed a/s meeting. We are requesting that the meeting be held on Tuesday, March 18 beginning at 10:00 a.m. in the Columbia office. Unless we hear differently, I will contact Ruth to get us a meeting room.

I have listed beside the agenda topics, the audit supervisor who will lead the discussion on that topic. Also listed are the names of person from the Cola office who the topic leader has asked to be involved in the discussions (guests). I will contact each of those persons to arrange their attendance.
Each leader will be responsible for forwarding any info he/she wants the supervisors and/or the guests to review prior to our meeting.

AGENDA:

Topic	Leader	Guest(s)
(1) Hospitals	Denise	Robby, Jan, Gary Heuer
(2) S & U Tax on Out-State Vendors	John C	Robby, Jan
(3) Statute Non-reg. T/p's	Denise	Robby — Sept Aug 1985
(4) Mfg S & U	John C	Gary Heuer
(5) Construction Contracts w/ Fed	Buddy	Robby
(6) ST-8 for Water Treatment Contractor	Buddy	Robby
(7) Large $ Audits & Issues	John S	
(8) Nexus Initiative	John S	
(9) EPMS Changes	Roger	
(10) Mini Data	David M	
(11) Data Project	David M	

Should there be questions, please call or e-mail. I will act as facilitator for this meeting. A new facilitator will be elected for any future meetings. THANKS!!!

Note: Unless Robby or R/M's veto this meeting, I will see you on Tuesday, March 18 at 10:00 a.m. in Cola. I will forward meeting room number at a later date.

CC: DONOVAN, TIM

000060

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General composition of blood.

On top of the formed elements is the blood plasma. This straw-colored fluid makes up approximately 55% of the total blood volume.

By weight, the composition of plasma is about 91.5 % water and 8.5% dissolved solutes. Most of the dissolved solutes are proteins. The remaining solutes are a mixture of nutrients, electrolytes, nitrogenous wastes, respiratory gases, and regulatory compounds.

End 2

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Plasma Proteins

Types	% (by wt.)	Functions
Albumins	60-80	Made by the liver. Creates osmotic pressure that prevents too much water from exiting the capillaries to the surrounding interstitial fluids. Add to blood viscosity. Transport lipids, hormones, & Ca^{2+}.
Globulins	36	Alpha & beta globulins: Made by liver. Transport lipids, fat-soluble vitamins, hormones, & metal ions. Gamma globulins: Antibodies made by lymphocytes.
Fibrinogen	4	Made by the liver. Forms fibrin during clotting process.

Close window

General composition of blood.

If a tube of blood is left standing or spun briefly in a centrifuge, the components will separate into layers, based on their density.

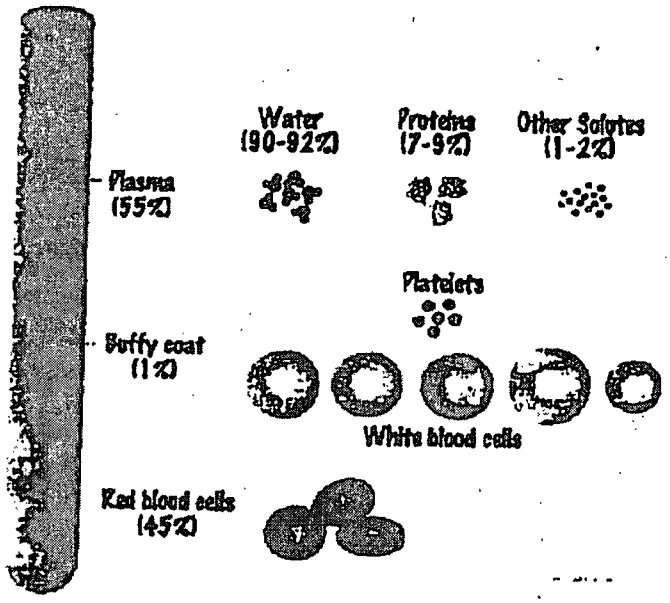
The bottom, red-colored layer is filled with red blood cells. Red blood cells normally occupy about 45% of the total blood volume (females = 37-48% & males = 45-52%).

Above the red blood cells is the "buffy coat". This narrow, white band is composed of white blood cells and cell fragments called platelets. Approximately 1% of the blood volume is occupied by these components.

Together, the RBCs, WBCs, and platelets are referred to as the blood's formed elements.

On top of the formed elements is the blood plasma. This straw-colored fluid makes up approximately 55% of the total blood volume.

By weight, the composition of plasma is about 91.5 % water and 8.5% dissolved solutes. Most of the dissolved solutes are proteins. The remaining solutes are a mixture of nutrients, electrolytes, nitrogenous wastes, respiratory gases, and regulatory compounds.



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End 2

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Selected Non-protein Plasma Solutes

Nutrient	mg/dl	Nutrient	mg/d
Glucose (dextrose)	70-110	HDLs	30-80
Amino acids	33-5	LDLs	82-185
Lipids (total)	450-850	Triglycerides	40-15
Cholesterol (total)	120-220	Phospholipids	8-12
Fatty acids	190-420	Nutrient	µg/dl
		Iron	50-15
Electrolytes	**mEq/L**	**Electrolytes**	**mEq/**
Sodium (Na^+)	135-145	Chloride (Cl^-)	100-10
Potassium (K^+)	3.5-5.0	Bicarbonate (HCO_3^-)	23.1-2
Magnesium (Mg^+)	1.2-2.1	Phosphate (HPO_4^{2-})	104-2
		Sulfate (SO_4^{2-})	0.0-1.2
Nitrogenous wastes	**mg/dl**	**Nitrogenous wastes**	**mg/dl**
Ammonia	0.02-0.09	Creatinine	0.8-1.
Urea	8-25	Uric acid	1.5-8.
Creatine	0.2-0.8	Bilirubin	0-1.0
Respiratory gases (O_2, CO_2, N_2)			Close windo

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14 7634-000 (Published August 1994)

Tetanus Immune Globulin (Human)

BayTet™

Solvent/Detergent Treated
250 Units

DESCRIPTION

Tetanus Immune Globulin (Human) — BayTet™ treated with solvent/detergent is a sterile solution of antitoxic hyperimmune antibody globulin for intramuscular administration. It contains no preservative. BayTet is prepared by cold ethanol fractionation from the plasma of donors immunized with tetanus toxoid. The antibody globulin is isolated from established Cohn Fraction II. The Fraction II solution is subjected to a final concentration of 0.3% tri-n-butyl phosphate (TNBP) and 1.0% sodium cholate. After the addition of solvent (TNBP) and detergent (sodium cholate), the solution is heated to 30°C and maintained at that temperature for not less than 6 hours. After the viral inactivation step, the reactants are removed by precipitation, filtration and finally by diafiltration and pasteurization. BayTet is formulated to a pH of 6.4–7.2 in 0.21–0.32 M glycine. BayTet is then transferred to the final container for 21–30 days at 20–27°C. The product is nonreactive against the U.S. Standard Antitoxin and the U.S. Control Tetanus Toxin and contains not less than 250 tetanus antitoxin units per container.

The removal and inactivation of lipid coated viruses and non-enveloped viruses during the manufacturing process for BayTet has been validated as laboratory studies. Human immunodeficiency virus, Type 1 (HIV-1), was chosen as the relevant virus for blood products; Sindbis Virus (Semliki Virus) (SVEV) was chosen to model Hepatitis C virus; Pseudorabies virus (PRV) was chosen to model Hepatitis B virus and the Herpes viruses; and Reo virus type 3 (Reo) was chosen to model non-enveloped viruses and for its resistance to physical and chemical inactivation. Significant removal of lipid coated and non-enveloped viruses is achieved at two steps in the Cohn fractionation process leading to the collection of Cohn Fraction II: the precipitation and removal of Fraction III in the processing of Fraction II + III suspension to Filtrate II and the filtration step in the processing of Filtrate II to Fraction II. Substantial inactivation of enveloped viruses is achieved at the time of treatment of solubilized Cohn Fraction II with TNBP/detergent mixture.

CLINICAL PHARMACOLOGY

The occurrence of tetanus in the United States has decreased dramatically from 840 reported cases in 1947, when national reporting began, to a record low of 48 reported cases in 1987.[1] This decline has resulted from widespread use of tetanus toxoid and improved wound management, including use of tetanus prophylaxis in emergency rooms.[2]

BayTet provides passive immunity to those individuals who have low or no immunity to the toxin produced by the tetanus organism, *Clostridium tetani*. The antibodies act to neutralize the free form of the powerful exotoxin produced by this bacterium. Maximizing such passive protection has prompted by extensive derived from equine or bovine sources; however, the foreign protein in these heterologous products often produced severe allergic manifestations, even in individuals who demonstrated negative skin and/or conjunctival tests prior to administration. Reminders of the frequency of these foreign protein reactions following treatment of equine origin tested from 5%–32%.[3-5] If passive immunization is needed, human tetanus immune globulin (TIG) is the product of choice. It provides protection longer than antisera of animal origin and causes few adverse reactions.[6]

Several studies suggest the value of tetanus toxoid antitoxin in the treatment of active tetanus.[7,8] In 1951 and 1952, Madsen et al,[7] using BayTet treated 257 patients with tetanus using single doses of 3,000 to 6,000 antitoxin units in combination with other accepted standard and supportive procedures. Six patients, all over 46 years of age, died of causes other than tetanus. The authors felt that this treatment was better than the 50% assigned death rate for tetanus reported from 1937 to 1950.[9] States et al,[8] however, found in a case analysis of 346 cases of tetanus reported to the Centers for Disease Control from 1965 to 1971 that received was no better with 6,000 units of TIG than with 500 units; however, an optimal dose could not be determined.

Serologic tests indicate that naturally acquired immunity to tetanus toxin does not occur in the United States. Thus, successful primary immunization, with subsequent maintenance of adequate antitoxin levels by means of appropriate booster doses of tetanus toxoid, is necessary to prevent tetanus among all age groups. Tetanus toxoid is a highly effective antigen; a completed primary series generally induces protective levels of serum antitoxin that persist for 5 to 10 years.[7]

Passive immunization with BayTet may be undertaken concomitantly with active immunization using tetanus toxoid in those persons who need receive an immediate injection of tetanus antitoxin and in whom it is desirable to begin the process of active immunization. Based on the work of Rubbo,[10] MacComb and Dwyer,[11] and Lowbe et al,[12] the physician may thus supply immediate passive protection against tetanus, and at the same time begin formation of active immunization in the injured individual which upon completion of a full series will provide long term need for protection.

Peak blood levels of IgG are obtained approximately 2 days after intramuscular injection. The half-life of IgG in the circulation of individuals with normal IgG levels is approximately 23 days.[13]

In a clinical study in eight healthy human adults receiving passive hyperimmune human globulin product treated with solvent/detergent, called Immune Globulin (Human), BayTet®, prepared by the same manufacturing process, detectable passive antibody were observed in the serum of all subjects by 24 hours post infusion and persisted through the 21 day study period. These results support the passive immunization with immune globulin products is not affected by the solvent/detergent treatment.

INDICATIONS AND USAGE

BayTet is indicated for prophylaxis against tetanus following injury in patients whose immunization is incomplete or uncertain (see below). It is also indicated, although evidence of effectiveness is limited, as the regimen of treatment of active cases of tetanus.[7,8,10]

Thorough attempt must be made to determine whether a patient has completed primary vaccination. Patients with antecedent or uncertain immunization histories should be considered to have had no previous tetanus toxoid doses. Persons who had ordinary combined childhood vaccines in the years 1941 can be considered to have received at least one dose, and although most of them may have completed a primary series of three doses, they cannot be assumed to have been immunized. Persons who have not completed a primary series may require tetanus toxoid and passive immunization at the time of wound cleaning and debridement.[7]

The following table is a summary guide to tetanus prophylaxis in wound management:

Guide to Tetanus Prophylaxis in Wound Management[7]

History of Tetanus Immunization (Doses)	Clean, Minor Wounds		All Other Wounds*	
	Td†	TIG‡	Td	TIG
Uncertain or less than 3	Yes	No	Yes	Yes
3 or more§	No¶	No	No¶	No

Such as, but not limited to, wounds contaminated with dirt, feces, soil, and saliva; puncture wounds; avulsions; and wounds resulting from missiles, crushing, burns and frostbite.

†Use type toxoid and diphtheria toxoid if the patient is up to 7 years old. DT is preferred to DTaP in children 7 years of age. Td is preferred to tetanus toxoid alone (see Dosage and Administration).

‡Tetanus Immune Globulin (Human)

§If only three doses of fluid tetanus toxoid have been received, a fourth dose of toxoid, preferably as adsorbed toxoid, should be given.

¶Yes if more than 10 years since the last dose.

Yes if more than 5 years since the last dose. (More frequent boosters are not needed and can accentuate side effects).

CONTRAINDICATIONS

A history

WARNINGS

Do not inject by the gluteal with caution in patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations.

Patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, BayTet should be given only if the expected benefits outweigh the risks.

CAUTIONS

General

BayTet should not be given intravenously. Intravenous injection of immunoglobulin intended for intramuscular use can cause shock. On occasion, a preexisting fall in blood pressure, and a picture not unlike anaphylaxis. Injections should only be made subcutaneously and should be taken to draw back on the plunger of the syringe before injection in order to be certain that the needle is not in a blood vessel. Intramuscular injections are preferably administered in the anterolateral aspects of the upper thigh and the deltoid muscle of

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[illegible] should not be given. The recommended injection of concentrated IgG solutions often causes a [illegible] which can be misinterpreted as a positive allergic reaction to antigens. This does not represent an allergy; rather it is localized tissue irritation. Misinterpretation of the results of such tests can lead the physician to withhold needed human antitoxin from a patient who is not actually allergic to the antitoxin. Two allergic responses to human IgG given in the prescribed intramuscular manner are rare.

Although systemic reactions to human immunoglobulin preparations are rare, epinephrine should be available for treatment of acute anaphylactic reactions.

Drug Interactions

Administration of immunoglobulin preparations may interfere with the response to live viral vaccines such as measles, mumps, polio, and rubella. Therefore, use of such vaccines should be deferred until approximately 3 months after [illegible] Ortho® pharmaceutical — BayTet® administration.

No interactions with other products are known.

Pregnancy Category C

Animal reproduction studies have not been conducted with BayTet. It is also not known whether BayTet can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. BayTet should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness in the pediatric population have not been established.

ADVERSE REACTIONS

Slight soreness at the site of injection and slight temperature elevation may be noted at times. Sensitization to repeated injections of human immunoglobulin is extremely rare.

In the course of routine injections of large numbers of people with immunoglobulin there have been a few isolated occurrences of angioneurotic edema, respiratory symptoms, and pulmonary shock after injection.

OVERDOSAGE

Although no data are available, clinical experience with other immunoglobulin preparations suggests that the only complications would be pain and tenderness at the injection site.

DOSAGE AND ADMINISTRATION

Passive prophylaxis (injury scheme)

Adults and children 7 years and older: BayTet, 250 units should be given by deep intramuscular injection (see PRECAUTIONS). At the same time, but in a different extremity and with a separate syringe, Tetanus and Diphtheria Toxoids Adsorbed (For Adult Use) (Td) should be administered according to the manufacturer's package insert. Adults with uncertain histories of a complete primary vaccination series should receive a primary series using the combined Td toxoid. To ensure continued protection, booster doses of Td should be given every 10 years.[1]

Children less than 7 years old: In small children the routine prophylactic dose of BayTet may be calculated by the body weight [4 d wording]. However, it may be advisable to administer the entire contents of the vial or syringe of BayTet (250 units) regardless of the child's size, since theoretically the larger amount of tetanus toxin produced in the child's body by the infecting tetanus organism has a and an adult's body. In the same way that to a different extremity and with a different syringe, Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed (DTP) or Diphtheria and Tetanus Toxoids Adsorbed (For Pediatric Use) (DT), if pertussis vaccine is contraindicated, should be administered per the manufacturer's package insert.

Note: The single injection of tetanus toxoid only ensures the same for producing active immunity in the recipient. The physician must impress upon the patient the need for further toxoid injections at 1 month and 1 year. Without such, the active immunization series is incomplete. If a contraindication to using tetanus toxoid-containing preparations exists for a person who has not completed a primary series of tetanus toxoid administration and that person has a wound that is neither clean nor minor, only passive immunization should be given using tetanus immune globulin.[2] See table under INDICATIONS AND USAGE.

Available evidence indicates that complete primary vaccination with tetanus toxoid provides long lasting protection (≥ 10 years for most recipients). Consequently, after complete primary tetanus immunization, booster doses for wound management need be given only every 10 years (most people and never) and uncontaminated. For other wounds, a booster is appropriate if the patient has not received tetanus toxoid within the preceding 5 years. Persons who have received all toxoid has been altered of tetanus toxoid rapidly develop antibodies.[3] The prophylactic dosage schedule for these patients and for those with incomplete or uncertain immunity is shown on the table in INDICATIONS AND USAGE.

Since tetanus is actually a local infection, proper wound care is of paramount importance. The use of antitoxin is adjunctive to this procedure. However, in approximately 50% of recent tetanus cases, no wound or other breach in skin or mucosal membrane could be implicated.[1]

Treatment of active cases of tetanus:

Standard therapy for the treatment of active tetanus including the use of BayTet must be instituted immediately. The dosage should be adjusted according to the severity of the infection.[1,2]

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. They should not be used if particulate matter and/or discoloration are present.

Directions for Syringe Usage

1. Remove the prefilled syringe from the package. Lift syringe by barrel, not by plunger.
2. Twist the plunger rod clockwise until the threads are locked.
3. With the rubber needle shield secured on the syringe tip, push the plunger rod forward a few millimeters to break any friction seal between the rubber stopper and the glass syringe barrel.
4. Remove the needle shield and expel air bubbles.
5. Proceed with hypodermic needle puncture.
6. Aspirate prior to injection to confirm that the needle is not in a vein or artery.
7. Inject the medication.
8. Withdraw the needle and dispose as directed.

HOW SUPPLIED

BayTet is supplied as 250 unit prefilled disposable syringes with attached needles and 250 unit single dose vials.

