

THE STATE OF SOUTH CAROLINA
In The Court Of Appeals

APPEAL FROM THE ADMINISTRATIVE LAW COURT

HONORABLE SHIRLEY C. ROBINSON, ADMINISTRATIVE 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.

**RECORD ON APPEAL
VOLUME II**

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CareAlliance Health Services d/b/a Roper	)	Civil Action No. 12-AJ-17-0405-CC
St. Francis Healthcare,	)	
	)	
Petitioner,	)	
	)	
vs.	)	<u>AMENDED MOTION FOR</u>
	)	<u>SUMMARY JUDGMENT AND</u>
	)	<u>MEMORANDUM IN SUPPORT OF</u>
South Carolina Department of Revenue,	)	<u>SAME</u>
	)	
Respondent.	)	
	)	

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.

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. See Ex. C, Affidavit of John McCrosson, M.D. ("McCrosson Aff.") at ¶1-2. He states that these devices are prescription devices and can only be sold by prescription. Id. at ¶3. 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 ¶4. He testified that his order for the orthopedic device is a prescription as required by law. Id. 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 5.

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. See Ex. D, Affidavit of Brett M. Baker, M.D. ("Baker Aff.") at ¶1-2. He testified that the Cardiac Devices are prescription devices and may only be sold by prescription. Id. at ¶3. He states that he issues an oral order for the Cardiac Devices he implants during surgery, which is when he finally determines the exact device, including the components and leads, the patient needs. Id. at 4. He considers this oral order to be a prescription as required by law. Id. 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 6.

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 states that a patient requiring a joint replacement will always be missing cartilage. McCrosson Aff. at ¶6. Additionally, during surgery, Dr. McCrosson removes more of the patient's joint to accommodate the prosthetic device he is implanting. Id. The orthopedic device replaces the missing cartilage and joint. Id. Although a formal stipulation has not been entered, it is Petitioner's understanding that the Department does not contest these facts.

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 Aff. at ¶7. The Cardiac Device replaces this missing cardiac tissue and restores the normal heart rhythm. Id.²

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. See Ex. E, Affidavit of M. Daud Nawabi, M.D. ("Nawabi Aff.") at ¶2. 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. Id. at ¶3. 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 ¶4. 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 ¶5. The blood proteins, which include, *inter alia*, immunoglobulins and albumin, are then processed in a similar way to the red blood cells and platelets (i.e. which can include screening for infectious diseases, re-suspending in a buffer and adding a preservative). Id. at ¶6. 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 ¶7. Nothing in the processing of the red blood cells, the platelets or the blood proteins extracted from the plasma in any way alters,

² Dr. Baker states 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 Aff. at ¶8.

modifies or changes their nature in any way. Id. at ¶8. The blood proteins are not synthetic, artificial or pharmaceutical. Id. at ¶9. They are not manufactured but rather are created by the human body. Id.

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. Id. at ¶10.

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.³ 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 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 (Cr. App. 2002). As discussed more fully below, Petitioner submits that the sales tax exemption statute at

³ 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.

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).⁴

The Secretary has exercised the authority above in 21 CFR § 801.109, which provides, *inter alia*, that:

⁴ Under S.C. Code Ann. 19-3-150, this Court may take judicial notice of foreign law, which could be interpreted to include federal statutes and regulations being applied to a case pending in state court.

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 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 stated 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 and size of device needed by their patients becomes known to them. See Ex. C, McCrosson Aff. at ¶4; Ex. D, Baker Aff. at ¶4. The physicians have further testified that these oral orders constitute their prescriptions as required by law. Ex. C, McCrosson Aff. at ¶4; Ex. D, Baker Aff. at ¶4. The physicians then memorialize the orders in writing. Ex. C, McCrosson Aff. at ¶5; Ex. D, Baker Aff. at ¶5. 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 orthopedic device replaces missing cartilage in the joint of the patient and any portion of the joint removed during surgery. Ex. C, McCrosson Aff. at Aff. at ¶6. 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 Aff. at Aff. at ¶6. 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 factual or medical basis on which to distinguish some items derived from blood as less "human" than others. The blood proteins are processed in a similar way to the red blood cells and platelets that the Department exempts from taxation. Ex. E, Nawabi Aff. at ¶¶3-6. 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 ¶¶2-9. The blood proteins are not synthetic, artificial or pharmaceutical. Id. at ¶10. 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 points out when he states that sales of blood require the order of a physician. See Ex. E, Nawabi Aff. at ¶11. Because this decision is unreported, has not been formally adopted by the Department of Revenue, is not memorialized in a revenue ruling or regulation, and is contradictory and based 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 cartilage.

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, depositions, affidavits and evidence of record in this case.

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Francis Healthcare

Charleston, South Carolina
August 28, 2013

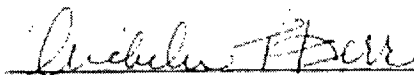
CERTIFICATE OF SERVICE

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
South Carolina Department of Revenue
301 Gervais Street (29201)
PO Box 12265
Columbia, SC 29211


Administrative Assistant

August 29, 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 through 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 Kendergast
Mary K. Kendergast

SWORN to and subscribed before me
this 23 day of August, 2013

[Signature] (L.S.)

Notary Public for the District of Columbia
My commission expires 10/31/2017



EXHIBIT 1

tum by weight of moisture. The fat content is not over 1½ per centum by weight unless otherwise indicated.

The term "milk", when used herein, means sweet milk of cows.

(Mar. 2, 1944, ch. 77, 58 Stat. 108; July 2, 1956, ch. 495, 70 Stat. 486.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act of June 25, 1938 (ch. 675, sec. 1, 52 Stat. 1040), referred to in text, probably means act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to this chapter (§ 301 et seq.). For complete classification of this Act to the Code, see section 301 of this title and Tables.

CODIFICATION

Section was not enacted as a part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter, but was made applicable thereto.

AMENDMENTS

1956—Act July 2, 1956, substituted "nonfat dry milk" for "nonfat dry milk solids or defatted milk solids".

§ 321d. Market names for catfish and ginseng

(a) Catfish labeling

(1) In general

Notwithstanding any other provision of law, for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)—

(A) the term "catfish" may only be considered to be a common or usual name (or part thereof) for fish classified within the family Ictaluridae; and

(B) only labeling or advertising for fish classified within that family may include the term "catfish".

(2) Omitted

(b) Ginseng labeling

(1) In general

Notwithstanding any other provision of law, for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)—

(A) the term "ginseng" may only be considered to be a common or usual name (or part thereof) for any herb or herbal ingredient derived from a plant classified within the genus *Panax*; and

(B) only labeling or advertising for herbs or herbal ingredients classified within that genus may include the term "ginseng".