STORAGE

Store at 2–8°C (36–46°F). Solution that has been frozen should not be used.

CAUTION

U.S. federal law prohibits dispensing without prescription.

LIMITED WARRANTY

A number of factors beyond our control could reduce the efficacy of this product or even result in an ill effect following its use. These include improper storage and handling of the product after it leaves our hands, diagnosis, dosage, method of administration, and therapeutic considerations of individual patients. Selection of these factors is the responsibility and the practice has always been followed properly and that the instructions be followed carefully during use.

No warranty, express or implied, including any warranty of merchantability or fitness is made. Representatives of the Company are not authorized to vary the terms or the contents of the printed labeling, including the package insert for this product, except by printed notice from the Company's headquarters. The promotion and sale of this product shall accept the terms hereof.

REFERENCES

1. Tetanus — United States, 1987 and 1988. *MMWR* 36(3): 53-61, 1988.
2. Diphtheria, Tetanus, and Pertussis: Recommendations for Vaccine Use and Other Preventive Measures. Recommendations of the Immunization Practices Advisory Committee (ACIP). *MMWR* 40 (RR-10): 1-28, 1991.
3. Weinstein: Has Tetanus prophylaxis and serum sensitivity been. *Br Med J* 1: 703-4, 1918.
4. Sylvester I. The uses and results of active tetanus immunization. *Bull NHO* 13: 371-94, 1935.
5. Edsall G. Tetanus prophylaxis in trauma. *JAMA* 177(4): 417-27, 1939.
6. Commission may Spare results from tetanus program. *JAMA* 179(4): 763-4, 1962.
7. Hanson HB. Preop ref. Active Sd. et al. Tetanus: the use of human hyperimmune globulin in treatment. *Calif Med* 92(5): 355-6, 1960.
8. Ellis M. Human antitoxin serum in the treatment of tetanus. *Br Med J* 1(5332): 1123-6, 1953.
9. Aranki HW, Hargrove JD. Tetanus in the United States: a review of the program. *Am J Public Health* 47(12): 1553-1559, 1957.
10. Gubo PA, Pittman RA, Swanson TW, et al. Serologic survey of tetanus in the United States, 1962-1977. *JAMA* 239(7): 674-6, 1978.
11. Pusey SO. New approaches to tetanus prophylaxis. *Lancet* 2(7461): 449-52, 1969.
12. McCants JA, Boyce PC. Passive-active immunization with tetanus immune globulin (human). *N Engl J Med* 268(10): 537-40, 1963.
13. Lowry L, McCants JA, Boyce PC, et al. Acknowledgment letter: [illegible] stock, source of blood, dose of tetanus immune globulin and timing of symptoms. *N Engl J Med* 274(4): 199-200, 1966.
14. Wadsworth TA, Director of Blood Bank Operations in the evaluation of immunoglobulins marketed by licensed firms in Model 8 (ed.) Immunoglobulins: biologic aspects and clinical uses. Washington, DC: Nat Acad Sci, 1968, p. 23-61.
15. MacKinnon GA Jr, Stewart GL, Marshall AH. Clinical trials and of tetanus antitoxin and human immune globulin in surgical management. *Lancet* 1(7742): 1969-71, 1971.
16. Recommendations of the Immunization Practices Advisory Committee (ACIP). *General recommendations on immunization. MMWR* 38(12): 205-14, 219-27, 1989.
17. Tetanus Cases in the United States, 1958-1980. *Annual Summary 1980. MMWR* 30 (54-61), 1982.

Bayer

Bayer Corporation

Pharmaceutical Division

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Other drug names: A-Am An-Az B C-Ch Ci-Cz D-Dh Di-Dz E F G H I-J K-L M-Mh Mi-Mz N-Nh Ni-Nz O P-Pl Pm-Pz Q-R S-Sn So-Sz T-Ta Te-Tz U-V W-Z 0-9

Immune Globulin Intravenous (Human) (Systemic)

Contents of this page:

- Brand Names
- Category
- Description
- Before Using This Medicine
- Proper Use of This Medicine
- Side Effects of This Medicine
- Additional Information

Brand Names

Some commonly used brand names are:

In the U.S.--

- Gamimune N 5%
- Gamimune N 10%
- Gamimune N 5% S/D
- Gamimune N 10% S/D
- Gammagard S/D
- Gammagard S/D 0.5 g
- Gammar-P IV
- Iveegam
- Polygam S/D
- Sandoglobulin
- Venoglobulin-I
- Venoglobulin-S

In Canada--

- Gamimune N 5%
- Gamimune N 10%
- Gamimune N 5% S/D
- Gamimune N 10% S/D
- Iveegam

Other commonly used names are IGIV and IVIG .

Category

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- **Antibacterial, systemic**
- **anti-Kawasaki disease, systemic**
- **antipolyneuropathy agent**
- **antiviral, systemic**
- **immunizing agent, passive**
- **platelet count stimulator, systemic**

Description

Immune globulin intravenous (IGIV) belongs to a group of medicines known as immunizing agents. IGIV is used to prevent or treat some illnesses that can occur when your body does not produce enough of its own immunity to prevent those diseases.

IGIV should be administered only by or under the supervision of your doctor or other health care professional. IGIV is available in the following dosage form:

Parenteral
- Injection (U.S. and Canada)

Before Using This Medicine

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For immune globulin intravenous (IGIV), the following should be considered:

Allergies—Tell your doctor if you have ever had any unusual or allergic reaction to intramuscular or intravenous immune globulins. Also tell your health care professional if you are allergic to any other substances, such as foods, preservatives, or dyes.

Diet—Make certain your health care professional knows if you are on any special diet, such as a low-sodium or low-sugar diet.

Pregnancy—Studies on effects in pregnancy have not been done in either humans or animals.

Breast-feeding—It is not known whether IGIV passes into the breast milk. Although most medicines pass into breast milk in small amounts, many of them may be used safely while breast-feeding. Mothers who are using this medicine and who wish to breast-feed should discuss this with their doctor.

Children—Although there is no specific information comparing use of IGIV in children with use in other age groups, this medicine is not expected to cause different side effects or problems in children than it does in adults.

Older adults—Many medicines have not been studied specifically in older people. Therefore, it may not be known whether they work exactly the same way they do in younger adults. Although there is no specific information comparing use of IGIV in the elderly with use in other age groups, this medicine is not expected to cause different side effects or problems in older people than it does in younger adults.

From: "Carol Solomons" <Solomoc@dor.state.sc.us>
Newsgroups: scdor.tax.sales
Sent: Friday, November 20, 1998 11:23 AM
Subject: Re: Hospital Audits - Purchases of Blood & Body

I agree with your recommendation, Ed.

C. E. "Ed" Poore, Jr. wrote:

> I am recommending that we do not impose a tax on human tissue, whole blood,
> plasma, blood products or blood derivatives in accordance with Code Section
> 44-43-10 and Samson v. Greenville Hospital System, 377 S.E.2d 311, 297 S.C.
> 409, which states that transplanting, injection or other transfer of such
> substances into the human body shall be considered a medical service. The
> court case also states the Legislature clearly did not intend for blood to
> be classified as a product.
>
> Based on this information I am requesting each of you to consider this
> matter and advise if you can live with decision and move on. If we can
> reach a consenus I will post the answer. Thanks.
>
> Jan Steensen Crangle wrote:
>
>> It appears we may have some issues about whether the sale of blood and
>> body parts to hospitals are taxable. See CD 92-26 which indicates the
>> sale of blood is a sale of tangible personal property, but may qualify
>> as a prescription medicine. Since the recent Associated Medical court
>> decision (arising from appeal of CD 94-58) concludes hospitals are users
>> and consumers and not eligible for prescription medicine exemption, it
>> appears we would need legislation to exempt these issues.
>>
>> It is my understanding that the hospital is billed directly for the body
>> part (cornea, skin, etc.) although there may be a prescription for a
>> specific patient since it is necessary to do certain tissue matching,
>> etc. Blood on the other hand may be purchased without a specific
>> patient prescription and stocked for emergencies. In some instances

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a Roper/St. Francis Medical Healthcare, Inc., Petitioner, vs. South Carolina Department of Revenue,	)	**Docket No. 12-ALJ-17-0405-CC** **RESPONDENT'S MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT**

TO: RAYMOND CARPENTER, ESQ., JOHN VON LEHE, ESQ., AND BRYSON M. GEER, ESQ., ATTORNEYS FOR THE PETITIONER.

PLEASE TAKE NOTICE that the undersigned, as attorneys for the Respondent, South Carolina Department of Revenue (Department), will not sooner than ten days from the date of service of this Motion, or as soon thereafter as counsel may be heard, move for an order for summary judgment pursuant to Rule 56(c), SCRCP. It is the position of the Department that there is no genuine issue of material fact in dispute on the issues delineated below and it is entitled to judgment as a matter of law.

Background

This action was brought by Petitioner to challenge the Department's denial of a refund request for sales and use taxes paid on the purchases of various medical devices and processed plasma derivative medicines for tax periods ending August 1, 2007 through November 30, 2010. The Petitioner is a healthcare corporation comprised of Roper and St. Francis hospitals located in Charleston, South Carolina. The Petitioner submitted multiple ST-14 forms for refund requests, totaling $5,014,576.76 for sales and

use tax on purchases of medical devices (predominantly joint replacement implants and cardiac pacemakers), bone, tissue, blood products, plasma derivatives, and oncology medicines. The Department deemed a large portion of the taxpayer's claim valid and paid approximately $1.3 million in refunds of sales and use taxes to date. Approximately $3.1 million of the refund claims were based on the assumption that such prosthetic devices purchased by the hospital should be exempt from taxation pursuant to S.C. Code Ann. § 12-36-2120(28)(a) (Supp. 2012) as "sold by prescription." Another $435,000 was predicated upon protein-based medicines derived from human plasma that were claimed to be exempt from taxation based upon the applications of a products liability statute found at S.C. Code Ann. § 44-43-10 (Supp. 2011).[1] The Department denied those remaining amounts by letter dated March 24, 2011,[2] and the taxpayer timely protested this denial on June 20, 2011. The Department Determination upholding the denial was issued on August 16, 2012, maintaining that the devices at issue were not exempt from taxation Title 44 did not control with regard to taxing sales of tangible personal property. Standard discovery was completed, and based upon the facts determined therein this motion followed.

Legal Analysis

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[1]The Department denied the claims made for surgical implants and plasma derivative medicines on the legal grounds that such items were not exempt, and thus did not complete a full review the veracity of the invoices and substantiation provided. Should this Court rule in favor of the Petitioner for those issues, these portions of the refund claim must be subject to further review by the auditor.

[2]The Department did complete a separate audit of the Petitioner for the tax years at issue in this case and issued an assessment of approximately $100,000.00. The taxpayer initially protested this assessment, but ultimately chose not to pursue that challenge after conceding them in its Prehearing Statement.

Rule 56(c), SCRCP, provides that a trial court may grant a motion for summary judgment "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." See Bovain v. Canal Ins., 383 S.C. 100, 105, 678 S.E.2d 422, 424 (2009).

When construing a statute, the cardinal rule is to ascertain the intent of the Legislature. Georgia-Carolina Bail Bonds, Inc. v. County of Aiken, 354 S.C. 18, 22, 579 S.E.2d 334, 336 (Ct. App. 2003). "All rules of statutory construction are subservient to the one that legislative intent must prevail if it can be reasonably discovered in the language used, and that language must be construed in the light of the intended purpose of the statute." Id. at 23, 579 S.E.2d at 336. The words of the statute must be given their plain and ordinary meaning without resorting to subtle or forced construction to limit or expand the statute's operation. Hitachi Data Sys. Corp. v. Leatherman, 309 S.C. 174, 178, 420 S.E.2d 843, 846 (1992). Furthermore, "[t]he construction of a statute by the agency charged with its administration will be accorded the most respectful consideration and will not be overruled absent compelling reasons." Brown v. S.C. Dep't of Health & Envtl. Control, 348 S.C. 507, 515, 560 S.E.2d 410, 414 (2002) (quoting Dunton v. S.C. Bd. of Examin'rs in Optometry, 291 S.C. 221, 223, 353 S.E.2d 132, 133 (1987)); see also Nucor Steel v. S.C. Pub. Serv. Comm'n, 310 S.C. 539, 543, 426 S.E.2d 319, 321 (1992) (recognizing that where an agency is charged with the execution of a statute, the agency's interpretation should not be overruled without cogent reason).

I. The Petitioner's purchases of surgical devices do not qualify as exempt from sales tax as prosthetics sold by prescription pursuant to § 12-36-2120(28).

S.C. Code Ann. § 12-36-910 (Supp. 2012) imposes sales tax upon the retail sale of tangible personal property in this State. S.C. Code Ann. § 12-36-120 (2000) defines "wholesale sales" as sales of "tangible personal property to licensed retail merchants, jobbers, dealers, or wholesalers for resale, and **do not include sales to users or consumers** not for resale[.]" (Emphasis added). It is well settled law in this State that medical practitioners are regarded as the end users of prosthetics if such devices are furnished as part of the services rendered. Doctors and hospitals are not sellers of products but rather purveyors of medical services. See In re Breast Implant Product Liability Litigation, 331 S.C. 540, 503 S.E.2d 445 (1998). S.C. Code Ann. § 12-36-110 (2000) clearly defines the terms "sale at retail" and "retail sale" to include:

> (i) sales of drugs, prosthetic devices, and other supplies to hospitals, infirmaries, sanitariums, nursing homes, and similar institutions, medical doctors, dentists, optometrists, and veterinarians, if furnished to their patients as a part of the service rendered. These institutions, companies, and professionals are deemed to be the users or consumers of the property[.]

S.C. Code Ann. Regs. 117-308.8 (Supp. 2011) states:

> Hospitals, infirmaries, sanitariums, nursing homes and like institutions are engaged primarily in the business of rendering services. They are not liable for the sales tax with respect to their gross proceeds or receipts from meals, bandages, dressings, drugs, x-ray photographs and other tangible personal property where such property is used in the rendering of the primary medical service to patients. This is true irrespective of whether or not such tangible items are billed separately to their patients. Hospitals, infirmaries, sanitariums, nursing homes and like institutions are deemed to be the users or consumers of such tangible personal property and the instate [sic] sellers of these items are required to report and remit the tax due on the sale of such property to the hospitals, infirmaries, sanitariums, nursing homes, and like institutions . . . .

Regulation 117-308.3 adds: "Doctors are the consumers of the supplies, medicines, office furniture and fixtures and special tools and equipment they use in the practice of their profession. Sales of such supplies and equipment to doctors are retail sales and subject to the sales tax."

Clearly, in the absence of an exemption, the sale of devices to a medical institution is considered a retail sale when the devices are furnished as part of the medical services rendered and thus are subject to sales tax. The fact that the taxpayer purchases these devices on a patient specific basis or bills patients for them separately does not remove the transaction between the hospital and manufacturer from the province of retail sales. These devices are furnished as part of the treatment provided, and in that regard the taxpayer is considered the end user and its purchases are subject to sales tax.

While there is an exemption from sales and use tax provided by § 12-36-2120(28)(a) for "medicine and prosthetic devices sold by prescription," the transactions at issue do not qualify since hospitals and medical practitioners can legally purchase and possess regulated devices and controlled substances as they see fit to perform their medical services. The Petitioner's refund claim for devices consists, predominantly, of orthopedic and cardiac surgical implants[3] – such as hip and knee replacements, heart

[3]The refund claim for devices was divided into two classes – Prosthetics Group A and Group B. While both were denied on the basis that the exemption did not apply, Group B (which is comprised of cardiac pacemakers and implantable cardioverter-defibrillators) was also denied on the grounds that such devices did not qualify as "prosthetics" as defined by S.C. Code Ann. Regs. 117-332 (Supp. 2011), since they did not replace a missing body part. While Group B's issue is one of fact, it is not presented for adjudication by this motion. Furthermore, should this Court rule in favor of the Department and find that § 12-36-2120(28)(a) does not exempt purchases made by

valves, and other implantable devices – and naturally a hospital is not required to be "prescribed" these devices before purchasing them.

In Home Med. Systems, Inc. v. S.C. Dep't of Revenue, our Supreme Court clarified the exemption found in § 12-36-2120(28)(a). Specifically, the court stated that "[i]n our opinion, however, the current statutory language – 'medicine . . . sold by prescription' – clearly evidences a legislative intent that the exemption be only for those medicines **requiring** a prescription." 382 S.C. 556, 566, 677 S.E.2d 582, 588 (2009) (emphasis added). The court further held that "[i]n order for this exemption to be applicable . . . **the sale must require a prescription and the device must actually be sold by prescription** . . . ." Id. at 564 (citing S.C. Rev. Rul. # 03-02 (2003) (emphasis added). Furthermore, the court found that Certificates of Medical Necessity[4] (CMNs) are not equivalent to a prescription, despite such a document containing patient specific information and an order from a doctor for a specific treatment. That holding clearly evinces that not all lawful orders of a physician constitute a prescription. It logically follows, therefore, that the exemption applies only to sales transactions in which the purchaser is required to use a prescription in order to obtain the device and the device is actually sold to the purchaser by prescription.

A similar situation was also addressed in Associated Med. v. S.C. Tax Comm'n, Unpub. Op. No. 97-UP-447 (Aug. 26, 1997). While this decision is unpublished and

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hospitals, the determination of whether Group B falls into the category of "prosthetic" devices will be rendered moot.