(2) Omitted

(Pub. L. 107-171, title X, § 10806, May 13, 2002, 116 Stat. 526.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (a)(1), (b)(1), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to this chapter. For complete classification of this Act to the Code, see section 301 of this title and Tables.

CODIFICATION

Section is comprised of section 10806 of Pub. L. 107-171. Subsecs. (a)(2) and (b)(2) of section 10806 of Pub. L. 107-171 amended section 343 of this title.

Section was enacted as part of the Farm Security and Rural Investment Act of 2002, and not as part of Federal Food, Drug, and Cosmetic Act which comprises this chapter.

SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES

§ 331. Prohibited acts

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 350d, 355, or 360bbb-3 of this title.

(e) The refusal to permit access to or copying of any record as required by section 350a, 350c, 350f(j), 350e, 354, 360bbb-3, 373, 374(a), 379aa, or 379aa-1 of this title; or the failure to establish or maintain any record, or make any report, required under section 350a, 350c(b), 350f, 350e, 354, 355(l) or (k), 360b(a)(4)(C), 360b(j), (f) or (m), 360ccc-1(l), 360e(f), 360i, 360bbb-3, 379aa, 379aa-1, 387i, or 387t of this title or the refusal to permit access to or verification or copying of any such required record; or the violation of any record-keeping requirement under section 3223 of this title (except when such violation is committed by a farm).

(f) The refusal to permit entry or inspection as authorized by section 374 of this title.

(g) The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 333(c)(2) of this title, which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, tobacco product, or cosmetic; or the giving of a guaranty or undertaking referred to in section 333(c)(3) of this title, which guaranty or undertaking is false.

(i)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 344 or 379e of this title.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing,

¹ See References in Text note below.

or the holding for sale or dispensing, of a counterfeit drug.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of section 344, 348, 350a, 350c, 355, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 360ccc, 360ccc-1, 360ccc-2, 374, 379, 379e, 387d, 387e, 387f, 387g, 387h, 387i, or 387t(b) of this title concerning any method or process which as a trade secret is entitled to protection; or the violating of section 346a(1)(2) of this title or any regulation issued under that section.² This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(l) Repealed. Pub. L. 105-115, title IV, § 421, Nov. 21, 1997, 111 Stat. 2380.

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of subsections (b) or (c) of section 347 of this title.

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 374 of this title.

(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter.

(p) The failure to register in accordance with section 360 or 387e of this title, the failure to provide any information required by section 360(j), 360(k), 387e(i), or 387e(j) of this title, or the failure to provide a notice required by section 360(j)(2) or 387e(i)(3) of this title.

(q)(1) The failure or refusal—

(A) to comply with any requirement prescribed under section 360h, 360j(g), 387c(b), 387g, 387h, or 387o of this title;

(B) to furnish any notification or other material or information required by or under section 360i, 360j(g), 387d, 387i, or 387t of this title;

or

(C) to comply with a requirement under section 360l or 387m of this title.

(2) With respect to any device or tobacco product, the submission of any report that is required by or under this chapter that is false or misleading in any material respect.

(r) The movement of a device or tobacco product in violation of an order under section 334(g) of this title or the removal or alteration of any mark or label required by the order to identify the device or tobacco product as detained.

(s) The failure to provide the notice required by section 350a(c) or 350a(e) of this title, the failure to make the reports required by section 350a(f)(1)(B) of this title, the failure to retain the records required by section 350a(b)(4) of this title, or the failure to meet the requirements prescribed under section 350a(f)(3) of this title.

(t) The importation of a drug in violation of section 381(d)(1) of this title, the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 353(c) of this title, the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 353(c)(2) of this title, the distribution of a drug sample in violation of section 353(d) of this title or the failure to otherwise comply with the requirements of section 353(d) of this title, or the distribution of drugs in violation of section 353(e) of this title or the failure to otherwise comply with the requirements of section 353(e) of this title.

(u) The failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary, under section 360b(a)(4)(A), 360b(a)(4)(D), or 360b(a)(5) of this title.

(v) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 350b of this title.

(w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 381(d)(3) of this title; the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with section 381(e) or 382 of this title, or with section 262(h) of title 42; or the failure to so export or to destroy such an article or portions thereof, or such a finished product.

(x) The falsification of a declaration of conformity submitted under section 360d(c) of this title or the failure or refusal to provide data or information requested by the Secretary under paragraph (3) of such section.

(y) In the case of a drug, device, or food—

(1) the submission of a report or recommendation by a person accredited under section 360m of this title that is false or misleading in any material respect;

(2) the disclosure by a person accredited under section 360m of this title of confidential

² So in original.

commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

(3) the receipt by a person accredited under section 360m of this title of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this chapter.

(z) Omitted.

(aa) The importation of a prescription drug in violation of section 384 of this title, the falsification of any record required to be maintained or provided to the Secretary under such section, or any other violation of regulations under such section.

(bb) The transfer of an article of food in violation of an order under section 334(h) of this title, or the removal or alteration of any mark or label required by the order to identify the article as detained.

(cc) The importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of, a person detained under section 335a(b)(3) of this title.

(dd) The failure to register in accordance with section 350d of this title.

(ee) The importing or offering for import into the United States of an article of food in violation of the requirements under section 381(m) of this title.

(ff) The importing or offering for import into the United States of a drug or device with respect to which there is a failure to comply with a request of the Secretary to submit to the Secretary a statement under section 381(o) of this title.

(gg) The knowing failure to comply with paragraph (7)(E) of section 374(g) of this title; the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.

(hh) The failure by a shipper, carrier by motor vehicle, or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the sanitary transportation practices prescribed by the Secretary under section 350e of this title.

(ii) The falsification of a report of a serious adverse event submitted to a responsible person (as defined under section 379aa or 379aa-1 of this title) or the falsification of a serious adverse event report (as defined under section 379aa or 379aa-1 of this title) submitted to the Secretary.

(jj)(1) The failure to submit the certification required by section 282(j)(5)(B) of title 42, or knowingly submitting a false certification under such section.

(2) The failure to submit clinical trial information required under subsection (j) of section 282 of title 42.

(3) The submission of clinical trial information under subsection (j) of section 282 of title 42 that is false or misleading in any particular under paragraph (5)(D) of such subsection (j).

(kk) The dissemination of a television advertisement without complying with section 353b of this title.

(ll) The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 355 of this title, a biological product licensed under section 262 of title 42, or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless—

(1) such drug or such biological product was marketed in food before any approval of the drug under section 355 of this title, before licensure of the biological product under such section 262 of title 42, and before any substantial clinical investigations involving the drug or the biological product have been instituted;

(2) the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, approving the use of such drug or such biological product in the food;

(3) the use of the drug or the biological product in the food is to enhance the safety of the food to which the drug or the biological product is added or applied and not to have independent biological or therapeutic effects on humans, and the use is in conformity with—

(A) a regulation issued under section 348 of this title prescribing conditions of safe use in food;

(B) a regulation listing or affirming conditions under which the use of the drug or the biological product in food is generally recognized as safe;

(C) the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier's determination that the use of the drug or the biological product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier;

(D) a food contact substance notification that is effective under section 348(h) of this title; or

(E) such drug or biological product had been marketed for smoking cessation prior to September 27, 2007; or

(4) the drug is a new animal drug whose use is not unsafe under section 360b of this title.

(mm) The failure to submit a report or provide a notification required under section 350f(d) of this title.

(nn) The falsification of a report or notification required under section 350f(d) of this title.

(oo) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 333(f) of this title.

(pp) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 387k of this title.

(qq)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing

any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(j) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

(rr) The charitable distribution of tobacco products.

(ss) The failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of their knowledge of tobacco products used in illicit trade.

(tt) Making any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that—

(1) the product is approved by the Food and Drug Administration;

(2) the Food and Drug Administration deems the product to be safe for use by consumers;

(3) the product is endorsed by the Food and Drug Administration for use by consumers; or

(4) the product is safe or less harmful by virtue of—

(A) its regulation or inspection by the Food and Drug Administration; or

(B) its compliance with regulatory requirements set by the Food and Drug Administration;

including any such statement or representation rendering the product misbranded under section 387c of this title.

(uu) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 350g of this title.

(vv) The failure to comply with the requirements under section 350b of this title.

(vw) The failure to comply with section 350i of this title.

(xx) The refusal or failure to follow an order under section 350j of this title.

(yy) The knowing and willful failure to comply with the notification requirement under section 350f(h) of this title.

(zz) The importation or offering for importation of a food if the importer (as defined in section 384a of this title) does not have in place a foreign supplier verification program in compliance with such section 384a of this title.

(June 25, 1938, ch. 675, § 301, 52 Stat. 1042; Dec. 22, 1941, ch. 613, § 1, 55 Stat. 851; July 6, 1945, ch. 281, § 1, 59 Stat. 463; Mar. 10, 1947, ch. 16, § 1, 61 Stat. 11; June 24, 1948, ch. 613, § 1, 62 Stat. 582; Mar. 16, 1950, ch. 61, § 3(b), 64 Stat. 20; Aug. 7, 1953, ch. 350, § 2, 67 Stat. 477; Pub. L. 85-929, § 5, Sept. 6, 1958, 72 Stat. 1788; Pub. L. 86-618, title I, § 104, 105(a), July 12, 1960, 74 Stat. 403; Pub. L. 87-781, title I, § 103(c), 104(e)(1), 106(c), 114(a), title III, § 304, Oct. 10, 1962, 76 Stat. 784, 785, 788, 791, 795; Pub. L. 89-74, § 5, 9(c), July 15, 1966, 79 Stat. 232, 235;

Pub. L. 90-399, § 103, July 13, 1968, 82 Stat. 352; Pub. L. 90-539, § 2(b), Oct. 24, 1968, 82 Stat. 1381; Pub. L. 91-513, title II, § 701(a), Oct. 27, 1970, 84 Stat. 1281; Pub. L. 92-387, § 4(e), Aug. 16, 1972, 86 Stat. 562; Pub. L. 94-295, §§ 3(b), 4(b)(1), 7(b), May 28, 1976, 90 Stat. 576, 580, 582; Pub. L. 96-359, § 5, Sept. 26, 1980, 94 Stat. 1193; Pub. L. 99-570, title IV, § 4014(b)(2), Oct. 27, 1986, 100 Stat. 3207-120; Pub. L. 100-293, § 7(a), Apr. 22, 1988, 102 Stat. 99; Pub. L. 101-502, § 5(j), Nov. 3, 1990, 104 Stat. 1289; Pub. L. 101-508, title IV, § 4755(c)(2), Nov. 5, 1990, 104 Stat. 1388-210; Pub. L. 102-300, § 3(a)(1), June 16, 1992, 106 Stat. 238; Pub. L. 102-571, title I, § 107(2), (3), Oct. 29, 1992, 106 Stat. 4489; Pub. L. 103-80, § 3(c), Aug. 13, 1993, 107 Stat. 775; Pub. L. 103-398, § 2(b)(1), Oct. 22, 1994, 108 Stat. 4154; Pub. L. 103-417, § 10(b), Oct. 25, 1994, 108 Stat. 4332; Pub. L. 104-134, title II, § 2103, Apr. 26, 1996, 110 Stat. 1321-319; Pub. L. 104-170, title IV, § 403, Aug. 3, 1996, 110 Stat. 1514; Pub. L. 104-250, § 5(d), Oct. 9, 1996, 110 Stat. 3156; Pub. L. 105-115, title I, § 125(a)(2)(A), (C), (b)(2)(B), title II, § 204(b), 210(c), title IV, § 401(b), 421, Nov. 21, 1997, 111 Stat. 2325, 2336, 2345, 2364, 2380; Pub. L. 106-387, § 1(a) [title VII, § 745(d)(1)], Oct. 28, 2000, 114 Stat. 1549, 1549A-39; Pub. L. 107-188, title III, § 303(b), 304(d), 305(b), 306(c), 307(b), 321(b)(2), 322(b), June 12, 2002, 116 Stat. 664, 668, 668, 670, 672, 675, 677; Pub. L. 107-250, title II, § 201(d), Oct. 26, 2002, 116 Stat. 1609; Pub. L. 108-136, div. A, title XVI, § 1603(c), Nov. 24, 2003, 117 Stat. 1690; Pub. L. 108-173, title XI, § 1121(b)(1), Dec. 8, 2003, 117 Stat. 2469; Pub. L. 108-214, § 2(b)(2)(A), Apr. 1, 2004, 118 Stat. 575; Pub. L. 108-282, title I, § 102(b)(5)(C), (D), Aug. 2, 2004, 118 Stat. 902; Pub. L. 109-59, title VII, § 7202(d), (e), Aug. 10, 2005, 119 Stat. 1913; Pub. L. 109-462, §§ 2(c), 3(b), 4(a), Dec. 22, 2006, 120 Stat. 3472, 3476; Pub. L. 110-85, title VIII, § 801(b)(1), title IX, § 901(d)(1), 912(a), title X, § 1005(d), Sept. 27, 2007, 121 Stat. 620, 939, 951, 958; Pub. L. 111-31, div. A, title I, § 103(b), June 22, 2008, 123 Stat. 1633; Pub. L. 111-353, title I, § 102(d)(1), 103(e), 105(c), 106(d), title II, § 204(j)(1), 206(d), 211(b), (c), title III, § 301(b), Jan. 4, 2011, 124 Stat. 3889, 3898, 3904, 3906, 3937, 3943, 3953, 3964.)