[4]A CMN is a standard form used by Medicaid and Medicare that contains patient specific information. See Exhibit A; see also Home Med., 382 S.C. at 566, 677 S.E.2d at 588.

therefore lacks precedential value, the Department has assimilated its holding into policy documents and its long standing administrative practice. For example, the Associated Medical decision was the basis of the Department's position in Home Medical, noted above, and thus remains an important source of guidance. In Associated Medical, the Court of Appeals decided that a professional medical association (an institution similar to the Petitioner) was the user and consumer of the drugs it administered to patients as part of its professional services. The court further determined that the sale of such drugs to the doctors did not qualify for the exemption for "medicine . . . sold by prescription" because the purchases did not actually require a prescription. Rather, the court recognized that doctors have the ability to purchase medicines without a prescription, regardless of whether one is written.[5] Additionally, interpreting § 12-36-2120(28)(a) to mean that "all prescription medicines purchased by doctors or hospitals or similar institutions for the benefit of a patient of the doctor, hospital or institution" are exempt would cause S.C. Code Ann. § 12-36-2120(63) to become superfluous. S.C. Rev. Rul. # 11-3 (2011). Section 12-36-2120(63) (Supp. 2012) exempts "**prescription** and over-the-counter **medicines** and medical supplies . . . **sold to a health care clinic** that provides

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[5] While it may appear curious that the exemption does not apply to Appellant in this case but would apply if Appellant's patients simply took a prescription to a pharmacist, purchased the . . . medicine, and returned to Appellant for administering of the drug, we believe the exemption's plain language, its legislative history, and Department's interpretation of the exemption clearly demonstrate the legislature's intent that the **transaction** be the focus of the tax.

Associated Medical, Op. No. 97-UP-447 (emphasis added).

medical and dental care without charge to all of its patients." (emphasis added). The "prescription medicine" and "sold to a health care clinic" portions of subsection (63) would have been unnecessary if subsection (28)(a) meant that all prescription medicines purchased by doctors or hospitals were exempt. Such a result would be improper, as our Supreme Court has clearly held, "[a] statute should be so construed that no word, clause, sentence, provision or part shall be rendered surplusage, or superfluous." In re Decker, 322 S.C. 215, 219, 471 S.E.2d 462, 463 (1995).

A. Not all lawful orders from a physician constitute a prescription.

The Petitioner mistakenly believes that because some of its purchases of prosthetic devices are made on a patient-by-patient basis, that somehow this process creates the existence of a prescription as it relates to the hospital's transactions with the manufacturer.[6] This proposition is without merit, as it conflates the doctor's relationship with the patient – a transaction for medical services – with the hospital's retail transaction with the manufacturer of the prosthetic devices. It is imperative to note that the transaction between the hospital and patient is completely irrelevant to the taxable transaction between the hospital and manufacturer.

In order to properly grasp the distinctions in this case it is vital to understand the legal definition of a prescription in this State. The S.C. Pharmacy Practice Act defines "prescription drug order" as "a lawful order from a practitioner for a **drug or device** for a specific patient, issued for a legitimate medical purpose within the prescriber's course of

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[6]The Director of Material Services (procurement manager) for the hospital testified in his deposition that the hospital does keep prescription plates, screws, rods, spinal implants, and heart valves in inventory, purchased for emergency trauma purposes, without any specific patient in mind. See Ferguson Dep. 22:1-22:23, 37:14-39:16.

legitimate practice and including orders derived from collaborative pharmacy practice." S.C. Code Ann. § 40-43-30(47) (2011) (emphasis added). The Pharmacy Practice Act also uses the following definition as it relates to electronic prescription processing: "'Prescription' or 'prescription drug order' means a lawful order of a practitioner for a **drug or device** for a specific patient that is communicated to a pharmacist." S.C. Code Ann. § 44-117-310(7) (Supp. 2012) (emphasis added). Additionally, the Petitioner's proposed expert witness – Mary Pendergast – testified that "[a]s far as the FDA is concerned, a prescription is simply an order or an instruction from a physician that a device can or should be used for a particular patient for a particular purpose." Pendergast Dep. 40:20 – 41:1.

Ms. Pendergast's overly broad definition does not meet statutory muster, however, as not every lawful order from a physician constitutes a prescription. For example, our Legislature chose to separately define a "chart order" as something different from a prescription drug order. Specifically, a chart order is defined as follows:

> [A] lawful order from a practitioner for a drug or device **for patients of a hospital** or extended care facility, or such an order prepared by another person and signed by a practitioner either immediately or at another time, issued for a legitimate medical purpose within the practitioner's course of legitimate practice and including orders derived on behalf of a practitioner from a practitioner approved drug therapy management.

S.C. Code Ann. § 40-43-30(5) (Supp. 2012) (emphasis added). If an order from a practitioner for a patient of a hospital constituted a prescription, then the definition of chart order would be entirely superfluous. Thus, an "order" for a patient of a hospital

does not constitute a prescription. This logic is also supported by the FDA regulation related to controlled substances:

> Prescription means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user **(e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).**

21 C.F.R. § 1300.01 (emphasis added). To reiterate, an order for a patient of a hospital does not constitute a prescription, and this is easily understood by evaluating the underlying practical purpose of prescriptions – to provide adequate directions for use and/or to prove to a third-party that a doctor lawfully authorized the dispensing of some regulated product. Because the patient in the hospital is being directly administered the regulated products by medical professionals, the lawful orders issued in the hospital are classified separately as chart orders as there is no practical or legal need for a prescription. In that regard, not all orders from a physician constitute a prescription and the Petitioner's methods for procuring some of the prosthetic devices at issue on a patient specific basis do not give rise to a prescription-based transaction.

Finally, a prescription drug order must contain specific information in order to constitute a valid prescription. S.C. Code Ann. § 40-43-86(E) (2011) states the following regarding prescription drug orders:

> A prescription drug order shall contain at a minimum, the:
>
> (1) full name and address of the patient;
> (2) name, address, telephone number, and degree classification of the prescriber; license number, and Drug Enforcement Agency registration number of the prescribing practitioner where required by law;
> (3) date of issuance;

> (4) name, strength, dosage form, and quantity of drug prescribed;
> (5) directions for use;
> (6) number of refills authorized. No prescription marked "PRN" or any other nonspecified number of refills may be refilled more than two years beyond the date it was originally written. Nothing in this subsection abridges the right of a pharmacist to refuse to fill or refill a prescription; and
> (7) a written order signed by the prescriber, which shall bear the name of the patient; name, strength, and quantity of the drug or device prescribed; directions for use; date of issue; and, either rubber stamped, typed, printed by hand, or typeset, the name, address, telephone number, and degree classification of the prescriber; and, if a controlled substance is prescribed, the prescriber's federal registration number;
> (8) only one drug and set of instructions for each blank, if preprinted;
> (9) a chart order is exempt from the requirements of this subsection.

These requirements also apply to all oral and electronically transmitted prescriptions. See S.C. Code Ann. §§ 40-43-86(H)(2), (4), & (5); 44-117-340(A) & (B) (Supp. 2012). Furthermore, all prescriptions must be kept in written form for future reference or inspection. See S.C. Code Ann. §§ 40-43-86(F), (H)(2), (H)(4), & (H)(5); 44-117-340(A) & (B), S.C. Code Ann. Regs. §§ 61-4.508, 61-4.513, 61-4.517 (2011) (requiring that oral prescriptions be reduced to writing); see also 21 C.F.R. § 1306.11 (requiring oral authorizations in emergency situations to be immediately reduced to writing) and 21 C.F.R. § 1306.21 (requiring that oral prescriptions be promptly reduced to writing). Therefore, all prescriptions must contain patient specific information and be reduced to writing. In this case, the Petitioner claims that the surgeon's practice of orally ordering a device from a manufacturer's sales representative within the Petitioner's hospital for a patient constitutes a prescription. This argument lacks merit, given the statutory

requirements for prescriptions above. Even assuming *in arguendo* that such oral order could be construed as a prescription, however, the prescription would attach to the patient's purchase of services and not the Petitioner's purchases of devices for use.

B. The sale of the prosthetic device from the manufacturer to the Petitioner must *require* a prescription.

In order to qualify for the exemption at issue, the Petitioner must first establish that the transactions at issue ***require*** a prescription. See Home Medical, 382 S.C. at 566. In this case, it is both common sense and statutorily established that the transaction between the Petitioner and the device manufacturers does not require a prescription. Pursuant to S.C. Code Ann. § 40-43-60(H) (2011) a licensed practitioner does not need a prescription in order to possess or administer drugs or devices. Specifically, § 40-43-60(H) unequivocally provides:

> Nothing in this chapter shall be construed to require a permit of or to prevent a licensed practitioner as defined under Section 40-43-30(45) from possessing or administering drugs or devices, or compounding drugs used for administration in the regular course of professional practice.

By virtue of the medical license to practice, doctors, medical professionals, and hospitals (which carry a facility license), all have the legal authority to purchase the regulated devices and controlled substances that are necessary to practice medicine. As a result it is absolutely clear that a prescription is not required for a physician to purchase prosthetic devices. Furthermore, when Ms. Pendergast was asked "[i]f selling it to a physician is the same thing as a sale by prescription, why would there be the distinction then in

subsection (a)(2)[7] for it ***to be sold only to or on the order of***," Pendergast Dep. 55:11 – 14, she responded as follows:

> Well, I mean, it's very practical. If you're a -- if you are handing a device to a doctor because the doctor has asked you to sell the doctor the device, that is an implicit -- the sale is an implicit order saying, give me this. And so **you only need a prescription or other order if it isn't being sold directly to the doctor** because then you have to memorialize that that's what the doctor is asking for, is prescribing, is wanting.

Pendergast Dep. 55:15 – 56:1 (emphasis added).

The fact that a doctor does not need a prescription to purchase a "prescription only" item is further evinced by the deposition testimony of Petitioner's other witnesses - Dr. Nawabi, Dr. McCrosson, and Scott Ferguson. Dr. Nawabi explained how medical supplies, including "prescription only" items, are purchased in his practice. His explanation clearly indicated that a prescription is not required for his office to purchase "prescription only" items. Specifically, he stated that prescription only items are kept in

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[7]Referring to 21 C.F.R. § 801.109(a)(2) which states the following:

> A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:
>
> (a) The device is:
>
> . . . .
>
> (2) **Is to be sold only to** or on the prescription or other order of **such practitioner** for use in the course of his professional practice.

(emphasis added).

inventory, prior to any patients' needs being involved. See Nawabi Dep. 7:21 – 24. He also stated that no patient specific information is provided to the vendor prior to ordering the prescription only items that are kept in inventory. See Nawabi Dep. 11:13 – 12:19. Since a prescription requires patient specific information, see supra pp. 9-10, a prescription could not have been required in order for Dr. Nawabi's office to purchase the items kept in inventory before any patient was there to use them. To that extent, it logically follows that simply because the Petitioner chooses to purchase expensive prosthetics on a patient-by-patient basis, such a business decision does not miraculously create a transaction where a prescription is required. Furthermore, the clear testimony of the Petitioner's own witnesses show evidence that purchases of prescription drugs and devices can be purchased at will, without prescriptions. This testimony is fatal to the Petitioner's case.

Similarly, Dr. McCrosson discussed "prescription only" items that were kept in his office. Specifically, he mentioned that cortisone and local anesthetic were kept in inventory, but that the artificial joint fluid was not. McCrosson Dep. 61:18 – 62:4. Regarding the artificial joint fluid, Dr. McCrosson explained that he "wrote a prescription and the patient would go get it filled and bring it back, because we lost money if we kept it in inventory." McCrosson Dep. 62:4 – 7. When asked about purchasing cortisone (a controlled substance) that was kept in inventory, Dr. McCrosson said the following: "All I know is the medical assistants just took inventory and did monthly orders or something like that. But I don't know what was involved with doing that. I don't remember ever signing anything as part of that." McCrosson Dep. 62:19 – 23. Dr. McCrosson did not indicate that any patient specific information was transmitted prior to the purchasing of

the cortisone. Furthermore, no patient specific information would have been available since the cortisone was purchased prior to any specific patient being identified. Importantly, there was no impediment to the doctor with regard to purchasing the controlled substance without a prescription.

Mr. Ferguson, the hospital procurement director for medical and surgical supplies, stated that the Petitioner does keep an inventory of certain "prescription only" items. Specifically, he stated that the Petitioner has "some inventories of plates and screws," Ferguson Dep. 21:10 – 11, and "a few heart valves in inventory," Ferguson Dep. 37:20 – 21. Heart valves are regulated under the exact same laws as joint replacements, yet the hospital purchases these in bulk for trauma inventory without prescriptions. Further, when asked what documentation the Petitioner sends to the manufacturers, Mr. Ferguson only said that the Petitioner sends a purchase order to the manufacturer, see Ferguson Dep. 14:7 – 10, which does not contain any patient-specific information. The hospital's business decision to purchase some items to keep in inventory and not all of them is ostensibly for economic reasons. See Ferguson Dep. 10:14 – 11:7. It bears repeating that simply choosing to purchase some items as they are needed for a patient does not create a transaction that requires a prescription.

Additionally, Melanie Hutcherson, a national sales manager for Zimmer, Inc. (one of the manufacturers often used by the Petitioner), explained that hospitals could keep an inventory of prosthetic devices if they so choose, but because the sales reps are so accommodating many hospitals do not. Hutcherson Dep. 15:18-23. She further explained that in instances where the hospital owns the inventory, the only type of documentation that Zimmer, Inc. requires from the hospital to make the sale is a purchase order.

Hutcherson Dep. 16:24 – 17:15. As such, no patient-specific information is sent by the Petitioner to the manufacturers when "prescription only" inventory items are purchased because a prescription is clearly not required for the transaction.

Further evidence supporting the fact that a prescription is not required in order for a hospital to purchase prosthetic devices is the common sense conclusion that a doctor cannot write a prescription for a hospital. S.C. Code Ann. § 40-47-113(A) (2011) states that "[i]t is unprofessional conduct for a licensee initially to prescribe drugs to an individual without first establishing a proper physician-patient relationship." Additionally, S.C. Code. Ann. Regs. 61-4.508.2 and 61-4.514.2 (2011) state that "[a] practitioner cannot usually acquire a valid patient-practitioner relationship with himself or herself." A doctor simply cannot create a doctor-patient relationship with a corporate entity, thus it naturally follows that the purchases made by a hospital can ***never*** be transactions that require a prescription.

Additionally, when discussing to whom Dr. McCrosson was authorized to prescribe something, Dr. McCrosson stated that "as long as I establish a physician/patient relationship and document that in a chart, I can prescribe most things to most people, but I cannot prescribe certain controlled substances to family members or inappropriate relationships, where it would be foggy whether I had a proper therapeutic relationship." McCrosson Dep. 34:6 – 12. Moreover, another medical witness for the Petitioner, Dr. Baker, stated that a doctor-patient relationship could not be formed with a hospital, nor could he write a prescription to a hospital. Baker Dep. 30:6 – 15. As previously stated, the exemption applies only to sales transactions in which the purchaser is required to use a prescription in order to obtain the device. The Petitioner is the purchaser in this case,

and the Petitioner can never actually obtain a prescription; consequently, it would be illogical and impossible for a prescription to be required in this transaction.

The Petitioner mistakenly asserts that a prescription is required because the box that the prosthetic devices come in says "Rx Only" on it, and the FDA requires that the devices only be sold by prescription. These two arguments are also without merit. The "Rx Only" symbol on the box does not mean that the Petitioner needs a prescription in order to purchase the devices. First, a doctor does not need a prescription in order to legally possess a "prescription only" item. See Section 40-43-60(H). Further, the testimony of the doctors demonstrates that they actually have possessed "prescription only" items without a prescription. See supra pp. 12-13. Additionally, Ms. Pendergast's testimony confirms that a doctor can possess a "prescription only" device without a prescription. See Pendergast Dep. 55:15 – 56:1. Finally, if "Rx Only" meant that a prescription was required at every change of hands in the stream of commerce, then "prescription only" medicines and devices discussed at length above could never be kept in inventory. Dr. Nawabi, Dr. McCrosson, Mr. Ferguson, and Ms. Hutcherson all testified about various "prescription only" items being kept in inventory. See supra pp. 12-13.

In addition, the Petitioner's argument that the FDA requires that the devices be sold only by prescription lacks merit. The Petitioner has not cited any law or provided any documentation that supports its assertion that a doctor or hospital cannot purchase a "prescription only" item without a prescription. To the contrary, the Petitioner's own purported expert, Ms. Pendergast, testified that doctors do not need a prescription to purchase these devices. See supra p. 12. The Petitioner mistakenly relies on 21 C.F.R. §

801.109 in its protest as dispositive proof that a prescription is required. Section 801.109 is wholly inapplicable to the issues in this case and any reliance upon it should be considered a "red herring" – that statute applies only to the labeling and branding of regulated devices. In fact, § 801.109 only applies to ***exemptions*** from the labeling requirements and has no application whatsoever to actual prescriptions or the requirements thereof. Generally, § 801.109 provides that adequate directions for use of a device are not necessary if certain conditions are met. One of those conditions is that the device is in the possession of a practitioner, such as a physician, licensed by law to use or order the use of the device. Another condition is that the device can be sold (1) only to, (2) on the prescription of, or (3) by order of such practitioner for use in the course of his or her professional practice.[8] If § 801.109 required a prescription for all transactions,

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[8]Section 801.109 reads as follows:

> A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe **except under the supervision of a practitioner licensed by law to direct the use of such device**, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:
> (a) The device is:
> (1)(i) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or
> (ii) **In the possession of a practitioner**, such as physicians, dentists, and veterinarians, **licensed by law to use or order the use of such device**; and
> (2) **Is to be sold only to** or on the prescription or other order of **such practitioner** for use in the course of his professional practice.

then the distinction between such devices being "sold only to" or "on the prescription of" would be unnecessary. Thus, this section does not create a legal requirement that doctors must have a prescription in order to purchase prescription devices exists. On the contrary, § 801.109 suggests that doctors, just like manufacturers and distributors, can legally possess prescription devices without a prescription and in that situation the FDA labeling and branding requirements for these devices are exempted.

The facts in this case clearly demonstrate that the Petitioner is not required to have a prescription in order to purchase prosthetic devices from a manufacturer. Not only does South Carolina law say that doctors can possess "prescription only" devices

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(b) The label of the device, other than surgical instruments, bears:

(1) The statement "Caution: Federal law restricts this device to sale by or on the order of a _____", the blank to be filled with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(2) The method of its application or use.

(c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented: *Provided, however,* That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

without a prescription, but a hospital can never actually be prescribed anything. Furthermore, the deposition testimony of Dr. Nawabi, Dr. McCrosson, Dr. Baker, Ms. Pendergast, Mr. Ferguson, and Ms. Hutcherson all support the fact that a doctor or hospital can purchase "prescription only" items at will simply by virtue of being a licensed practitioner. Finally, assuming for a moment that a prescription is actually used, the conclusion that a prescription is required does not necessarily follow. For example, Dr. McCrosson admitted that he could write a prescription for an over-the-counter medication, and that the reason for doing that would be "[f]or insurance purposes." McCrosson Dep. 42:1 – 9. As a result, a prescription can be used even when it is not required.