REFERENCES IN TEXT

Section 223 of this title, referred to in par. (e), was in the original "section 304 of the FDA Food Safety Modernization Act", meaning section 204 of Pub. L. 111-353, which enacted section 223 of this title and amended this section and section 381 of this title.

AMENDMENTS

2011—Par. (d), Pub. L. 111-353, § 102(d)(1), inserted "350d," after "344."

Par. (e), Pub. L. 111-353, § 204(j)(1), 211(c), substituted "350f(j)" for "350f(g)" and inserted before period at end "or the violation of any recordkeeping requirement under section 223 of this title (except when such violation is committed by a farm)".

Par. (uu), Pub. L. 111-353, § 103(e), added par. (uu).

Par. (vv), Pub. L. 111-353, § 105(c), added par. (vv).

Par. (ww), Pub. L. 111-353, § 108(d), added par. (ww).

Par. (xx), Pub. L. 111-353, § 206(d), added par. (xx).

Par. (yy), Pub. L. 111-353, § 211(b), added par. (yy).

Par. (zz), Pub. L. 111-353, § 301(b), added par. (zz).

2008—Par. (a) to (c), Pub. L. 111-31, § 103(b)(1)-(3), inserted "tobacco product," after "device."

Par. (e), Pub. L. 111-31, § 103(b)(4)(B), which directed substitution of "79aa-1, 387i, or 387j of this title or the refusal to permit access to" for "or 79aa-1 of this title or the refusal to permit access to", was executed by

making the substitution for "or 379aa-1 of this title, or the refusal to permit access to", to reflect the probable intent of Congress.

Pub. L. 111-31, §103(b)(4)(A), struck out period after "360ccc-1(1)".

Par. (g), (h). Pub. L. 111-31, §103(b)(5), (6), inserted "tobacco product," after "device,".

Par. (j). Pub. L. 111-31, §103(b)(7), struck out period after "360ccc-2" and substituted "379, 379a, 387d, 387e, 387f, 387g, 387h, 387i, or 387u(b)" for "379, or 379e".

Par. (k). Pub. L. 111-31, §103(b)(8), inserted "tobacco product," after "device,".

Par. (p). Pub. L. 111-31, §103(b)(9), added par. (p) and struck out former par. (p) which read as follows: "The failure to register in accordance with section 360 of this title, the failure to provide any information required by section 360(j) or 360(k) of this title, or the failure to provide a notice required by section 360(j)(2) of this title."

Par. (q)(1). Pub. L. 111-31, §103(b)(10), added subpar. (1) and struck out former subpar. (1) which read as follows: "The failure or refusal to (A) comply with any requirement prescribed under section 360h or 360(g) of this title, (B) furnish any notification or other material or information required by or under section 360i or 360(j) of this title, or (C) comply with a requirement under section 360n of this title."

Par. (q)(2). Pub. L. 111-31, §103(b)(11), substituted "device or tobacco product," for "device,".

Par. (r). Pub. L. 111-31, §103(b)(12), inserted "or tobacco product" after "device" in two places.

Par. (oo) to (tt). Pub. L. 111-31, §103(b)(13), added pars. (oo) to (tt).

2007—Par. (e). Pub. L. 110-85, §1005(d)(1), substituted "350c, 350f(g)," for "350c," and "350c(b), 350f" for "350c(b)".

Par. (jj). Pub. L. 110-85, §801(b)(1), added par. (j).

Par. (kk). Pub. L. 110-85, §801(d)(1), added par. (kk).

Par. (ll). Pub. L. 110-85, §912(a), added par. (ll).

Pars. (mm), (nn). Pub. L. 110-85, §1005(d)(2), added pars. (mm) and (nn).

2006—Par. (e). Pub. L. 109-462, §3(b), substituted "374(a), 379aa, or 379aa-1" for "374(a), or 379aa" and "360bbb-3, 379aa, or 379aa-1" for "360bbb-3, or 379aa".

Pub. L. 109-462, §2(c), substituted "374(a), or 379aa" for "374(a)" and "360bbb-3, or 379aa" for "374(a), or 360bbb-3".

Par. (ll). Pub. L. 109-462, §4(a), added par. (ll).

2005—Par. (e). Pub. L. 109-59, §7202(d), inserted "350e" before "354," in two places.

Par. (hh). Pub. L. 109-59, §7202(e), added par. (hh).

2004—Par. (e). Pub. L. 108-282, §102(b)(5)(C), which directed the substitution of "360b(a)(4)(C), 360b(j), (i) or (m), 360ccc-1(1)," for "360b(a)(4)(C), 360b(j), (i) or (m)" was executed by making the substitution for "360b(a)(4)(C), 360b(j), (i), or (m)", to reflect the probable intent of Congress.

Par. (j). Pub. L. 108-282, §102(b)(5)(D), substituted "360j, 360ccc, 360ccc-1, 360ccc-2," for "360j".

Par. (gg). Pub. L. 108-214 amended par. (gg) generally. Prior to amendment, text read as follows: "The knowing failure of a person accredited under paragraph (2) of section 374(g) of this title to comply with paragraph (7)(E) of such section; the knowing inclusion by such a person of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report."

2003—Par. (d). Pub. L. 108-138 substituted "section 344, 356, or 360bbb-3" for "section 344 or 355".

Par. (e). Pub. L. 108-138 inserted "360bbb-3," after "35c, 354," and substituted "360j, or 360bbb-3" for "or 360j".

Par. (aa). Pub. L. 108-173 substituted "prescription drug in violation of section 384" for "covered product in violation of section 384".

2002—Par. (e). Pub. L. 107-188, §306(c)(1), substituted "by section 350a, 350b, 354, 373, or 374(a) of this title" for "by section 350a, 354, or 373 of this title" and "under section 350a, 350c(b)" for "under section 350a".

Par. (j). Pub. L. 107-188, §306(c)(2), inserted "350c," after "350a,".

Par. (w). Pub. L. 107-188, §322(b), amended par. (w) generally. Prior to amendment, par. (w) read as follows: "The making of a knowingly false statement in any record or report required or requested under subparagraph (A) or (B) of section 381(d)(3) of this title, the failure to submit or maintain records as required by sections 381(d)(3)(A) and 381(d)(3)(B) of this title, the release into interstate commerce of any article imported into the United States under section 381(d)(3) of this title or any finished product made from such article (except for export in accordance with section 381(e) or 382 of this title or section 262(h) of title 42), or the failure to export or destroy any component, part or accessory not incorporated into a drug, biological product or device that will be exported in accordance with section 381(e) or 382 of this title or section 262(h) of title 42."