C. The prosthetic devices must actually be sold to the Petitioner by prescription.

In addition to the transaction requiring a prescription, a prescription must ***actually*** be used during the transaction, meaning in this case the Petitioner must actually submit a prescription to the manufacturer. This requirement is set forth in the second prong of Home Medical, which states that the "medicine" must actually be "sold by prescription." 382 S.C. at 566. Here, no prescription is or was ever sent to the manufacturer, and thus, the seller is certainly not making sales pursuant to any patient specific prescriptions. During the audit and throughout discovery, the Petitioner has yet to provide any evidence or document to the Department purported to be a prescription. Mr. Ferguson, the actual hospital employee who completes the purchase of these devices, stated that with regard to the purchase of joint replacements he has "not seen a written prescription." Ferguson Dep. 17:5 – 9. Additionally, when asked if any of the information that is statutorily

required to be on a prescription drug order is incorporated into any of the documentation that the Petitioner sends to the manufacturer, Mr. Ferguson said that it is not. See Ferguson Dep. 35:4 – 15. Furthermore, Ms. Hutcherson testified about the procedure that is generally followed when a hospital, like the Petitioner, purchases a device from Zimmer, Inc.:

> **Once the case has been completed**, so the implant has been implanted into the patient, there is a requisition sheet that has the patient sticker put on it, identifies information about the patient, produced by the hospital, put on the requisition sheet, and then the rep will take the bar code stickers from each of the products that were consumed and put that on the sticker sheet, along with the pricing.
>
> At that point in time they'll review that document with the OR nurse or the circulating nurse **to make sure that both parties are in agreement to the product that was implanted into the patient**, and then that requisition sheet then typically goes to a buyer to input the requisition into the system to create the purchase order.
>
> At the same time our rep will scan . . . the stickers on the sticker sheet, and that will go into our system, so we recognize what products have been consumed or used in the patient.
>
> And at that point in time **we'll wait for the purchase order to reconcile between what the rep sent in and what the purchase order presented to make sure that both are intact**. And then we will go ahead and add the purchase order so that we can generate the invoice.

Hutcherson Dep. 10:1 – 25 (emphasis added). If a prescription was legally required in order for the sale to take place, the hospital would have to send a prescription to the manufacturer prior to the transaction occurring. Here, the Petitioner never sent anything remotely resembling a prescription to the manufacturer, and the manufacturer does not receive any documentation from the Petitioner until after "the case has been completed."

Id. Additionally, the documentation that the manufacturer does receive is clearly for billing purposes, as evidenced by Ms. Hutcherson's testimony. Id. The Department's position is further established, therefore, when the manufacturers sell these prosthetic devices to hospitals without ever receiving a memorialized prescription. As previously mentioned, Mr. Ferguson stated that he never sees a prescription during the transaction between the Petitioner and the manufacturer, see Ferguson Dep. 17:5 – 9, and he only sends a purchase order to the manufacturer, see Ferguson Dep. 13:13 – 14:10. Thus, the prosthetic devices are not actually sold to the Petitioner by prescription.

Furthermore, the manufacturers do not ask for a prescription prior to selling the prosthetic devices to the Petitioner. In fact, the Petitioner does not send anything to the manufacturer until after the prosthetic device has been implanted in the patient. Ms. Hutcherson testified that the only two documents Zimmer, Inc. receives from hospitals like the Petitioner are a requisition sheet and a purchase order. Hutcherson Dep. 10:1 – 25, 14:9 – 15:2. In addition, Mr. Ferguson never mentioned that the manufacturers ask the Petitioner for a prescription prior to selling the prosthetic devices to the Petitioner. See Ferguson Dep., specifically 13:13 – 14:10. Based on the testimony of Ms. Hutcherson and Mr. Ferguson, the devices are not sold to the Petitioner by prescription.

Finally, if prescriptions were actually used in the transactions at issue, records of those prescriptions would have to exist. See, e.g., Section 40-43-86(F), (J), (N), (X), (Z). In this case, no records of prescriptions for the prosthetic devices at issue have been presented. Not only has the Petitioner failed to provide any prescriptions for prosthetic devices through discovery, but Dr. McCrosson testified that he does not have any records of the prescriptions he allegedly made. McCrosson Dep. 40:24 – 41:1. Furthermore, Dr.

McCrosson could not identify who, if anyone, kept a record of the prescriptions he allegedly made. McCrosson Dep. 41:2 – 4. Since records of prescriptions are legally required to be maintained, and no records of prescriptions exist in this case, a prescription was obviously not used in the transaction between the Petitioner and the manufacturer.

The Petitioner asserts that a prescription is used when the doctor simply calls out what device he needs while in the operating room. This assertion is flawed for two reasons: 1) a doctor calling out the name of a device while operating on a patient does not constitute a prescription, but rather, is more akin to a chart order as discussed above, and 2) the transaction at issue is not between the operating doctor and sales representative, but between the Petitioner and the manufacturer. Dr. McCrosson described what he believes is his oral prescription as follows:

> During surgery -- we make all the preparations for certain sizes, et cetera, and then **I call it out. I say, I want** E 3 10 29 (ph), and those would be the four sizes of the -- and they know what implant I use each time on a standard case. Of course, if it's not standard, then I say more specifics than E 3 10 29.

McCrosson Dep. 41:12 – 18.

As previously mentioned, a prescription drug order must contain patient specific information and must be reduced to writing. When Dr. McCrosson was asked whether the "order" that he makes in the operating room has all of the information required by § 40-43-86(E) to be in a prescription drug order, he said "[n]o. That's not a prescription drug order, potentially, either." McCrosson Dep. 40:14 – 18. He then admitted that even though a prescription drug order applies to devices, "[i]t doesn't mean that's the only way a device can be ordered . . . ." McCrosson Dep. 40:19 – 23. Based on the description of

how Dr. McCrosson orders the prosthetic devices he needs, it is clear that he is ordering a device for a patient of a hospital, which does not constitute a prescription. See supra pp. 8-9.

Evan assuming for argument's sake that the doctor's actions in this case do constitute a prescription, that prescription would be for the patient – not for the Petitioner. As previously explained, a prescription can only be written for a patient once a doctor-patient relationship has been formed, and a doctor-patient relationship simply cannot be formed with a hospital. To that extent, that pseudo-prescription cannot possibly be for the hospital. In this case, the transaction where the purported prescription is being used is between the doctor and the patient, not the Petitioner and the manufacturer. Therefore, a prescription is not actually being used by the Petitioner when it purchases the devices from the manufacturer.

In conclusion, the hospital's purchases of all medicines and devices, whether controlled or regulated, are deemed retail sales because the hospital is considered the end user. To that extent those sales are subject to sales and use tax. It should be noted here that the Petitioner's refund requests did not include the copious amounts of controlled substances purchased for its on-site pharmacy. The same faulty logic asserted by the Petitioner in regards to prosthetics, ostensibly, would apply to all "prescription only" items. One can only speculate as to this inconsistency. Regardless, for the reasons set forth above, none of the hospital's purchases qualify for the exemption pursuant to § 12-36-2120(28)(a).

II. The taxpayer's purchases of medicines manufactured from plasma derivatives do not qualify as exempt from sales tax pursuant to § 12-36-2120(28) as medicines sold by prescription.

In 1968, the South Carolina General Assembly enacted a products liability statute known commonly as the "blood shield" law. This law is now codified as S.C. Code Ann. § 44-43-10 (Supp. 2011) and reads:

> The implied warranties of merchantability and fitness are not applicable to a contract for the sale, procurement, processing, distribution, or use of human tissues including, but not limited to, corneas, bones or organs, whole blood, plasma, blood products, or blood derivatives. Human tissue, whole blood, plasma, blood products, and blood derivatives must not be considered commodities subject to sale or barter, and the transplanting, injection, transfusion, or other transfer of these substances into the human body are considered a medical service.

The legislative intent of this law was to encourage a readily available supply of blood, bone, and tissue with protection from products liability claims. See Samson v. Greenville Hosp. System, 297 S.C. 409, 377 S.E.2d 311 (1989). This statute, as is apparent from its plain language, simply does not contemplate tax applications.

On February 28, 1992, the South Carolina Tax Commission agreed, and held in Commission Decision #92-26 that the provisions of § 44-43-10 were not controlling with respect to sales and use tax and that blood products were tangible personal property as defined under S.C. Code Ann. § 12-36-60 (2000). In Re: A Finding Concerning A Claim For Refund Filed By XYZ Blood Center, Inc., Comm'n Decision 92-26, 1992 WL 535427 (S.C. Tax Comm'n Feb. 28, 1992). The Commissioners further held, in determining whether blood products were exempt from the sales and use tax, that the blood products of the taxpayer were used to treat diseases and injuries and were prescription "medicines for purposes of § 12-28-2120(28)." Id. As discussed above, that part of the decision has since been tempered by jurisprudence, and the exemption is only

extended to transactions where a prescription is required and actually used. See Home Medical, 382 S.C. at 566.

The Department has never taken a formal position, nor issued any official policy on whether or not human body parts, whole blood, and blood derivatives (red blood cells, white blood cells, plasma, and platelets) are wholly exempt from the sales and use tax. Sales of manufactured medicines made from plasma derivatives have been taxed unless the transaction qualifies under § 12-36-2120(28) as a "medicine sold by prescription." It is important to note that an express statutory tax exemption for human tissue, bone, and blood has never been enacted by the South Carolina General Assembly.

The medicines at issue in this case are manufactured from individual proteins that are isolated and derived from human plasma. These proteins include globulin, fibrinogen, and albumin. Pharmaceutical manufacturers take these proteins, immunize them from viruses, and then generally mix them with various solutions such as capyrlates (a salt or ester of caprylic acid) or glycine. Treatment involving these medicines typically involves intravenous injections, and is often mixed further onsite into a mixture of dextrose and water for buffering. One drug at issue, which represents a majority of the purchases by the Petitioner, is called "Gamunex©," and consists of only nine to eleven percent of the globulin protein.

First and foremost, the primary basis for why sales and use tax applies to sales of these medicines is the absence of any express statutory exemption. For the exact same reasoning applied to both classes of devices above, the sale of medicine to a hospital does not constitute a transaction that requires a prescription. As a hospital, the taxpayer has the ability to purchase these medicines from the manufacturers as it sees fit, regardless of

whether the orders are placed individually or in bulk. The hospital is deemed the end user for these injectable plasma derivatives, as they are furnished on-site as part of the services rendered. For this reason, the purchases of manufactured plasma derivatives by the taxpayer are not eligible for the exemption pursuant to § 12-36-2120(28).

The Petitioner argues that these manufactured plasma derivatives fall within the enumerated categories of human parts of § 44-43-10, and thus the Department is inconsistent by taxing these medicines in light of its failure to tax corneas, bones, organs, whole blood, plasma, blood products, and blood derivatives. Once again, the Petitioner's argument lacks merit. The Department has no authority to extend Title 44's blood shield law to sales and use tax. The language of § 44-43-10 contains no reference to sales and use taxes and there is no evidence the General Assembly intended to extend this statute to taxation. As stated earlier in Commission Decision #92-26, the Tax Commission considered blood products "tangible personal property" under Title 12, and only exempted the blood products at issue therein as "medicines" under § 12-36-2120(28) – rejecting any application of § 44-43-10.[9]

Even if Title 44 was meant to extend to taxation, the type of transaction at issue here falls outside of the language contained therein. The blood shield law limits human products as medical services only for the "transplanting, injection, transfusion, or other transfer of these substances into the human body." The transaction at issue here, between

[9]To the extent that the Department or any of its employees has relied upon § 44-43-10 to exempt human tissue, blood, and related products from sales and use taxes – such action was erroneous. Audits of such purchases will need to examine whether prescriptions exist to support the purchase of human tissue, blood, and blood derivatives in order to exempt the same as "medicines sold by prescription."

the hospital and manufacturer, does not constitute any semblance of the verbiage contained in Title 44. The transaction at issue should be considered nothing more than a retail sale of tangible personal property between two corporate entities, and thus without an express exemption it is subject to sales and use tax.

As further evidence that the Legislature did not intend for these plasma derived medicines to be exempt, the Legislature recently enacted an amendment to § 12-36-2120 in June of 2012 to include subsection (80), which states:

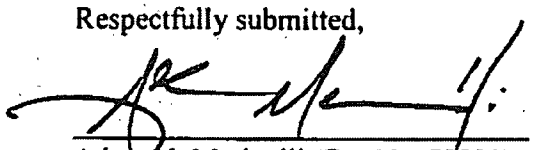
> (a) Effective on July first immediately following a forecast meeting the requirements of subitem (b), injectable medications and injectable biologics, so long as the medication or biologic is administered by or pursuant to the supervision of a physician in an office which is under the supervision of a physician, or in a Center for Medicare or Medicaid Services (CMS) certified kidney dialysis facility.

This new exemption would be superfluous if such items were already exempt under Title 44 and § 12-36-2120(28)(a). As such, it can be inferred that prior to this amendment, including the tax years at issue, such products were not exempt.

Finally, the proteins at issue here are derived from plasma and then manufactured into various medicines. Despite the lack of relevance of the "Blood Shield Law" to matters of taxation, the technological dilution of the plasma derivatives for drugs such as Gamunex© is quite far removed from the blood derivatives contemplated in Title 44. Regardless of this distinction, plasma derivatives do not have an express statutory exemption, and thus they are subject to sales and use tax as medicine furnished as part of the medical services provided by the Petitioner.

THEREFORE, by the undersigned counsel as attorneys for the Respondent, the Department respectfully requests that this Court grant this Motion for Partial Summary Judgment for the lack of a genuine issue of material fact under Rule 56(c), SCRCP.

Respectfully submitted,



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Columbia, South Carolina
August 26, 2013

EXHIBIT A

SOUTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES MEDICAID CERTIFICATE OF MEDICAL NECESSITY FORM FOR ORTHOTICS, PROSTHETICS AND DIABETIC SHOES

SECTION A; MUST BE COMPLETED BY DME PROVIDER:

(1) Recipient's name: _____ Medicaid # (10 digits): _____

(2) DOB: ____/____/____; Sex: __ HT: _____(in); WT: _____ Date of Service: _____

(3) Provider's name: _____ Provider's DME # _____ NPI# _____

(4) Street address: _____ City: _____ State: _____ Zip: _____ Local telephone #: _____

(5) Provider's signature: _____ Date: _____

(6) LIST ALL PROCEDURE CODES THAT ARE ORDERED BY THE TREATING/ORDERING PHYSICIAN FOR ORTHOTICS, PROSTHETICS, AND/OR DIABETIC SHOES. _____

_____

PLEASE NOTE: FOR ALL PROCEDURE CODES THAT ARE COVERED BUT DO NOT HAVE AN ESTABLISHED PRICE, YOU MUST INCLUDE MANUFACTURER PRICE LIST.

SECTION B: ALL FIELDS IF APPLICABLE MUST BE COMPLETED BY TREATING/ORDERING PHYSICIAN:

(7) Diagnosis codes (ICD-9): _____ Diagnosis (s): _____

_____ _____

_____ _____

(8) Give a detailed description of the severity of the recipient's condition(s) as related to orthotics, prosthetics, and/or diabetic shoes.

Orthotics and/or Prosthetics:

_____

_____

_____

Diabetic Shoes: Does the patient have one or more of the following conditions? Check all that apply:

____History of previous foot ulcerations ____Peripheral neuropathy with evidence of callus formation ____Foot deformity

____Poor circulation ____History of partial or complete amputation of the foot ____History of pre-ulcerative callus

Is additional information attached on a separate sheet? ____Yes ____No (If "yes," enter recipient's name and Medicaid I.D. number on attachment)

(9) Please indicate the date that the patient was seen for the equipment/supplies prescribed: _____

(10) Prescription Date: _____

(11) Duration of need (Maximum of 12 months): _____
(Please indicate duration by months, not to exceed 12).

I certify that I am the treating/ordering physician identified in Section B of this form. Any statement attached hereto has been reviewed and signed by me. I certify that the medical necessity information is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability. Additionally, I certify that the requested equipment/supplies are appropriate for the patient.

(12) PHYSICIAN'S NAME: _____ NPI # _____

PHYSICIAN'S SIGNATURE: _____ DATE ____/____/____ (SIGNATURE AND DATE STAMPS ARE NOT ACCEPTABLE)

PLEASE REFER TO THE MEDICAID CMN POLICY IN THE DME MEDICAID PROVIDER MANUAL.

DME 004 – Dated 01/01/11

INSTRUCTIONS FOR COMPLETING THE MEDICAID CERTIFICATE OF MEDICAL NECESSITY FOR ORTHOTICS, PROSTHETICS AND DIABETIC SHOES

SECTION A: MUST BE COMPLETED BY DME PROVIDER

RECIPIENT'S NAME AND MEDICAID #:	Indicate the patient's name and his/her Medicaid # (10 digits).
PATIENT DOB, SEX, HEIGHT, WEIGHT:	Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds.
DATE OF SERVICE:	Indicate the date of service (DOS). The date of service must be the same as the delivery date.
PROVIDER'S NAME, DME # AND NPI#:	Indicate the name of the DME company (Provider name), Provider's DME# and NPI#.
PROVIDER'S PHYSICAL ADDRESS AND TELEPHONE NUMBER:	Indicate the provider's physical address (provider's location) and telephone number.
PROVIDER SIGNATURE AND DATE:	Signature of DME provider representative and date.
HCPCS CODES:	List all HCPCS procedure codes for items ordered by the treating/ordering physician. Note: For all procedure codes that are covered, but do not have an established price, you must include manufacturer price list.

SECTION B: MUST BE COMPLETED BY TREATING/ORDERING PHYSICIAN:

DIAGNOSIS CODES:	In the first field, list the ICD-9 diagnosis code(s) that represent(s) the primary reason(s) for ordering this item. In the second field, list the description(s) for each ICD-9 diagnosis code(s).
QUESTION SECTION:	This section is used to gather clinical information to help Medicaid determine the medical necessity for the item(s) being ordered. Answer each question which applies to the items ordered.
DATE PATIENT WAS SEEN FOR EQUIPMENT/SUPPLIES PRESCRIBED:	Indicate the date patient was seen by the treating/ordering physician, nurse practitioner or physician assistant for the equipment/supplies prescribed. The treating/ordering physician, nurse practitioner or physician assistant must examine the beneficiary within 60 days before prescribing equipment and/or supplies.
PRESCRIPTION DATE:	Indicate the prescription date. The prescription date must be within 60 days of the date of treating/ordering physician's signature and the date the beneficiary was seen by the physician, nurse practitioner, or physician assistant. All MCMNs that are not signed within this time frame will be returned (if submitted with a PA) or rejected (if attached to a claim) and the MCMN will be deemed invalid.
EST. LENGTH OF NEED:	Indicate the estimated length of need (the length of time the physician expects the patient to require use of the order item) by filling in the appropriate number of months, up to 12 months. An MCMN can be valid up to a maximum of 12 months from the date the patient was seen for the equipment/supplies prescribed.
PHYSICIAN ATTESTATION:	The physician signature certifies (1) the CMN which he/she is reviewing includes Sections A and B; (2) answers in Section B are correct and the self-identifying information in Section A is correct.
PHYSICIAN SIGNATURE AND DATE:	After completion and/or review by the physician of Sections A and B the physician's must sign and date the CMN in Section B, verifying the Attestation appearing in this Section. The physician's signature also certifies the item(s) order is medically necessary for this patient.

EXHIBIT B

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT DIVISION
Docket No. 12-ALJ-17-0405-CC

Roper St. Francis Medical Healthcare, Inc.,

Petitioner,

v.

South Carolina Department of Revenue,

Respondent.

COPY

DEPOSITION OF

CHARLES PRESCOTT FERGUSON

****

Friday March 29, 2013
9:10 a.m. - 10:40 a.m.

The deposition of CHARLES PRESCOTT FERGUSON, taken on behalf of the Respondent at Roper St. Francis Healthcare, 125 Doughty Street, Suite 720, Charleston, South Carolina, on the 29th day of March, 2013 before Sara L. Quattlebaum, Court Reporter and Notary Public in and for the State of South Carolina, pursuant to Notice of Deposition and/or agreement of counsel.

APPEARANCES:

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Also Present:
Britt C. Dobbins, Colonial Consulting Group

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EXHIBITS

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Defendant Exhibit Number 2 4
(retained by Counsel)
Defendant Exhibit Number 3 4
(40-43-60)
Defendant Exhibit Number 4 4
(Pre-Op Planning Checklist)
Defendant Exhibit Number 5 4
(Purchase Order)

STIPULATIONS

It is stipulated and agreed that this deposition is being taken pursuant to the Administrative Procedures Act and the South Carolina Rules of Civil Procedure.

It is stipulated by and between counsel and the witness that the reading and signing of the following deposition be, and the same are, hereby waived.

(Defendant's Exhibit Numbers 1 - 5 were marked for identification purposes.)

CHARLES PRESCOTT FERGUSON, having been duly sworn, testifies and deposes as follows:

MR. FERGUSON - EXAMINATION BY MR. MARINELLI:

Q: Mr. Ferguson, my name is Adam Marinelli, and I work for the South Carolina Department of Revenue. Today we are taking your deposition in the case of Roper St. Francis, I believe is the taxpayer's name, versus the South Carolina Department of Revenue.

MR. MARINELLI: I'm assuming we're going to stipulate that this deposition is being taken in accordance with the rules of South Carolina Civil Procedure and the Administrative Law Court rules.

Q: I'll try to be as clear as I can. If I ask you any questions that you don't understand or that you need to have clarified or restated, feel free to do so. Any question that you do answer, I am going to assume that you understood it. Have you ever taken a deposition before?

A: Yes, I have.

Q: This is a standard question; take no offense.

Are you under the influence of any drugs or have a disability that would impair your understanding of questions or the ability to answer questions in any way today?

A: No.

Q: Please state your full name for the record.

A: It's Charles Prescott Ferguson.

Q: And briefly go through your educational background.

A: I have an undergraduate degree in business administration with marked emphasis from Whittenburg University. And I have a master's degree in health care and hospital administration from the Ohio State University.

Q: Okay. And who are you currently employed with?

A: Roper St. Francis Health Care.

Q: And what is your position currently?

A: Director of material services.

Q: And could you give me a brief job description for that title?

A: I have responsibility for the purchasing and distribution of all medical, surgical, and administrative supplies and equipment across the system.

Q: And how long have you held that position?

A: Ten years.
Q: And who were you employed with prior to that?
A: I was employed by Covenant Health, a system up in Knoxville, Tennessee.
Q: And what was your job title there?
A: It was the vice-president of materials management.
Q: And before that?
A: Before that I was the -- I'm trying to remember because I was a -- what my final title was. I worked for a consulting firm in Knoxville called Pershing Yoakley, and I was a supervisory consultant with them.
Q: How did you become involved in this case?
A: Certainly, as far as --
Q: What brings you here today?
A: What brings me here today? Well, basically my boss asked me to.
Q: And who's your boss?
A: I work for Brett Johnson, who is the CFL assistant.
Q: And he was alerted to the fact that there is a pending lawsuit?
A: Yes.
Q: And he said that you needed to be a witness in

this case?

A: Yes.

Q: Were you approached by him first or the attorneys in this case?

A: To be honest with you, I am not aware of who I was approached by. If it was -- it may have been -- at that point, I think it was probably on the finance side. It was somebody -- I don't remember specifically, but it was somebody from the finance side that said they would like to have us included in it.

Q: And what type of conversations did you have regarding this case prior to being brought on?

A: I really had no conversations until I was brought on.

Q: As you understand it today, what are the issues in this case?

A: My understanding is, you know, the question of is, you know, with the medical devices they were currently purchasing, are we purchasing those under a physician's order?

Q: Are you being paid for your testimony?

A: No.

Q: How were the issues conveyed to you in this case? Were they in writing or just

conversations in a conference room somewhere?

A: Just conversations.

Q: Before we get into the nuts and bolts of the case, let's give a forest-for-the-trees type perspective. Are you familiar at all with South Carolina tax law?

A: I would say a very, very cursory idea. Most of it comes from simply just, you know, talking to individuals, legal representation and other -- but I've not sat and read specific statutes or regulations or anything like that.

Q: So in your day-to-day operation of being material services manager, you don't contemplate or handle any tax matters; is that correct?

A: That's correct.

Q: How did you prepare for the deposition today?

A: I just spent about 30 minutes previous to this with the folks in this room.

Q: And what did those conversations entail?

A: Generally, we just talked about the issues that related to the case.

Q: Could you be more specific?

A: We talked about, you know, what is a physician's order versus a prescription. We

talked about that. We also talked about, you know, some of the different types of, you know, of implants because we, obviously, purchase a number of different implants across the system.

Q: As you understand it, what is the difference between a physician's order and a prescription?

A: In my world, there isn't a difference.

Q: Okay. Let's talk about your world. Go through the day-to-day operation of the material services manager.

A: Can you be more specific? Because I could spend the next three hours talking about that, and I don't think you want to hear all that so --

Q: You're probably right. Say a doctor needs a hip replacement for a patient, how does he go about getting it?

A: Well, there are two things. If it's not an approved item --

Q: Approved by whom?

A: Approved by the system. Then he or she must submit a specific request that details why they want the implant, and it only can be submitted by a physician. There is nobody else who can submit it. And then we do have a

formal process where we will review that request; make sure it's -- it has appropriately met the approval, etcetera and then any financial impact. And so there is a formal process for a physician requesting an item.

Q: Let me interrupt you right there. When you say there is no -- a financial impact. What does that specifically mean?

A: Well, if we're buying Implant A and that is the same thing, and Implant B costs twice as much. And so we look at the --

Q: The cost benefit analysis type thing?

A: Correct.

Q: Do economics play a large role in your decision-making process?

A: They are significant, but they are not the only thing. I mean, that is a fairly good rule where we focus primarily -- that's really -- it really comes secondary. We look at the quality, the patient first before we focus on the financial side of it.

Q: Are you in charge of keeping inventories of various items and supplies in the hospital?

A: Yes.

Q: And does the system that you've created

incorporate economics into that system or into that inventory process?

A: I'm not sure I understand the economics -- what your question is.

Q: Is it part of your position to keep overhead low?

A: Yes.

Q: Okay. Backing up just a moment. Have you reviewed any documents in preparation for this deposition?

A: I certainly didn't review any today. We talked about this a couple of months ago. I may have reviewed some. Honestly, I don't remember if I reviewed anything.

Q: That's fine. So assuming that the item has been approved and it's in the system, how does the doctor get it?

A: If -- it depends what it is. But, for example, if it's an orthopedic joint component, the vendors have available stock. The hospital has no ownership, no association with it. The physician -- once the physician schedules the case, the physician's office will notify the rep, the vendor rep that this is what I need for this case. The vendor has that implant

available the day of surgery. The physician implants it. Then after the case, we're notified via the OR nurse in the case what was implanted. And then we pay for that device, whatever was implanted at that point in time.

Q: So when you say the vendor holds the stock that we have no ownership in. So your overhead is limited by allowing the vendor to basically act as a warehouse for you where you pick and choose what you need at any given moment?

A: Well again, we don't pick and choose. We have no association. We do what the vendor -- in other words, they are the ones that really choose, based on the physician's order.

Q: How does the hospital choose what vendors it deals with?

A: The vendors, frankly, are chosen by who the physicians want to use. Our role in it simply is we negotiate the economics of what we are going to pay for that device.

Q: Are there agreements, written agreements, between you and the vendors?

A: We have pricing agreements. And again, it depends on what type of devices you are talking about. But we do have some pricing agreements.

Q: Have you provided those to your counsel?
A: I'm not aware of what -- I'm not aware of what we've provided at this point. I'm not sure we have provided those pricing agreements.
MR. MARINELLI: Could we get those from just one particular vendor, say like Zimmer?
MR. CARPENTER: I'm sure we could.
MR. MARINELLI: That would be good to see.
A: And these are essentially more of a matrix type; they are very short and sweet because it just establishes the pricing schematics of who will pay for the device.
Q: What type of documentation is forwarded to -- let's say we are talking about Zimmer. Say you need a joint replacement from Zimmer, what do you send them? Do you call it in? Is there an email? Do you ship them an invoiced purchase order? What is it?
A: Well, what happens after the case in the room, and the vendor rep is almost always there essentially because they are pulling the supplies used by the physician for the implants. They fill out what's called a special purchase request.
Q: Who is they?

A: They being the vendor rep.
Q: Okay.
A: They fill it out saying this is what was used. The circulating nurse in the room signs off on it, you know, initials that request. And then that in turn goes to purchasing where we then actually -- we will take that. And based on that, we will submit a purchase order to -- for example, in the case of Zimmer, to do whatever company we buy it from.
Q: But this is all subsequent to the actual implantation?
A: Correct. It all happens after.
Q: Okay. And so the vendor rep is in the room for all of this?
A: Yes, a majority of it, they are in the room.
Q: And do they have all materials that they need for the surgery at that point --
A: All the implants; that's correct.
Q: -- without knowing what was needed at the time? So -- I'm slightly confused.
A: Well, just if you -- you may recall what I previously mentioned is that when the physician's office schedules the case, they notify the vendor rep what implants they are

going to use. So the vendor rep, they may know two or three weeks in advance.

Q: Okay. How does that notification take place?

A: There is a communication from the physician's office directly to the vendor rep. And it's usually -- I'm sure it happens a couple of different ways depending on the physician's office, if it's by fax or by email or via phone call.

Q: Okay. So it could be either oral or written?

A: Yes, that's correct.

Q: For the written orders, what does it look like? What type of document does it have?

A: I'm not familiar with exactly what they look like.

Q: So you've never actually seen one; is that correct?

A: If I have, it's been a long time. So I don't recall specifically if I've seen a specific order that was sent to a vendor.

Q: All right. I'm going to hand you what's been pre-marked as Defendant's Exhibit Number 4. Would you take a look at it and identify that document if you can for the record, and whether or not you have seen one of these?

A: This specific one or this one, I've not seen before.
Q: But have you seen documents like this?
A: No. I mean again, if I had seen something like this many -- a number of years or months ago, I don't recall. This is not something I generally would be -- that I am going to be looking at.
Q: Okay. Do you have any idea what it is?
A: By just reading at the very top, it's a pre-op planning checklist. That's how I know what it is.
Q: So you have no idea of knowing if this is the type of communication that goes from the doctor to the vendor?
A: Again, as I mentioned before, I don't routinely see that type of communication.
Q: Okay.
A: But I know that there is something that goes to the vendors.
Q: So as far as your day-to-day job function is concerned, everything has already happened when you are brought in?
A: Correct.
Q: So it's already been implanted. It's already

been sent from the vendor. You're simply making sure that they are being paid for what's happened; is that correct?

A: Correct.

Q: Okay. Have you ever seen a prescription, a written prescription, in regards to the purchase of one of these joint replacements?

A: I've not seen a written prescription; that's correct.

Q: Okay. Do you know what a prescription is?

A: Having been a patient myself, if you're talking about particularly for medications, I mean, I know what that kind of prescription is, yes.

Q: Could you tell us what, in your mind, a prescription would be?

A: A prescription is simply a means of a physician ordering whatever it is with that patient care. It could be, again, a number of obviously medications, devices, what have you for that specific patient.

Q: I'm going to hand you what has been pre-marked as Defendant's Exhibit Number 3. All right. At the bottom of the page, do you see the Subsection E that starts, "a prescription drug order shall contain at the minimum?"

A: Yes, I do.
Q: And then there is a laundry list of various pieces of information that are required. Do you see that?
A: I do.
Q: Do you have any reason to not believe that that's the legal requirements for what a prescription should have?
A: I'm certainly not -- I haven't read this, and I'm not an expert on it, so I wouldn't -- I really can't answer that.
Q: Have you ever seen a document that contains all that information in regards to the purchase of the items that we have been discussing?
A: I have not.
Q: Okay. Do you handle all of the drug purchases, as well?
A: No.
Q: So you solely deal with joint replacements for --
A: As I mentioned before, it is the medical, surgical and administrative supplies and equipment; but I do not deal with the purchase of pharmaceuticals.
Q: Is there another person in your office that

handles solely pharmaceuticals?
A: No, there's not. That's done all through the pharmacy.
Q: You have an in-building pharmacy?
A: I'm sorry?
Q: Is it in the Roper Hospital?
A: Yes.
Q: And is it owned by Roper Hospital?
A: Yes, it is.
Q: So the pharmacist is employed by Roper?
A: That's correct.
Q: And when a doctor needs a drug from that pharmacist, how does that go about?
A: I can give you the general, but, again, that's certainly not my area. I mean, certainly, there has to be an order that is given for that particular medication. And again, in the clinical area, you know, how that order gets transmitted to the pharmacy, I can't give you the specifics.
Q: That's fine. How does the pharmacy order its drugs?
A: Since -- I can't tell you that because I'm not part of the -- because I don't -- the pharmacy orders their drugs specifically.

Q: Okay.
A: We don't -- in my area, we have no role in ordering the drugs.
Q: Would you assume that they do it in the same fashion that you order the medical supplies?
A: We have a whole range of medical supplies. We order anything from orthopedic implants to band aids. And the ordering process for those is very different.
Q: Does it vary from vendor to vendor or from item to item?
A: It's item commodity to commodity so --
Q: Is it safe to assume that the pharmacy handles those, you know, types of items? You guys do keep some sizeable inventories of various items?
A: Again, it depends on what type of item it is. Obviously, as you mentioned earlier, our goal is to keep -- limit our overhead or inventory.
Q: Sure.
A: But we obviously have to keep enough sufficient for patient care.
Q: Is that your primary goal, limiting overhead?
A: No, our primary goal is to make sure supplies are available to take care of the patient.

Q: Okay. And to do that, some inventories have to be kept; is that correct?
A: That's correct.
Q: Are any of the inventories that you order considered prescription-only items?
A: We do have -- we do have some of that; that is correct.
Q: Could you give me an example of one of those?
A: Well, and again, I'm going to use your term prescription only. For example, we do have some inventories of plates and screws. And we do not use them until a physician orders them. But we have to have those on standby. In other words, if a case comes in that is emergent, the physician needs them, we can't say, wait a minute, let's run down the street, we'll have to get them for you. So we will only replace that upon use by physicians. So we understand -- so if you are talking about physicians or whatever, we do have an inventory that is a physician order, you know, that would be one that is.
Q: And you consider plates and screws a prescription-only item?
A: Yes, in that we only use inventory by a

physician. We only purchase it if it is ordered by a physician.

Q: You would only purchase it?

A: Correct.

Q: Could I, as a common citizen, purchase plates and screws?

A: To my understanding, you could not.

Q: But you keep an inventory on these items, correct?

A: Correct.

Q: So they are purchased before there is any specific patient in mind?

A: They are, but back to what I indicated about how we have new products approved, we will only put an item in inventory in our formula if it's been approved by a physician for their use. But again, we have to have the standby use. It has to be there, you know, when a patient is brought into the ER or OR or whatever.

Q: But just to reiterate, these items are purchased without a specific patient in mind?

A: These specific items are because of the emergency standby nature of what we do.

Q: And how does that purchase take place? Do you just put in an order for 100 of one kind or

what?

A: Well, what we do on a routine basis, it's a little bit of a variation of what I told you related to the orthopedic joints is after the case is finished, let's say we use two screws, and we pulled those out of inventory. After the case is finished, we would reorder those two screws to replenish so we would have that in inventory.

Q: Okay. Are any of the actual joint replacements kept in inventory?

A: No.

Q: And why?

A: Those are strictly the responsibility of the vendor because we don't -- again, we're not going to know -- when the patient is coming into the hospital, the communication of what is needed is between the physician's office and the vendor rep. So we don't know what they are going to use until they come into the hospital.

Q: Is it safe to assume that they are very highly specialized items?

A: Yes.

Q: Each one is different size-wise, material-wise?