Par. (bb). Pub. L. 107-188, §303(b), added par. (bb).

Par. (cc). Pub. L. 107-188, §304(d), added par. (cc).

Par. (dd). Pub. L. 107-188, §305(b), added par. (dd).

Par. (ee). Pub. L. 107-188, §307(b), added par. (ee).

Par. (ff). Pub. L. 107-188, §321(b)(2), added par. (ff).

Par. (gg). Pub. L. 107-250 added par. (gg).

2000—Par. (aa). Pub. L. 106-387 added par. (aa).

1997—Par. (e). Pub. L. 105-115, §125(b)(2)(B), struck out "357(d) or (g)," after "355(i) or (k)".

Par. (i)(1). Pub. L. 105-115, §125(a)(3)(C), struck out "356, 357," before "or 379e of this title".

Par. (j). Pub. L. 105-115, §125(a)(2)(A), struck out "356, 357," before "360".

Par. (i). Pub. L. 105-115, §421, struck out par. (i) which read as follows: "The using, on the labeling of any drug or device or in any advertising relating to such drug or device, of any representation or suggestion that approval of an application with respect to such drug or device is in effect under section 355, 360e, or 360(g) of this title, as the case may be, or that such drug or device complies with the provisions of such section."

Par. (x). Pub. L. 105-115, §204(b), added par. (x).

Par. (y). Pub. L. 105-115, §210(c), added par. (y).

Par. (a). Pub. L. 105-115, §401(b), temporarily added par. (a) which related to dissemination of information in violation of section 360aaa of this title. See Effective and Termination Dates of 1997 Amendment note below.
1996—Par. (e). Pub. L. 104-250 inserted "354," before "or 373 of this title" and "354," before "355(i) or (k)".
Par. (j). Pub. L. 104-170 inserted before period at end of first sentence "or the violating of section 346a(1)(2) of this title or any regulation issued under that section."

Pars. (u) to (w). Pub. L. 104-134 redesignated par. (u) relating to introduction into interstate commerce of unsafe dietary supplement as (v) and added par. (w).

1994—Par. (s). Pub. L. 103-396, §2(b)(1)(A), substituted "357(d) or (g), 360b(a)(4)(C)," for "357(d) or (g)".

Par. (u). Pub. L. 103-417 added par. (u) relating to introduction into interstate commerce of unsafe dietary supplement.

Pub. L. 103-396, §2(b)(1)(B), added par. (n) relating to failure to comply with regulations or orders of Secretary.

1993—Par. (j). Pub. L. 103-80, §3(c)(1), substituted "379, or 379e" for "379e, or 379".

Par. (s). Pub. L. 103-80, §3(c)(2), substituted "350a(e)" for "350a(d)".

1992—Par. (i)(1), (j). Pub. L. 102-571 substituted "379e" for "378".

Par. (q)(1)(C). Pub. L. 102-300 added cl. (C).

1990—Par. (e). Pub. L. 101-502 substituted "or (k)" for "or (j)".

Par. (j). Pub. L. 101-508 inserted at end "This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committees or any joint committee of Congress or any subcommittee of such joint committee."

1988—Par. (t). Pub. L. 100-293 added par. (t).

1986—Par. (s). Pub. L. 99-570 amended par. (s) generally. Prior to amendment, par. (s) read as follows: "The

failure to provide the notice required by section 350a(b) or 350a(c), the failure to make the reports required by section 350a(d)(1)(B), or the failure to meet the requirements prescribed under section 350a(d)(2)."

1980—Par. (e). Pub. L. 96-359, §5(b), inserted reference to section 350a of this title in two places.

Par. (j). Pub. L. 96-359, §5(c), inserted reference to section 350a of this title.

Par. (s). Pub. L. 96-359, §5(a), added par. (s).

1976—Par. (e). Pub. L. 94-295, §3(b)(2), inserted references to sections 360e(f) and 360i of this title.

Par. (j). Pub. L. 94-295, §3(b)(3), inserted references to sections 360, 360c, 360d, 360e, 360f, 360h, 360i, 360j, and 379 of this title.

Par. (h). Pub. L. 94-295, §3(b)(4), substituted "drug or device" for "drug" wherever appearing, and inserted references to sections 360e and 360j(g) of this title.

Par. (p). Pub. L. 94-295, §4(b)(1), substituted "section 360(j) or 360(k) of this title," for "section 360(j) of this title."

Par. (q). Pub. L. 94-295, §3(b)(1), added par. (q).

Par. (r). Pub. L. 94-295, §7(b), added par. (r).

1972—Par. (p). Pub. L. 92-387 added failure to provide information required by section 360(j) of this title, and failure to provide notice required by section 360(j)(2) of this title as prohibited acts.

1970—Par. (q). Pub. L. 91-513 struck out par. (q) which set out penalties for illegal manufacture, sale, disposition, possession and other traffic in stimulant and depressant drugs. See section 801 et seq. of this title.

1968—Par. (e). Pub. L. 90-399, §103(1), struck out "or" before "357(d) or (g)" and inserted ", or 360b(j), (l), or (m)" after "357(d) or (g)". Amendment striking out "or" was executed as described, notwithstanding directory language that "or" before "357," be stricken out, to reflect the probable intent of Congress.

Par. (j). Pub. L. 90-399, §103(2), inserted reference to section 360b of this title.

Par. (q). Pub. L. 90-639 divided cl. (3), which referred simply to possession in violation of section 360a(c) of this title, into subcls. (A) and (B) which refer, respectively, to possession in violation of section 360a(c)(1) of this title and possession in violation of section 360a(c)(2) of this title.

1966—Par. (i). Pub. L. 89-74, §9(c), designated existing provisions as subpar. (i) and added subpars. (2) and (3).

Par. (q). Pub. L. 89-74, §8, added par. (q).

1962—Par. (e). Pub. L. 87-781, §103(c), 106(c), prohibited the failure to establish or maintain any record, or make any report, required under sections 355(i) or (j) and 367(d) or (g) of this title, or the refusal to permit access to, or verification or copying of, any such required record.

Par. (h). Pub. L. 87-781, §104(e)(1), inserted "approval of" before "an application", and substituted "in effect" for "effective".

Par. (o). Pub. L. 87-781, §114(a), added par. (o).

Par. (p). Pub. L. 87-781, §304, added par. (p).

1960—Par. (i). Pub. L. 86-618, §106(a), struck out references to sections 346(b), 354, and 364 of this title and inserted reference to section 378 of this title.