A: There are a number of variations, so that would

be -- yeah, that would be correct.

Q: And is it safe to assume that the technology regarding that field is constantly changing?

A: You know, I'm not -- I'm certainly not an expert on joints or orthopedic joints. There is a lot of different metallurgies that go into it. Yeah, it is changing.

Q: My $2,000 TV I bought two years ago is obsolete now. So I'm assuming the medical field is moving pretty fast.

A: It is. I think you have -- again, you have to look at your different type of items. And, again, I'm not the expert. But orthopedic joints would be a little bit different than your, you know, certainly a little bit different that some of your high-end electronic devices, cardiac rhythm, etcetera. So they are all a little bit different.

Q: Would you say that the reason that you don't pull an inventory on those items is because they are so highly specialized, or one reason?

A: I mean, the reason we really don't hold an inventory is that these are planned procedures. And we're only going to use these or purchase these upon a physician's order. And so because

we don't know what the physicians -- we know that the communication of what's needed will occur before the procedure. So there is no need to hold anything in inventory since we know what's going to be used.

Q: They are pretty expensive; aren't they?

A: Yes, they are.

Q: Is that another reason you don't keep an inventory?

A: That's certainly economically -- certainly that would be a part of it. .

Q: If the hospital wanted to order a bunch of joint replacements, could it?

A: We -- my understanding is we cannot order it unless we have a physician's order.

Q: And who told you that?

A: You know, my general understanding, and I will be the first one to say I'm not a legal expert, but my understanding just from -- my understanding, you know, the FDA, and with respect also with some of the South Carolina pharmacy regs, you know, again, we need a physician order before we actually purchase these.

Q: I'm going to hand you what has been pre-marked

as Defendant's Exhibit 1. This is a copy of the federal regulations that have been brought to the attention of everyone at this table. I think it's in one of the Plaintiff's exhibits that we looked at yesterday. Let me find it in here. Now, obviously this is related specifically to prescription devices. And I don't think there is any question that people, like myself, couldn't just order one of these things from Zimmer. The question today really is can a doctor or a medical practitioner order anything that's generally limited to prescription-only purchases without needing a prescription for its purchase or use? And so if you will look down the page, do you see Subsection 2 under Subsection A?

A: Yes.

Q: Could you read that for the record for me? It's sort of a broken sentence, but we will clear it up.

A: "Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice."

Q: Now reading that fragmented sentence, why do you think there is a distinction or rather the

conjunction "or" placed between the sale to a practitioner in the use of his medical practice verus or on the prescription or order of? If it needed a prescription in every instance, why do you think that conjunction was needed in that sentence?

A: You know, looking at this, to be honest with you, I don't -- I mean, I'm not sure in reading this. I mean --

Q: If you look at that sentence, does it appear to you that as long as it's being sold to a doctor, it's okay?

A: Again, and this is my interpretation, if I understand what this is saying, it's -- there are two instances sold only to or on the prescription of. So there is a direct sale to the physician or on the order of a physician.

Q: And assuming that on the order of the physician, that would mean a third party with proof that the physician said, yeah, sell it to this guy; is that right?

A: I mean, again, I'm not -- in reading through it, that sounds reasonable, but I'm not -- this is the first time I've seen this one.

Q: Sure, sure. Well, this is the federal

regulation that's really going to be where the rubber hits the road here. So we're trying to figure out what it really means.

A: Okay.

Q: So if I lost my leg in Iraq, and I needed a new peg leg or whatever you call it, and I'm going to where they make these things, which is some durable medical equipment salesman rep, I can't just walk in and get a fake leg; can I?

A: My understanding is you can't.

Q: I would need a prescription; wouldn't I?

A: Right.

Q: And that would be the second part of that clause?

A: Uh-huh (affirmative response).

Q: Right?

A: Correct.

Q: The guy that's selling those legs, could he buy them from a vendor without a prescription? Let me ask it in a different way. Do you, in the course of your ordinary job function, do you purchase from third-party distributors in any instance; non-manufacturers, simply vendors?

A: We buy -- there are supplies that we have to -- you know, again, we buy a whole range of

supplies. And certainly a large number amount of our supplies are bought from distributors because that is an efficient way in the healthcare supply chain. But most -- the majority of those are not implants.

Q: Okay. But would any of those be prescription devices or medicines?

A: And again, we don't purchase any medicine or drugs, at least through my area. And again, from -- to my knowledge, as far as through distributors that, I mean, the majority of the implants we buy, we buy directly from the manufacturers, not -- to be careful -- or to be very clear is that a number of these orthopedic joint companies we work with are technically distributors.

Q: Okay. There's been some discussion that it would be illegal to even be in possession of one of these devices without a prescription. How do you think a distribution, a third-party distribution center, gets those prescription devices from the vendor?

A: Well, to be clear, when we're talking about these distributors, and to use your example, since you brought up the Zimmer, we'll use

that. These are authorized -- these are companies that work directly with the manufacturer. In other words, they are authorized for a certain, you know, and I'm not an expert in that area. But as far as -- they have a certain distribution area like all of South Carolina, for example. And so they are authorized -- they are basically an agent of the manufacturer in terms of selling, you know, in terms of selling. So it's more of sort of a sales arm, I guess I'd call it that. They're not -- they're not necessarily a warehouse of all of the product.

Q: Are all of the prescription devices that you are aware of that are at issue in this case, are they all handled in the same fashion with the vendor onsite?

A: Yes. And let me rephrase that a little bit because we, -- again, as we've mentioned previously, we handle -- there are different implants we handle a little bit differently. Like, for example, we talk about orthopedic joints. Those are only -- we don't own them, we're not inventory. The vendor makes them available the day of the surgery. Whereas we

do have, again, some inventory with the plates and screws that we do have. So there are going to be some different variations of how we handle it.

Q: What about pacemakers?

A: Those would be handled similar to what we have for orthopedic joints. In other words, the vendors have them; they are available. They are brought in a lot of times for the case. They do have -- normally in that case the vendor will leave because of late-night emergencies; they will have a few on the shelf as consignment. You know, so they are strictly -- they are not owned by the hospital, but they are there from again, a standby emergency, but we don't own the inventory.

Q: How many would you say you guys keep on the shelf under consignment on average?

A: I don't really know that. I'd have to look. I don't think it's a large amount, but I'd have to look. I am not familiar with how many.

Q: Yesterday there was some discussion of the fact that these joint replacements come in boxes with all of the components needed. Why would you need to purchase an inventory of plates and

screws if that was the case?

A: The plates -- particularly the screws, those are not going to -- those are not going to specifically come with the boxes. And again, to be very clear, those screws are used for other trauma surgery that we, again, we need to have those available.

Q: So there are multiple uses for these types of items?

A: For certain items, like plates -- for the screws and plates, particularly the screws, there would be some multiple uses for that.

Q: So if I shattered my leg in a motorcycle accident, you guys have enough on hand to --

A: Correct.

Q: -- rebuild me like a bionic man?

A: We hope to, yes.

Q: Me, too. I don't really ride motorcycles. So that's a good thing to know.

MR. MARINELLI: Can we take a five-minute break?

MR. CARPENTER: Sure.

(Off the Record)

Q: I have very little left. You're doing a great job so far. I'm going to hand you what has been pre-marked as Defendant's Number 5. This

is what appears to be a purchase order. Is this what you sent to the manufacturer?

A: Yes, this is what we send. That's correct.

Q: And to your knowledge, assuming the doctor orally transmitted what you needed to the vendor, is this the only documentation that would be sent to the manufacturer?

A: Yes, that's correct.

Q: Okay. Do you see a patient name on this document anywhere?

A: Hopefully, I don't.

Q: We had the HIPAA conversation.

A: Yeah.

Q: Do you see any redacted patient names? It could be that it very well wasn't redacted. I don't know. It looks like there might have been something down here.

MR. MARINELLI: Would you know?

MR. CARPENTER: Actually, this stuff was redacted before it ever got to me.

Q: How about this. Let's ask it in a different way. When you send a purchase order, does it have a patient name on it?

A: No, it does not have a patient name on it.

Q: Does it have any identifying information

whatsoever?
A: The one piece, and I can't tell you -- I would have to confirm. It might have been redacted. And this is -- we sometimes put a medical record number, but it is not -- there is no patient identifying information on this.
Q: And what would be the purpose of the medical identifying number -- identification number?
A: Just to make -- that would be to help the vendor make sure they've got the right patient.
Q: And accounting purposes, obviously?
A: Yeah. But it's not -- we wouldn't use it. But I don't -- I think as I mentioned previously with that special purchase request that is, you know, filled out by the vendor rep and given to the buyer for approval, that -- I don't know how the vendor would tie -- they may have a way to tie that to the purchase order request so that they can -- for the actual purchase request coming across.
Q: Do you still have Title 40, where it describes what a prescription should have in it? This is going to get redundant but just bear with me a second. I think it's Defendant's Exhibit 4. Let me see here. It's the first thing I gave

you, I believe. There it is.

A: This right here, Number 3?

Q: Number 3, I'm sorry. And I know I have asked you this once already. But in any of the documentation, including the one that you see in front of you, which has been pre-marked as Number 5, does any of that batch of information that's required to be on a prescription, is that ever incorporated in any documentation that you give to a manufacturer?

A: We're talking about whether your Exhibit Number 5, which you have given me?

Q: Yes, the purchase order.

A: It is not incorporated in that. Again, this Number 5 is not a physician's order.

Q: So in your mind, is the purchase of any of these devices completed when you send this? And is payment accompanied with this?

A: To just go -- there is a purchase and a receipt that occurs at the same time for these that have already been implanted. And so as soon as that occurs and the invoice is sent to us by the vendor, then that's when payment occurs.

Q: Do they send the invoice after you send them this?

A: Yes.
Q: And then you go check with your accounting department?
A: Correct.
Q: You don't wait for the patient to pay or their insurance provider?
A: No, no. And that's the same across the board. We pay based on our purchases of the supplies, not whether the physicians pay.
Q: You pay for the use of those supplies as opposed to -- the patient's transaction is completely separate from --
A: That is correct.
Q: Okay. I think that might be it. Is the device always implanted in the patient prior to the transaction being completed?
A: Can you say that one more time?
Q: Are the devices always surgically implanted in the patient prior to the transaction being completed between the hospital and the manufacturer?
A: Yes.
Q: So there's never ever a situation where you have purchased devices before putting them in a patient other than the plates and screws?

A: Other than -- if it's in inventory, that's correct. Again, we purchase a lot of stuff. So I should say that's correct to my understanding that we would do that.

Q: And your attorneys have told me that they can prepare sort of watered-down list of what exactly you purchased hopefully in some sort of categories that I can understand because I'm not a medical practitioner. Could you give me a roundabout idea of other than plates and screws, what types of items you keep in inventory?

A: Now, are we talking about --

Q: Prescription devices. Anything that you think in your mind would require a prescription that I, as a common citizen, could not buy on my own.

A: Again, this is to the best of my memory since we have -- we maintain a fairly large inventory of non-implantable devices. But we do have a few heart valves in inventory.

Q: How do you purchase those?

A: It would be the same process as we talked about with the plates and screws, that the physicians have to order it. You know, we work with them

to say --

Q: We would like this kind of heart valve.

A: But we have them to approve it. We work with them to approve what we are going to have and have it -- again, it has to be there on standby because if the patient needs it, they need it. We don't have time to go out. But it is the same process as plates and screws, as the ones that are used and implanted in a patient, then we would reorder that based on the use of that device. There may -- we may have a couple of other, you know, I think, spine products that we keep in inventory. There may be a couple of other things -- typoplastic, I think, is one I can think of. But -- and there may be some odds and ends of items. But we don't have that much except for -- the majority of the largest inventory we keep of implantable devices would be your plates and screws and rods for the -- most of that would be orthopedics.

Q: When you purchase these items, do you purchase them one at a time or do you take, like I say, the end of the week's orders and send them all at the same time? How does it generally work?

A: We generally drive it based on, again, when

it's used. We have set levels that we know that we have to keep to have. And we work based on what the physician will use in the case. And so we know what we have to have available. In particular, if it's a long week, you might have two or three -- a couple of prompt cases going on. And so we have to have enough to support the, you know, the patient care. But we -- at that point, we will only reorder what we need to bring our levels up to, you know, up to a point where we can support the patient care.

Q: And when you're talking about supporting the patient care for possible traumas, you're talking about the items you keep in inventory?

A: Correct.

Q: What about all of the other devices? Say you've got a bunch of hip-joint replacements. When do you send the purchase order, at the end of each one?

A: Correct. Those aren't -- the process, whether it's in inventory or not, are pretty much similar that we send the purchase order at the end of the procedure once it's been, you know, implanted in the patient.

Q: So you have a stack of surgeries on your desk that you need to pay the devices for; is that correct?

A: We have buyers who work in surgery. And so at the end of the day, yes, that's exactly right. They would have it from the day's transit. They would have a list of -- and again, theirs is triggered by when it's implanted in the patient, then they would -- and it's approved where it's across -- everything has been verified that it is the correct device, they would then submit the PO.

Q: I think that's it. Thank you.

MR. CARPENTER: No questions.

(There being no further questions, the deposition concluded at 10:40 a.m.)

CERTIFICATE

This is to certify that the deposition of **CHARLES PRESCOTT FERGUSON**, consisting of Forty (40) pages, is a true and correct transcript of the testimony given by said deponent after being duly sworn; said deposition was reported by the method of Stenomask with Backup.

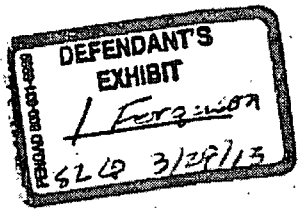
I further certify that I am neither employed by nor related to any of the parties in this matter or their counsel; nor do I have any interest, financial or otherwise, in the outcome of same.

IN WITNESS WHEREOF I have hereunto set my hand and seal on April 18, 2013.

Sara L. Quattlebaum
Court Reporter

Notary Public for South Carolina
My Commission Expires: July 12, 2012

Code of Federal Regulations
Title 21. Food and Drugs
Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)
Subchapter H. Medical Devices
Part 801. Labeling (Refs & Annos)
Subpart D. Exemptions from Adequate Directions for Use



21 C.F.R. § 801.109

§ 801.109 Prescription devices.

Currentness

A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(a) The device is:

(1)(i) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and

(2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(b) The label of the device, other than surgical instruments, bears:

(1) The statement "Caution: Federal law restricts this device to sale by or on the order of a _____", the blank to be filled with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(2) The method of its application or use.

(c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented: *Provided, however*, That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards,

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§ 40-43-60. Chief drug inspector; staff inspectors; duties; violation corrections or prosecution; duties of board; adulterated or misbranded drugs; destruction at owner's expense; seal of drugs and devices under control of licensee when license suspended or revoked; complimentary drug samples; optometric supplies.

(A) There must be an administrator of the Board of Pharmacy who must be a pharmacist licensed in the State of South Carolina and who must be the chief drug inspector. When a vacancy occurs, the position of administrator of the Board of Pharmacy shall be filled in accordance with Section 40-1-50.

(B) The Board of Pharmacy shall have its own staff of inspectors who must be pharmacists licensed in South Carolina and shall conduct all pharmacy inspections and investigations and shall report to and be supervised by the administrator of the Board of Pharmacy.

(C) The chief drug inspector, or his designee, shall visit biennially all permitted facilities in this State and inspect them to see that the laws relating to the licensing of pharmacists are obeyed and to see that all of the provisions of this chapter are obeyed and carried out by the permitted facilities and pharmacists of this State. If a violation of this chapter is discovered, the inspector either shall require the pharmacist or permit holder of the permitted facility in default immediately to correct the violation or shall prosecute the offender under the law, using his discretion after consulting with the board if considered necessary. The inspector or his designee may swear out warrants for offenders who violate the provisions of this chapter.

(D) The board shall:

(1) regulate the practice of pharmacy;

(2) regulate the sale and dispensing of drugs, poisons, and devices;

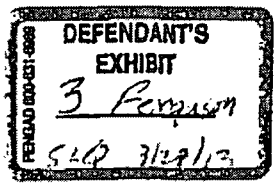
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§ 40-43-86. Facility requirements for pharmacies; presence of pharmacist-in-charge; consultant pharmacists; prescription drug orders; transferring of prescriptions; substitution of drugs; label requirements; patient records and counseling; policies and requirements for automated systems; unlawful practices; sales to optometrists and home medical equipment providers; code of ethics; sale of poisons and returned medications; permit fees; compounding regulations and restrictions.

* * *

(E) A prescription drug order shall contain at a minimum, the:

(1) full name and address of the patient;



(2) name, address, telephone number, and degree classification of the prescriber; license number, and Drug Enforcement Agency registration number of the prescribing practitioner where required by law;
(3) date of issuance;
(4) name, strength, dosage form, and quantity of drug prescribed;
(5) directions for use;
(6) number of refills authorized. No prescription marked "PRN" or any other nonspecified number of refills may be refilled more than two years beyond the date it was originally written. Nothing in this subsection abridges the right of a pharmacist to refuse to fill or refill a prescription; and
(7) a written **order** signed by the prescriber, which shall bear the name of the patient; name, strength, and quantity of the drug or device prescribed; directions for use; date of issue; and, either rubber stamped, typed, printed by hand, or typeset, the name, address, telephone number, and degree classification of the prescriber; and, if a controlled substance is prescribed, the prescriber's federal registration number;
(8) only one drug and set of instructions for each blank, if preprinted;
(9) a **chart order** is exempt from the requirements of this subsection.

* * *

8/14/29.

John MacPherson, M.D.
Pre-Op Planning Checklist

Pt. Name _____

Surg. Date 3-25-2013 12:38.

Right (Left) Bilateral

Difficulty Assessment (for scheduling)
1- Standard
2- More difficult, obese, or other factor
3- Plan for extra time; total time

- ☑ Total Knee (TKA)
- ☐ Total Hip (THA)
- ☐ Revision Knee
- ☐ Revision Hip
- ☐ Uni Knee M/L
- ☐ Removal Knee prosthesis and spacer placement
- ☐ Removal Hip prosthesis and spacer placement

If predonation of pRBC units recommended, # units _____

Special Pre-op Tests
- ☐ ESR and CRP
- ☐ Albumin
- ☐ Joint aspiration
- ☐ NIV arterial study BLE

Special Implants/Sets
- ☐ Micro
- ☐ Macro
- ☐ LCCK
- ☐ Stryker Restoration
- ☐ cemented stem
- ☐ Wagner Stem
- ☐ OOH stem
- ☐ ZMR
- ☐ TM cup
- ☐ Big Heads and liners
- ☐ Constrained liner
- ☐ All-polyethylene cup
- ☐ Antiprotrusio cage
- ☐ TM augments
- ☐ Pelvic recon. plates
- ☐ Cables
- ☐ Trochanteric Claw
- ☐ Biomet Spacer Molds

Grafts
- ☐ Zimmer Collagraft
- ☐ DBM paste/putty
- ☐ Strut Allografts
- ☐ Crushed Cancellous allograft
- ☐ Fresh Frozen Bone Allograft

Special Instrument
- ☐ Cell Saver
- ☐ Cement extraction instruments
- ☐ Cup explant set
- ☐ Revision/Implant removal instruments/osteotomes/curettes
- ☐ Small saw blade for implant removal (also used for troch. osteotomy)
- ☐ Gold Reamers
- ☐ Pressure Sentinel reamers
- ☐ Special screwdriver(s) / Synthes screw removal set as backup
- ☐ Long sharp drill bit
- ☐ Trephines
- ☐ Sterile self-contained bronchoscope or similar not requiring extra light source or monitor (for looking down femoral canal)
- ☐ Maestro with many back-up attachments (below)
  - ☐ Pencil Tip Burrs (bone cutting)
  - ☐ Stryker 3.2X18.3 Hemicoidal Rasp, Med., Ref 5120-80-30 (metal cutting)
  - ☐ Diamond Discs (metal cutting)
  - ☐ 9 mm acorn tip (bone removal)
  - ☐ 5 mm round tip (patella peg removal)

Untd. 2-24-12

DEFENDANT'S EXHIBIT 4 Ferguson SLC 3/29/13

McKESSON
Empowering Healthcare

PO Number: 805129
PO Date: 12/04/2012

Vendor:
ZIMMER INC
8684 CROWN CRESCENT CT

CHARLOTTE,NC 28227

LIANDY

Ship To
10-4810 RH OR TW
ROPER HOSPITAL
316 CALHOUN STREET

CHARLESTON, SC 29401
Attn:
Phone: 843-724-2331 Fax: 843-937-8401

Bill To:
01-7203 ACCOUNTS PAYABLE CAMSLO
316 CALHOUN STREET

CHARLESTON, SC 29401

Phone: 843-937-8132 Fax: 843-937-8401

Vendor Comm: 1800420
PO Type: S/L
PO Status: Complete
Customer No: 07000000004

Comments:
*****BILL ONLY*****
FT:CBT
DR:MCCORMICK
DOP:12/04/12
*****BILL ONLY*****

Requested By: Jennie Visser
Terms: NET 30
FOB: CHICAGO
Delivery Date: 12/04/2012
Tax ID Number:

Line Number	Vendor Catalog	Order Quantity	Unit Catalog Description	Charge Dept. Sub-Ledger	Project Sub-Project	Price Discount List Price	Ext. Price Tax Ext Price w/ Tax
Event: 807b9			K1 ZIMMER KNEE METAL TIBIA				
1	K100822	1 EA	K100822	10-4810-71.0210		$3,300.00	$3,300.00 $150.00 $3,450.00

PO Sub Total: $3,300.00 | Tax Total: $150.00 | Purchase Order Total: $3,450.00

Signature(s):

Page: 2
Total Pages Printed: 2

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ROPER_00034

EXHIBIT C

STATE OF SOUTH CAROLINA

ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a Roper St. Francis Healthcare, Petitioner, vs. South Carolina Department of Revenue, Respondent.	Civil Action No. 12-ALJ-17-0405-CC

Washington, D.C.

Wednesday, May 1, 2013

Deposition of:

MARY KATHERINE PENDERGAST

called for oral examination by counsel for Respondent, pursuant to notice, at the office of Nelson Mullins Riley & Scarborough, 101 Constitution Avenue, Northwest, Washington, D.C., before Blaire G. Benefield, FPR, of Capital Reporting Company, a Notary Public in and for the District of Columbia, beginning at 1:03 p.m., when were present on behalf of the respective parties:

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APPEARANCES

On behalf of Petitioner (telephonically):
BRYSON M. GEER, ESQUIRE
Nelson Mullins Riley & Scarborough
151 Meeting Street, Sixth Floor
Charleston, South Carolina 29401
(843) 853-5200

- AND -

RAYMOND P. CARPENTER, ESQUIRE
Raymond P. Carpenter and Associates, LLC
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Roswell, Georgia 30075
(770) 998-2722

3

APPEARANCES (cont'd.)

On behalf of Respondent (telephonically):
ADAM N. MARINELLI, ESQUIRE
Counsel for Litigation
Office of General Counsel for Litigant
South Carolina Department of Revenue
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Columbia, South Carolina 29211
(803) 898-5153

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PROCEEDINGS

(Pendergast Exhibit Nos. 1-10 were previously marked for identification.)

WHEREUPON,
MARY KATHERINE PENDERGAST
called as a witness, and having been first duly sworn, was examined and testified as follows:

MR. CARPENTER: Adam, once again, can you give this court reporter a roll call of who is here, so -- she just needs the names and whatnot.

MR. MARINELLI: My name is Adam Marinelli. I represent the Department of Revenue for South Carolina.

MR. CARPENTER: Anyone else that you want to put on the record?

MR. MARINELLI: I'll be the only one speaking. I think that's the purpose of that, right?

MR. CARPENTER: Okay. Yes. Bryson Geer with Nelson Mullins is also in the Nelson Mullins office in Charleston, and myself. That's it.

Adam, you're on.

MR. MARINELLI: Okay. Ray, do you want to

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or on the order of a physician.
Q Let's discuss that language in depth because this is where I think the rubber meets the road in this case. In subsection 2 under subsection (a), could you read that aloud for the record?
A "The device is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice."
Q Now, you're an attorney, so you've obviously interpreted plenty of statutes and regulations.
Why do you think there is a need to make the distinction between being sold to or on the order of a physician?
If every transaction required a prescription or the order of a doctor, why wouldn't they just say that as opposed to just selling it to a doctor?
A Well, I think that that's taking into account the varieties of different ways in which doctors practice medicine. Are they in their medical office or are they in a surgical suite in a hospital or where are they and what are they doing? And that takes into account the variety of ways in which it

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might happen.
Q Okay. Now, back up to the previous subsection. Why do you think there would be an entire subsection related simply to possession of these devices by a medical doctor?
A Okay. What they're basically saying is this is a nod to reality that -- so a company makes a device, right? But then they might give it to a trucking company to drive the device to a hospital. So section (a)(1)(i) says if it's in the possession of a person lawfully engaged in the transportation of the device, then it's okay -- then that trucker doesn't need to have adequate directions for lay-use.
So what it's doing is it's saying -- FDA likes to follow things from the time they're manufactured until the time they're used, and every step along the way it has to be lawful. And so there --
Q In your mind, what is the -- I'm sorry. Go ahead.
A So what they're saying is that it isn't an illegal act for the company to give it to a

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distributor or a wholesaler or a trucker in the normal course of business.
Q Okay. And then the next section deals with possession by a physician, correct?
A Right. And these are "or"s. It's okay if it's this way; it's okay if it's this way. So it's okay if it's somebody in the stream of commerce, and then it's okay if it's in the practice of a person who is using it or ordering it.
Q Doctors don't need adequate directions for use, do they?
A Well, this is the whole point. Right, and that's why, if it's in the possession of the practitioner, it doesn't need to have adequate directions for use because they already know what they are.
Q Well, let's hope they do, right?
A Well, there's that.
Q What in your mind is a prescription?
A As far as the FDA is concerned, a prescription is simply an order or an instruction from a physician that a device can or should be used for a

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particular patient for a particular purpose.
Q What about a hospital? Can a hospital as an institution prescribe something?
A A hospital as an institution?
The people who prescribe things are licensed medical practitioners and the FDA regulations say basically we're leaving it up to the states to decide in their state who gets to be a licensed healthcare practitioner because some states only have a few and some states have broader.
But the hospital as an institution as a corporate entity doesn't prescribe things. The chief of surgery --
Q In your list of --
A The chief of surgery --
Q I'm sorry. Go ahead.
A The chief of surgery might order things or prescribe things, but the hospital as a -- I don't know. I'm struggling picturing how a hospital could, as a corporate corporation, prescribe something.
Q In your mind is there a difference between the sale and the dispensing or administering of these

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received -- if I represented that to you -- obviously, I mean, there's no way for you to know that. But if that is the only document they received, do you think that satisfies the federal requirement that these things are sold by prescription?
A Well, it does name a -- it does name a physician on here. And I'm sure -- I mean, Zimmer would have to prove up to the FDA that it was sold by prescription, so they would have to trace it from the time it left its plant to the knee and making sure that all along the way it was done appropriately and that it was given to a patient properly on a doctor's order.
Q How would Zimmer prove that with one document?
A Well, it would have to go -- then it would have to go -- if the FDA was really saying to Zimmer, prove it up, they would have to go to the hospital, they'd have to get the hospital records and, you know, so on and so forth.
Q But in your mind, that purchase order qualifies as a prescription?

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A Yes. Using the industry standards, it's got a physician's name on it, and a hospital.
Q So in your mind, selling it to a doctor is the same thing as a sale by prescription?
A Well, a doctor -- well, I mean, yes, if you think it about, because it's the doctor who is making the decision. A prescription is a memorialization of a decision made by a doctor.
Q Okay. Go back to Exhibit 7 for me, please.
A Okay. Just a second. Okay.
Q If selling it to a physician is the same thing as a sale by prescription, why would there be the distinction then in subsection (a)(2) for it to be sold only to or on the order of?
A Well, I mean, it's very practical. If you're a -- if you are handing a device to a doctor because the doctor has asked you to sell the doctor the device, that is an implicit -- the sale is an implicit order saying, give me this. And so you only need a prescription or other order if it isn't being sold directly to the doctor because then you have to memorialize that that's what the doctor is asking for,

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is prescribing, is wanting.
Q Do prescriptions require patient data?
A Do they require patient data? Only --
Q Let's take the heart valve, for example. In your mind, if they order hundreds of heart valves to keep in inventory, do you still consider that a prescription even though they are not meant for any particular patient yet?
A Yes, because at the end of the day there's got to be a prescription and it's got to be kept in a little box or file at the hospital.
Q And so if South Carolina law dictates that a prescription have very specific patient information, would that change your mind?
A Well, it's hard to describe. I mean, from a federal perspective, it doesn't quite matter what South Carolina says about a prescription.
Q Well, I think a South Carolina judge would not like to hear that.
A Well, I know, but -- I'm sorry, but like the FDA, you've got regulations about what pharmacies can compound and you've probably been reading all of this

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information about the pharmacies that were compounding and have had to take all of these drugs off the market.
Well, the State of South Carolina's compounding law is more lenient or permits more compounding than the FDA would feel comfortable with. So that's all I mean is that there doesn't have to be identity between state and federal law. In other words, something could meet federal law and not meet your technical requirements.
Q But you testified earlier, though, that the FDA did not regulate what a prescription should look like; is that right?
A As long as -- right. It's an order of a physician that ultimately has to be memorialized so that it's traceable so that you can determine whether or not somebody is violating the labeling and misbranding laws.
Q And could you point me to the law or federal regulation that says that?
A Yes, I can. If you look at section 21 USC 331, and you look at (a), (b), (c) and (k), they're

that he was using in his medical practice. It was -- I think it was called the Dynatron or something. And the FDA basically thought it was medical quackery, and the FDA went after the doctor on the ground that there was no prescription.

And the court said basically, give us a break. If it's the doctor, he doesn't need to have the prescription in writing. I mean, they -- the FDA lost that case.

So that's why the FDA doesn't require -- sort of common-sensically doesn't require a doctor who has the device in his own possession for use on his own patients to have a prescription.

Q You don't remember the case of that name of that case; do you?

A Well, all FDA cases start with United States versus an article of device, and then later on you get to the name of the -- Diapulse. I think it's Diapulse, D-I-A-P-U-L-S-E. But I'm relying on my memory now, which is not a good idea.

Q Did you say D-I-A-P or -F?

A "P" like taking your pulse, D-I-A-P-U-L-S-E.

MR. MARINELLI: All right. I think that about does it. Mary, thank you so much for your time today. I hope I wasn't too confusing.

THE WITNESS: No, thank you. You were great. Thank you.

MR. CARPENTER: Adam, we are done. Thank you.

MR. MARINELLI: I'll be in the office all day today if you guys want to drop me a line and talk about scheduling or anything you've got.

MR. CARPENTER: Okay. The court reporter wanted to know if we would waive, and we will waive.

MR. MARINELLI: Absolutely.

(Signature waived.)

(Whereupon, at 3:00 p.m., the deposition of MARY PENDERGAST was concluded.)

CERTIFICATE OF NOTARY PUBLIC

I, BLAIRE G. BENEFIELD, FPR, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was taken by me in stenotypy and thereafter reduced to typewriting under my direction; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by and of the parties to the action in which this deposition was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

BLAIRE G. BENEFIELD
Notary Public in and for the
Commonwealth of Virginia

My commission expires:
January 31, 2016
Notary Registration No.: 7530333

CERTIFICATE OF NOTARY PUBLIC

I, BLAIRE G. BENEFIELD, FPR, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was taken by me in stenotypy and thereafter reduced to typewriting under my direction; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.



Blaire Benefield

BLAIRE G. BENEFIELD
Notary Public in and for the
Commonwealth of Virginia

My commission expires:
January 31, 2016
Notary Registration No.: 7530333

EXHIBIT D

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

CARE ALLIANCE D/B/A ROPER ST. FRANCIS MEDICAL HEALTH CARE, INC., Petitioner, vs. SOUTH CAROLINA DEPARTMENT OF REVENUE, Respondent.	DOCKET NO. 12-ALJ-17-0405-CC

* *

DEPOSITION OF:	M. DAUD NAWABI, M.D.
DATE TAKEN:	Friday, June 14, 2013
TIME:	10:00 a.m.
PLACE:	125 Doughty Street Suite 720 Charleston, SC
REPORTED BY:	TERI L. SAMPSON, RPR, Notary Public and Certified Live Note Reporter

* *

POST OFFICE BOX 21784
CHARLESTON, SOUTH CAROLINA 29413-1784

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ALSO PRESENT:

BRITT DOBBINS

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I N D E X

WITNESS: M. DAUD NAWABI, M.D.

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1	Highlights of Prescribing Information, Gamunex-C	14
2	21 U.S.C.A. 321 (West)	21

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S T I P U L A T I O N S

It is hereby stipulated and agreed by and between the parties hereto, through their respective counsel, that the reading and signing of the transcript is waived by the Deponent.

Electronically signed by Teri Sampson (401-251-957-7637)
0dc4827a-97c1-4f91-86d7-cc0b2c0b49cc

CHARLESTON, SOUTH CAROLINA, FRIDAY, JUNE 14, 2013

9:55 A.M.

P R O C E E D I N G S

- - - - -

WHEREUPON,

M. DAUD NAWABI, M.D.,

being first duly sworn, testified as follows:

EXAMINATION

BY MR. MARINELLI:

Q Dr. Nawabi, my name is Adam Marinelli. I represent the State of South Carolina and the South Carolina Department of Revenue. This case is Care Alliance doing business as Roper St. Francis Care versus the South Carolina DOR.

Could you please state your full name for the record?

A Mohammad Daud Nawabi.

Q Have you ever been deposed before?

A No.

Q Okay. What I'm going to do is just going to ask you a bunch of brief, hopefully concise questions. If you don't understand any of my questions, you need to clarify, feel free to tell me to do so. If you need a break at any time, feel free to ask for one, but I don't think this one will be very long.

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various cancer organizations, national cancer organizations.

Q Okay. And in those treatment plans, is the prescription of medicines included?

A Yes.

Q And what type of medicines do you typically prescribe your patients with cancer?

A We usually use chemotherapy and the supportive medications for chemotherapies.

Q Okay. And when you are -- is your office within Roper's buildings, or is this an off-site outpatient facility?

A These are off-site outpatient facilities.

Q Okay. And it's owned wholly entirely by Roper St. Francis?

A The practices are owned.

Q Okay.

A The properties are leased.

Q Okay. What type of medical supplies do you keep on site at your doctor's office?

A We keep chemotherapeutics, we keep the support drugs necessary, we keep pumps, I.V. bags, whatever is necessary to administer chemotherapy that we administer in the office. We keep, you know, other equipment, gloves, tongue depressors, gauze, the usual

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Q Do you keep some form of immunoglobulins in your office?

A Not regularly.

Q Okay. Has your attorney told you that globulins of that nature are pretty much the lion's share of the blood derivatives at issue in this case?

A Yes.

Q Are you familiar with those types of drugs?

A Yes.

Q Can you testify adequately to those drugs today?

A I believe so.

Q Okay, good. Going back briefly to the other prescription drugs that you keep in inventory, when your office makes purchases to stock those inventories, say they're on sale and you want to buy a big bulk of them like you said earlier, what type of information do you provide, does your office provide to the vendor?

A I think that in order to establish a relationship with a vendor, we've already provided them with our license numbers, our credit, our address and the normal stuff necessary in order to purchase those drugs.

Q So is it all online? Is it just a computer system that you log on and buy what you need, or is

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it --

A I believe so.

Q Okay.

A Yeah. I don't think that there's -- you can call them, but I believe that it can be ordered, I think you can also set up your storage device to automatically order. There are some things that we -- you know, that keeps an inventory and when we -- when the machine knows that we've used a certain amount, it automatically places an order for certain things.

Q So you don't even have to be involved in the process at that point, it just comes in the mail?

A We set where the -- we set what our stock should be and we can change that.

Q Okay. But when you're stocking inventory drugs that you need for any given patient, you don't provide any sort of patient-specific data to the vendor, do you?

A No.