Par. (j). Pub. L. 86-618, §104, inserted reference to section 378 of this title.

1958—Par. (j). Pub. L. 85-929, inserted reference to section 348 of this title.

1953—Par. (n). Act Aug. 7, 1953, added par. (n).

1950—Par. (m). Act Mar. 18, 1950, added par. (m).

1948—Par. (k). Act June 24, 1948, inserted "(whether or not the first sale)" so as to make it clear that this subsection is not limited to the case where the act occurs while the article is held for the first sale after interstate shipment, and extended coverage of subsection to acts which result in adulteration.

1947—Par. (j). Act Mar. 10, 1947, inserted reference to sections 358 and 367 of this title.

1945—Par. (i). Act July 8, 1945, inserted reference to section 367 of this title.

1941—Par. (i). Act Dec. 22, 1941, inserted reference to section 356 of this title.

EFFECTIVE DATE OF 2011 AMENDMENT

Amendment by section 103(e) of Pub. L. 111-353 effective 18 months after Jan. 4, 2011, and applicable to a

small business (as defined in the regulations promulgated under section 360g(a) of this title) beginning on the date that is 6 months after the effective date of such regulations and to a very small business (as defined in such regulations) beginning on the date that is 18 months after the effective date of such regulations. See section 103(i) of Pub. L. 111-353, set out as an Effective Date note under section 350g of this title.

Pub. L. 111-353, title III, §301(d), Jan. 4, 2011, 124 Stat. 3956, provided that: "The amendments made by this section (enacting section 384a of this title and amending this section and section 381 of this title) shall take effect 2 years after the date of enactment of this Act [Jan. 4, 2011]."

EFFECTIVE DATE OF 2007 AMENDMENT

Pub. L. 110-85, title IX, §909, Sept. 27, 2007, 121 Stat. 950, provided that:

"(a) EFFECTIVE DATE.—This subtitle (subtitle A (§§901-909) of title IX of Pub. L. 110-85, enacting sections 353b and 365-1 of this title, amending this section, sections 333, 352, and 355 of this title, and section 262 of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under sections 352, 355, and 355a of this title) takes effect 180 days after the date of the enactment of this Act [Sept. 27, 2007]."

"(b) DRUGS DEEMED TO HAVE RISK EVALUATION AND MITIGATION STRATEGIES.—

"(1) IN GENERAL.—A drug that was approved before the effective date of this Act [probably means "this subtitle", see above] is, in accordance with paragraph (2), deemed to have in effect an approved risk evaluation and mitigation strategy under section 505-1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355-1) (as added by section 907) (referred to in this section as the "Act") if there are in effect on the effective date of this Act elements to assure safe use—

"(A) required under section 314.520 or section 601.42 of title 21, Code of Federal Regulations; or

"(B) otherwise agreed to by the applicant and the Secretary for such drug.

"(2) ELEMENTS OF STRATEGY; ENFORCEMENT.—The approved risk evaluation and mitigation strategy in effect for a drug under paragraph (1)—

"(A) is deemed to consist of the timetable required under section 505-1(d) and any additional elements under subsections (e) and (f) of such section in effect for such drug on the effective date of this Act; and

"(B) is subject to enforcement by the Secretary to the same extent as any other risk evaluation and mitigation strategy under section 505-1 of the Act, except that sections 303(f)(4) and 502(y) and (z) of the Act (21 U.S.C. 333(f)(4), 352(y), (z)) (as added by section 902) shall not apply to such strategy before the Secretary has completed review of, and acted on, the first assessment of such strategy under such section 505-1.

"(3) SUBMISSION.—Not later than 180 days after the effective date of this Act, the holder of an approved application for which a risk evaluation and mitigation strategy is deemed to be in effect under paragraph (1) shall submit to the Secretary a proposed risk evaluation and mitigation strategy. Such proposed strategy is subject to section 505-1 of the Act as if included in such application at the time of submission of the application to the Secretary."

EFFECTIVE DATE OF 2006 AMENDMENT

Amendment by section 2(c) of Pub. L. 109-462 effective 1 year after Dec. 21, 2006, see section 2(a)(1) of Pub. L. 109-462, set out as a note under section 352 of this title.

Amendment by section 3(b) of Pub. L. 109-462 effective 1 year after Dec. 21, 2006, see section 3(d)(1) of Pub. L. 109-462, set out as a note under section 343 of this title.

Pub. L. 109-462, §4(b), Dec. 21, 2006, 120 Stat. 3475, provided that: "The amendment made by this section (amending this section) shall take effect 1 year after the date of enactment of this Act [Dec. 21, 2006]."

EFFECTIVE DATE OF 2005 AMENDMENT

Pub. L. 109-59, title VII, §704, Aug. 10, 2005, 119 Stat. 1914, provided that: "This subtitle [subtitle B (H7201-7204) of title VII of Pub. L. 109-59, enacting section 350e of this title, amending this section, sections 342 and 373 of this title, and section 5701 of Title 49, Transportation, omitting sections 5702 to 5714 of Title 49, and enacting provisions set out as a note under section 301 of this title] takes effect on October 1, 2005."

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107-188, title III, §321(c), June 12, 2002, 116 Stat. 676, provided that: "The amendments made by this section [amending this section and sections 360 and 381 of this title] take effect upon the expiration of the 180-day period beginning on the date of the enactment of this Act [June 12, 2002]."

Pub. L. 107-188, title III, §322(c), June 12, 2002, 116 Stat. 678, provided that: "The amendments made by this section [amending this section and section 381 of this title] take effect upon the expiration of the 90-day period beginning on the date of the enactment of this Act [June 12, 2002]."

EFFECTIVE AND TERMINATION DATES OF 1997 AMENDMENT

Amendment by sections 204, 210, and 421 of Pub. L. 105-115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as a note under section 321 of this title.

Amendment by section 401(b) of Pub. L. 105-115 effective 1 year after Nov. 21, 1997, or upon Secretary's issuance of final regulations pursuant to section 401(c) of Pub. L. 105-115, whichever is sooner, and ceases to be effective Sept. 30, 2006, see section 401(d), (e) of Pub. L. 105-115, set out as an Effective and Termination Dates note under former section 360aaa of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103-396 effective upon adoption of final regulations under section 2(c) of Pub. L. 103-396, set out as a Regulations note under section 360b of this title, see section 2(d) of Pub. L. 103-396, set out as a note under section 360b of this title.

EFFECTIVE DATES OF 1990 AMENDMENT

Section 4755(c)(2) of Pub. L. 101-508 provided that the amendment made by that section is effective as if included in subtitle D of title VI of the Omnibus Budget Reconciliation Act of 1989, Pub. L. 101-219, title VI, §1691, 6902, Dec. 19, 1989, 103 Stat. 2245, see 42 U.S.C. 300aa-1 note, 300aa-10 note.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-283 effective upon expiration of 90 days after Apr. 22, 1989, see section 8(a) of Pub. L. 100-283, set out as a note under section 353 of this title.

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by Pub. L. 92-387 effective on first day of sixth month beginning after Aug. 16, 1972, see section 5 of Pub. L. 92-387, set out as a note under section 369 of this title.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91-513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91-513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1968 AMENDMENTS

Amendment by Pub. L. 90-399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90-399, set out as an Effective Date and Transitional Provisions note under section 380b of this title.

Amendment by Pub. L. 90-639 applicable only with respect to violations of this chapter committed after Oct. 24, 1968, see section 6 of Pub. L. 90-639, set out as an Effective Date of 1968 Amendments; Transitional Provisions note under section 321 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89-74 effective Feb. 1, 1966, see section 11 of Pub. L. 89-74, set out as a note under section 331 of this title.

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by sections 103(c) and 106(c) of Pub. L. 87-781 effective on first day of seventh calendar month following Oct. 1962, and amendment by section 104(e)(1) of Pub. L. 87-781 effective Oct. 10, 1962, see section 107 of Pub. L. 87-781, set out as a note under section 321 of this title.

Section 114(b) of Pub. L. 87-781 provided that: "This section [amending this section] shall take effect on the first day of the seventh calendar month following the month in which this Act is enacted [October 1962]."

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86-618 effective July 12, 1960, subject to provisions of section 203 of Pub. L. 86-618, see section 202 of Pub. L. 86-618, set out as a note under section 379a of this title.

EFFECTIVE DATE OF 1958 AMENDMENT

Amendment by Pub. L. 85-929 effective Sept. 6, 1958, see section 6(a) of Pub. L. 85-929, set out as a note under section 342 of this title.

EFFECTIVE DATE OF 1950 AMENDMENT

Amendment by act Mar. 16, 1950, effective July 1, 1950, see section 7 of that act, set out as an Effective Date note under section 347 of this title.

REGULATIONS

Secretary of Health and Human Services to promulgate regulations to implement amendments made by section 401 of Pub. L. 105-115 not later than 1 year after Nov. 21, 1997, see section 401(c) of Pub. L. 105-115, set out as a note under section 360aaa of this title.

SAVINGS PROVISION

Amendment by Pub. L. 91-513 not to affect or abate any prosecutions for violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now the Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91-513, set out as a note under section 321 of this title.

CONSTRUCTION OF 2011 AMENDMENT

Nothing in amendments by sections 103(e), 106(c), 106(d), 204(j)(1), 211(b), (c), and 301(b) of Pub. L. 111-353 to be construed to apply to certain alcohol-related facilities, see section 2206 of this title.

Nothing in amendments by Pub. L. 111-353 to be construed to alter jurisdiction and authorities established under certain other Acts or in a manner inconsistent with international agreements to which the United States is a party, see sections 2251 and 2262 of this title.

CONSTRUCTION OF 2009 AMENDMENTS

Pub. L. 111-31, div. A, title I, §103(p), June 22, 2009, 123 Stat. 1838, provided that: "Nothing in this section [amending this section and sections 333, 334, 356, 360a, 372 to 374, 375, 378a, 381, 393, 399, and 679 of this title and enacting provisions set out as notes under sections 333 and 387c of this title] is intended or shall be construed to expand, contract, or otherwise modify or amend the

existing limitations on State government authority over tribal restricted fee or trust lands."

CONSTRUCTION OF 2003 AMENDMENTS

Pub. L. 107-188, title III, § 315, June 12, 2002, 116 Stat. 675, provided that: "Nothing in this title (enacting sections 350c, 350d, 398, 399, and 679c of this title, sections 3363, 3354, 3319, and 3320 of Title 7, Agriculture, and section 247b-20 of Title 42, The Public Health and Welfare, amending this section, sections 334, 335a, 342, 343, 380, 372, 374, and 381 of this title, and section 43 of Title 18, Crimes and Criminal Procedure, and enacting provisions set out as notes under this section and sections 341, 350c, 350d, and 381 of this title), or an amendment made by this title, shall be construed to alter the jurisdiction between the Secretaries of Agriculture and of Health and Human Services, under applicable statutes and regulations."

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare (now Health and Human Services), and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see notes set out under section 321 of this title.

§ 332. Injunction proceedings

(a) Jurisdiction of courts

The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown¹ to restrain violations of section 331 of this title, except paragraphs (h), (i), and (j).

(b) Violation of injunction

In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this chapter, trial shall be by the court, or, upon demand of the accused, by a jury.

(June 25, 1938, ch. 675, § 302, 52 Stat. 1043; Pub. L. 87-781, title I, § 103(d), title II, § 201(c), Oct. 10, 1962, 76 Stat. 784, 793; Pub. L. 103-80, § 3(d), Aug. 13, 1993, 107 Stat. 775.)

AMENDMENTS

1993—Subsec. (a). Pub. L. 103-80, § 3(d)(1), struck out "and subject to the provisions of section 17 (relating to notice to opposite party) of the Act entitled 'An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes', approved October 15, 1914, as amended (U.S.C., 1934 ed., title 28, sec. 381)" after "for cause shown".

Subsec. (b). Pub. L. 103-80, § 3(d)(2), struck out at end "Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 22 of such Act of October 15, 1914, as amended (U.S.C., 1934 ed., title 28, sec. 387)."

1992—Subsec. (a). Pub. L. 87-781, § 103(d), struck out "(e)," after "paragraphs".

Pub. L. 87-781, § 201(c), struck out "(f)," after "paragraphs".

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by section 103(c) of Pub. L. 87-781 effective on first day of seventh calendar month following October 1962, see section 107 of Pub. L. 87-781, set out as a note under section 321 of this title.

Section 203 of title II of Pub. L. 87-781 provided that: "The amendments made by this title (amending this section and section 374 of this title and enacting provi-

sions set out as notes under sections 321 and 374 of this title) shall take effect on the date of enactment of this Act [Oct. 10, 1962]."

§ 333. Penalties

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than \$1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than \$10,000, or both.

(b) Prescription drug marketing violations

(1) Notwithstanding subsection (a) of this section, any person who violates section 331(t) of this title by—

(A) knowingly importing a drug in violation of section 381(d)(1) of this title,

(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 353(c)(1) of this title,

(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 353(c)(2) of this title, or

(D) knowingly distributing drugs in violation of section 353(e)(2)(A) of this title,

shall be imprisoned for not more than 10 years or fined not more than \$250,000, or both.