Q Okay. Let talk about Gamunex or globulins in general, really. As you understand it, what are those drugs made of, what are they?

A So immunoglobulins are pooled immunoglobulins. Immunoglobulins are proteins that are found in the blood that are created by plasma cells.

Electronically signed by Teri Sampson (401-251-957-7637)

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C E R T I F I C A T E

STATE OF SOUTH CAROLINA:

COUNTY OF BERKELEY:

I, TERI L. SAMPSON, Registered Professional Reporter, Notary Public and Certified Live Note Reporter, State of South Carolina at Large, certify that I was authorized to and did stenographically report the foregoing deposition; and that the transcript is a true record of the testimony given by the witness.

I further certify that I am not a relative, employee, attorney or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

WITNESS MY HAND AND OFFICIAL SEAL this 16th day of June, 2013, in the Town of Goose Creek, County of Berkeley, State of South Carolina.



Teri L. Sampson, RPR,
Notary Public and Certified
Live Note Reporter
My commission expires:

Electronically signed by Teri Sampson (401-251-957-7637)
0dc4827a-97c1-4f91-86d7-cc0b2c0b49cc

EXHIBIT E

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

CAREALLIANCE HEALTH SERVICES d/b/a ROPER ST. FRANCIS HEALTHCARE,	)	CIVIL ACTION NO: 12-ALJ-17-0405-CC
Petitioner,	)	
vs.	)	
SOUTH CAROLINA DEPARTMENT OF REVENUE,	)	
Defendant.	)	

* * * * * * * * * * * * * * * * *

DEPOSITION OF: JOHN MCCROSSON, M.D.

DATE TAKEN: Thursday, April 25, 2013

TIME: 3:15 p.m.

PLACE: Roper St. Francis Healthcare
125 Doughty Street, Suite 720
Charleston, South Carolina

REPORTED BY: EVE WILBANKS
Registered Professional
Reporter, Certified LiveNote
Reporter and Notary Public

* * * * * * * * * * * * * * * * *

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ALSO PRESENT: BRITT C. DOBBINS

Electronically signed by Eve Wilbanks (101-177-349-6970)
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** Exhibit Nos. 3, 10, 11, 13 and 14 were not entered.

Electronically signed by Eve Wilbanks (101-177-349-6970)
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STIPULATIONS

It is hereby stipulated and agreed by and between the parties hereto, through their respective counsel, that the reading and signing of the transcript is waived by the Deponent.

JOHN MCCROSSON, M.D., SWORN.

DIRECT EXAMINATION

BY MS. ACQUAVIVA:

Q. Good afternoon, Dr. McCrosson. My name is Lauren Acquaviva, and I represent the Department in this case and I will be taking your deposition. Have you ever had your deposition taken before?

A. Yes.

Q. Do you know about how many times?

A. Fifteen.

Q. Since you probably know how the procedure works, just briefly, if I ask you a question and you don't understand it, will you tell me that you don't understand the question?

A. Sure.

Q. And if you don't tell me that you don't understand it, I will assume that you did understand my question. Is that okay?

A. Okay.

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Electronically signed by Eve Wilbanks (101-177-349-6970)

Q. Could you write yourself a prescription for something?

A. Yes. I actually could write you one, but I would have to make a chart and establish that we had some kind of -- I wouldn't do that in this situation. But as long as I establish a physician/patient relationship and document that in a chart, I can prescribe most things to most people, but I cannot prescribe certain controlled substances to family members or inappropriate relationships, where it would be foggy whether I had a proper therapeutic relationship.

Q. Can you give me an example or a couple of examples of things that you have written prescriptions for?

A. Yes. Most commonly, pain medication after surgery, antibiotics. Those are, by far, the most common prescriptions I write.

Q. Now, you're going to have bear with me through these questions because I might not understand your answers.

A. Okay.

Q. How do you know what you need to write a prescription for and what you don't need to write a prescription for? Is there a book that tells

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the name, address, telephone number and degree classification of the prescriber; and if a controlled substance is prescribed, the prescriber's federal registration number." 8, "Only one drug and set of instructions for each blank, if preprinted." 9, "A chart order is exempt from the requirements of this subsection."

Q. So would you say that any time you write a prescription for pain medicine, it has all of this information on it?

A. It may or may not. I'm not sure that it does. Let's see. Yeah, pain medication certainly has all of those on there.

Q. When you write a prescription for a prosthetic device, does it have all of these things on it?

A. No. That's not a prescription drug order, potentially, either.

Q. Can we look back at the definition of a prescription drug order? And it includes devices, correct?

A. Right. It doesn't mean that that's the only way a device can be ordered, though.

Q. Do you have records of prescriptions that you've written for prosthetic devices?

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A. No.
Q. Do you know if someone would have records of those?
A. No.
Q. Is it an oral prescription or a written prescription?
A. For --
Q. For the prosthetic devices.
A. For these knee and hip replacements, it's oral.
Q. How do you make that oral prescription?
A. During surgery -- we make all the preparations for certain sizes, et cetera, and then I call it out. I say, I want E 3 10 29 (ph), and those would be the four sizes of the -- and they know what implant I use each time on a standard case. Of course, if it's not standard, then I say more specifics than E 3 10 29.
Q. Do you know what the vendor does with that information after you call it out?
A. Yes. He gets the box and hands it to the Registered Nurse in the room.
Q. Does he ever write it down, keep a record of it?
A. Probably so, for billing purposes.

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Q. Now, could you write a prescription to a patient for an over-the-counter medication?

A. Yes.

Q. Why would a doctor do that?

A. For insurance purposes.

Q. But the prescription wouldn't be required in that case, would it?

A. That's right. The patient could get the medicine without the prescription.

Q. Now I want to get into talking about medical devices in general. I want to go back to the emergency situation real quick.

A. Yes.

Q. When the vendor isn't there, and -- let's say the part that you need is in that stockroom and you're orally prescribing that part --

A. Right.

Q. -- who writes that down?

A. I'm not sure.

Q. Do you know if anyone keeps track of that?

A. I'm sure the hospital wants them to so they can bill for it. Or the vendor wants to get paid for it, et cetera. So probably so, but I'm

were in your private practice -- back in 2000, I think you said you started?

A. Right.

Q. Was that your first job out of medical school?

A. After fellowship, yes. So you're really employed as a resident and fellow too. So this whole six years I had a job, and it was my first time out in real practice.

Q. So when you were in private practice, who was your employer?

A. The corporation known as Orthopaedic Specialists of Charleston that I became a partner of two years later.

Q. So they paid you? That's where you got your paychecks?

A. Right.

Q. When you were in private practice, did you ever administer anything in your office that would be considered by prescription only?

A. Yes.

Q. Like what?

A. Like injections, knee joint injections, cortisone or Viscosupplementation, artifical joint fluid. Those come to mind. Braces -- knee

Electronically signed by Eve Wilbanks (101-177-349-6970)

0d95a6e3-60fe-41e1-bf25-82cc9fbe72da

braces.

Q. Did you have those on-site in inventory?

A. The cortisone and local anesthetic we did. The artificial joint fluid I did not. I wrote a prescription and the patient would go get it filled and bring it back, because we lost money if we kept inventory. And braces, we had -- DonJoy handled our durable medical equipment. So it was in our office, but we did not own the inventory or profit from it.

Q. You said you kept an inventory of the cortisone shots --

A. Yes.

Q. -- or I guess the fluid that would go in the --

A. Right, right.

Q. How did you get those? Do you know how they were purchased?

A. No. All I know is the medical assistants just took inventory and did monthly orders or something like that. But I don't know what was involved with doing that. I don't remember ever signing anything as part of that.

Q. Do you know where they ordered them from?

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CERTIFICATE OF REPORTER

I, Carol Denise Lauder, Registered Professional Reporter and Notary Public for the State of South Carolina at Large, do hereby certify that the foregoing transcript is a true, accurate, and complete record.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof.

Witness my hand, I have hereunto affixed my official seal this 16th day of June, 2013 at Charleston, Charleston County, South Carolina.



Carol Denise Lauder
Registered Professional
Reporter, CP
My Commission expires
August 2, 2017

EXHIBIT F

In the Matter of:

CareAlliance Health Services

v

South Carolina Dept. of Revenue

MELANIE HUTCHERSON

May 08, 2013

COPY

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STATE OF SOUTH CAROLINA

ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a Roper/St. Francis Medical Healthcare, Inc., Petitioner, v. South Carolina Department of Revenue, Respondent.	) Docket No. 12-ALJ-17-0405-CC

DEPOSITION of MELANIE HUTCHERSON

DATE: Wednesday, May 8, 2013
TIME: 3:28 p.m.
PLACE: Faegre Baker & Daniels
111 East Wayne Street, Eighth Floor
Fort Wayne, Indiana

Called as a witness herein in accordance with the Rules of Civil Procedure before Tonya Esparza, Registered Professional Reporter and Notary Public

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APPEARANCES:

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111 East Wayne Street, Suite 800
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(260) 424-8000
peter.meyer@faegrebd.com

On behalf of the Witness and Zimmer, Inc.

Also Present: Lisa Dunkin

TELEPHONIC APPEARANCES:

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ATTORNEY AT LAW
300A Outlet Pointe Boulevard
Columbia, South Carolina 29210
(803) 898-5153

On behalf of the Respondent;

MR. JOHN C. VON LEHE, JR., ESQ.
NELSON MULLINS RILEY & SCARBOROUGH
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(843) 853-5200
john.vonlehe@nelsonmullins.com

On behalf of the Petitioner.

Also announced as present: Raymond Carpenter
Bryson Geer
Lauren Acquaviva
Britt Dobbins

W I T N E S S I N D E X

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E X H I B I T I N D E X

(None)

Melanie Hutcherson,

called as a witness herein, having been first duly sworn, as hereinafter certified, was examined and testified as follows:

DIRECT EXAMINATION OF MELANIE HUTCHERSON

BY MR. MARINELLI:

Q. Hi, Melanie. My name is Adam Marinelli. How are you?

A. I'm good. Thank you.

Q. I'm an attorney for the South Carolina Department of Revenue. I'm going to try to move quickly through this depo so we don't waste anybody's time.

Have you ever been deposed before?

A. Have I ever been to what?

Q. Have you ever been deposed before?

A. I don't think so.

Q. Okay. Well --

MR. MEYER: Have you ever given a deposition?

Q. -- what's going to happen, I'm going to ask you some basic questions about this case. If there's any question you don't understand, feel free to ask me to clarify it, we'll repeat it. Any question you do answer, I'm going to assume that you understood the question. Okay?

Once the case has been completed, so the implant has been implanted into the patient, there is a requisition sheet that has the patient sticker put on it, identifies information about the patient, produced by the hospital, put on the requisition sheet, and then the rep will take the bar code stickers from each of the products that were consumed and put that on the sticker sheet, along with the pricing.

At that point in time they'll review that document with the OR nurse or the circulating nurse to make sure that both parties are in agreement to the product that was implanted into the patient, and then that requisition sheet then typically goes to a buyer to input the requisition into the system to create the purchase order.

At the same time our rep will the scan that stickers -- the stickers on the sticker sheet, and that will go into our system, so we recognize what products have been consumed or used in the patient.

And at that point in time we'll wait for the purchase order to reconcile between what the rep sent in and what the purchase order presented to make sure that both are intact. And then we will go ahead and add the purchase order so that we can generate the invoice.

say that's how it generally happens. How else can it happen?

A. That's typically the process flow that the folks use. The content and the manner in which -- the documents that are shared between facilities and the sequence in which things occur can be slightly varied, but that is the typical process that we follow across many, if not all, of our hospitals.

Q. Okay. Is the requisition sheet the only document that Zimmer receives from the hospital?

A. No.

Q. What other documents do they receive?

A. We receive a purchase order.

Q. Okay. And how is that different from the requisition sheet?

A. Essentially the purchase order provides a purchase order number indicating that they've authorized that product to be used and billable.

Q. Okay. So it's more of a accounting document; is that right? Is it a way to track the device as far as billing goes?

A. Yes.

Q. Okay.

A. It --

Q. And is that the only other document that the hospital

passes on to Zimmer?
A. Yes.
Q. Does Zimmer ever receive patient specific prescriptions when these devices are purchased?
MR. MEYER: Objection. I think the term prescription is something that's been debated in -- amongst the lawyers on both sides and kind of calls for a legal conclusion. And so I --
MR. MARINELLI: Okay. That's fine.
MR. MEYER: I would see if you could rephrase.
BY MR. MARINELLI:
Q. Does Zimmer request patient specific information before it sells its devices to a hospital?
A. I'm -- I'm not exactly sure how to answer that question.
Q. Let me pose it a different way.
A. Okay.
Q. If a hospital called you, if you were a sales rep, and said, "I want an inventory, a large quantity of these items," would Zimmer sell it to them?
A. We would, but after further investigation as to why a large purchase would be made. That's -- that's not our typical practice.
Q. Okay.
A. So we would determine why that large quantity was

needed first.
Q. Say, for example, for trauma victims they want to keep a stock on hand for trauma victims, would that be the extent of your -- tell me what the investigation would include, I guess.
A. I guess would department on your definition of a large quantity.
Q. More than one?
A. More than one?
Q. Yeah.
A. Yes, we would sell more than one without hesitation to a customer specifically for trauma product. But I guess my definition of large would be something much larger than one.
Q. Well, let's just go down that rabbit hole, I guess. How many would be too many?
A. Well, typically the distributor offices know the inventory that's at the hospitals. So if they ordered something that was exceptionally large from what they already had on stock or would typically need, there would be a question as to is there a change in practice, either at the hospital or with the surgeon that's performing the surgery at that hospital.
Q. Okay. Okay. And do most hospitals have an inventory of your products on site?

A. That varies hospital by hospital, but yes, a lot of hospitals do have our inventory on site.
Q. And are those owned by Zimmer or the hospital's already purchased those?
A. Both.
Q. Both, it just depends on --
A. It --
Q. -- the hospitals?
A. It does. It does.
Q. Okay. And in the instances where the hospital owns that inventory, what type of documentation does Zimmer require to make that sale to stock the inventory?
A. Purchase order.
Q. And that's it?
A. Uh-huh.

MR. MEYER: Can we make a distinction here between types of products? Because I think we're getting confused. At least I'm a little confused.

MR. MARINELLI: Let's just, for the rest of these questions, assume I'm talking about hip replacements.

MR. MEYER: Okay.

MR. MARINELLI: Does that work?

MR. MEYER: Yeah, that's fine, because I think the answers will likely vary depending on what type of product we're discussing.

CERTIFICATE

I, TONYA ESPARZA, a Registered Professional Reporter and Notary Public authorized to administer oaths and to take and certify depositions, do hereby certify that the above-named witness was by me, before the giving of their deposition, first duly sworn to testify the truth, the whole truth, and nothing but the truth to questions propounded at the taking of the foregoing deposition in a cause now pending and undetermined in said court.

I further certify that the deposition above set forth was reduced to writing by me by means of machine shorthand and was later transcribed from my original shorthand notes; that this is a true record of testimony given by the witness; and that said deposition was taken at the aforementioned time, date, and place, pursuant to notice or stipulations of counsel.

IN WITNESS WHEREOF, I have set my hand and seal this 2nd day of May, 2013.

Tonya Esparza

Tonya Esparza, RPR
Notary Public in the County
of Allen, State of Indiana
My Commission expires:
May 23, 2017

EXHIBIT G

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA

CareAlliance Health Services d/b/a Roper St. Francis Healthcare,	)	CIVIL ACTION NO: 12-ALJ-17-0405-CC
Plaintiff,	)	
vs.	)	
SOUTH CAROLINA DEPARTMENT OF REVENUE,	)	
Defendant.	)	

* * * * * * * * * * * * * * * * * *

DEPOSITION OF: BRETT M. BAKER, M.D.

DATE TAKEN: June 25, 2013

TIME: 2:40 P.M.

PLACE: Roper St. Francis
125 Doughty Street
Charleston, SC

REPORTED BY: DENISE LAUDER
Registered Professional
Reporter and Notary Public

* * * * * * * * * * * * * * * * * *

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Electronically signed by Denise Lauder (301-268-293-2597)

A P P E A R A N C E S

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STIPULATIONS

It is hereby stipulated and agreed by and between the parties hereto, through their respective counsel, that the reading and signing of the transcript is expressly waived by the Deponent.

(RESPONDENT EXH. 1, Copy of CV, was marked for identification.)

BRETT M. BAKER, M.D.,

being first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MS. ACQUAVIVA:

Q. Good afternoon, Dr. Baker. My name is Lauren Acquaviva and I will be taking your deposition in this case; it's CareAlliance doing business as Roper St. Francis Healthcare System versus the South Carolina Department of Revenue. Have you ever had your deposition taken before?

A. Yes.

Q. How many times?

A. Four or five.

Q. Okay. And since you kind of know how this works, if at any time during the deposition you need a break, feel free to ask. If I ask you a question that you don't understand, will you tell

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are you authorized to prescribe something to?

A. I mean, I guess it would be a patient under your care, where, you know, you have the appropriate background and training to recommend a remedy or treatment.

Q. Can you prescribe something to a hospital?

A. In terms of saying -- I don't know that I would understand.

Q. Can you form a doctor/patient relationship with a hospital?

A. No.

Q. Okay. So you couldn't write a prescription to a hospital, then, correct?

A. No. I mean, it doesn't seem like...

MS. ACQUAVIVA: Let's take a break.

(A recess transpired.)

BY MS. ACQUAVIVA:

Q. What do you consider to be a body part?

A. In terms of -- I mean, I guess it would be a structure in the body.

Q. Do you consider the heart's electrical system to be a body part?

A. I think that it's -- it's a combination of things. I mean, I think that I would argue that

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I, Carol Denise Lauder, Registered Professional Reporter and Notary Public for the State of South Carolina at Large, do hereby certify that the foregoing transcript is a true, accurate, and complete record.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof.

Witness my hand, I have hereunto affixed my official seal this 26th day of June, 2013 at Charleston, Charleston County, South Carolina.

Carol Denise Lauder
Registered Professional
Reporter, CP
My Commission expires
August 2, 2017

Electronically signed by Denise Lauder (301-268-293-2597)
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