(2) Any manufacturer or distributor who distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative's employment or association with that manufacturer or distributor, violated section 331(t) of this title because of a violation of section 353(c)(1) of this title or violated any State law prohibiting the sale, purchase, or trade of a drug sample subject to section 353(b) of this title or the offer to sell, purchase, or trade such a drug sample shall, upon conviction of the representative for such violation, be subject to the following civil penalties:

(A) A civil penalty of not more than \$50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period.

(B) A civil penalty of not more than \$1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10-year period.

For the purposes of this paragraph, multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation.

¹S; in original. Probably should be followed by a comma.

²So in original. Words "of this section" probably should not appear.

INFORMATION CONCERNING REPORTING REQUIREMENTS FOR DEVICE USER FACILITIES

Section 2(d) of Pub. L. 101-629 directed Secretary of Health and Human Services, during the 18-month period beginning on Nov. 28, 1990, to inform device user facilities (as defined in 21 U.S.C. 360i(b)(5)(A)) and manufacturers and distributors of devices respecting the requirements of 21 U.S.C. 360i(b), and, to the extent practicable, provide persons subject to such requirements assistance in the form of publications regarding such requirements.

STUDY OF REPORTING REQUIREMENTS; COMPLIANCE BY DEVICE USER FACILITIES; ACTIONS BY MANUFACTURERS; COST EFFECTIVENESS; RECOMMENDATIONS

Section 2(e) of Pub. L. 101-629 directed Comptroller General of the United States, not more than 36 months after Nov. 28, 1990, to conduct a study of compliance by device user facilities with the requirements of 21 U.S.C. 360i(b), actions taken by manufacturers of devices in response to reports made to them, cost effectiveness of such requirements and their implementation, and any recommendations for improvements to such requirements, with Comptroller General to complete the study and submit a report on the study not later than 45 months from Nov. 28, 1990, to appropriate committees of Congress.

REPORT TO CONGRESS ON REPORTING REQUIREMENTS FOR DEVICE USER FACILITIES

Section 2(d) of Pub. L. 101-629 directed Secretary of Health and Human Services, not later than 36 months after Nov. 28, 1990, to prepare and submit to appropriate committees of Congress a report containing an evaluation of the requirements of 21 U.S.C. 360i(b), consisting of an evaluation of the safety benefits of the requirements, the burdens placed on the Food and Drug Administration and on device user facilities by the requirements, and the cost-effectiveness of the requirements and recommendations for legislative reform.

§360j. General provisions respecting control of devices intended for human use

(a) General rule

Any requirement authorized by or under section 351, 352, 360, or 360i of this title applicable to a device intended for human use shall apply to such device until the applicability of the requirement to the device has been changed by action taken under section 360c, 360d, or 360e of this title or under subsection (g) of this section, and any requirement established by or under section 351, 352, 360, or 360i of this title which is inconsistent with a requirement imposed on such device under section 360d or 360e of this title or under subsection (g) of this section shall not apply to such device.

(b) Custom devices

Sections 360d and 360e of this title do not apply to any device which, in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing) necessarily deviates from an otherwise applicable performance standard or requirement prescribed by or under section 360e of this title if (1) the device is not generally available in finished form for purchase or for dispensing upon prescription and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and (2) such device—

(A)(i) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated) and is to be made in a specific form for such patient, or

(ii) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated), and

(B) is not generally available to or generally used by other physicians or dentists (or other specially qualified persons so designated).

(c) Trade secrets

Any information reported to or otherwise obtained by the Secretary or his representative under section 360c, 360d, 360e, 360f, 360h, 360i, or 374 of this title or under subsection (f) or (g) of this section which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5 by reason of subsection (b)(4) of such section shall be considered confidential and shall not be disclosed and may not be used by the Secretary as the basis for the reclassification of a device from class III to class II or class I or as the basis for the establishment or amendment of a performance standard under section 360d of this title for a device reclassified from class III to class II, except (1) in accordance with subsection (h) of this section, and (2) that such information may be disclosed to other officers or employees concerned with carrying out this chapter or when relevant in any proceeding under this chapter (other than section 360c or 360d of this title).

(d) Notices and findings

Each notice of proposed rulemaking under section 360c, 360d, 360e, 360f, 360h, or 360i of this title, or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

(1) the manner in which interested persons may examine data and other information on which the notice or findings is based, and

(2) the period within which interested persons may present their comments on the notice or findings (including the need therefor) orally or in writing, which period shall be at least sixty days but may not exceed ninety days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause therefor.

(e) Restricted devices

(1) The Secretary may by regulation require 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,

if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot

otherwise be reasonable assurance of its safety and effectiveness. No condition prescribed under subparagraph (B) may restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device. No such condition may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a Board. A device subject to a regulation under this subsection is a restricted device.

(2) The label of a restricted device shall bear such appropriate statements of the restrictions required by a regulation under paragraph (1) as the Secretary may in such regulation prescribe.

(f) Good manufacturing practice requirements

(1)(A) The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this chapter.

(B) Before the Secretary may promulgate any regulation under subparagraph (A) he shall—

(i) afford the advisory committee established under paragraph (3) an opportunity to submit recommendations to him with respect to the regulation proposed to be promulgated;

(ii) afford opportunity for an oral hearing; and

(iii) ensure that such regulation conforms, to the extent practicable, with internationally recognized standards defining quality systems, or parts of the standards, for medical devices.

The Secretary shall provide the advisory committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A).

(2)(A) Any person subject to any requirement prescribed by regulations under paragraph (1) may petition the Secretary for an exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as he shall prescribe and shall—

(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this chapter,

(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, facilities, and controls prescribed by the requirement, and

(iii) contain such other information as the Secretary shall prescribe.

(B) The Secretary may refer to the advisory committee established under paragraph (3) any petition submitted under subparagraph (A). The advisory committee shall report its recommendations to the Secretary with respect to a petition referred to it within sixty days of the date of the petition's referral. Within sixty days after—

(i) the date the petition was submitted to the Secretary under subparagraph (A), or

(ii) if the petition was referred to an advisory committee, the expiration of the sixty-day period beginning on the date the petition was referred to the advisory committee,

whichever occurs later, the Secretary shall by order either deny the petition or approve it.

(C) The Secretary may approve—

(i) a petition for an exemption for a device from a requirement if he determines that compliance with such requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this chapter, and

(ii) a petition for a variance for a device from a requirement if he determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, controls, and facilities prescribed by the requirement are sufficient to assure that the device will be safe and effective and otherwise in compliance with this chapter.

An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of the device to be granted the variance under the petition as may be necessary to assure that the device will be safe and effective and otherwise in compliance with this chapter.

(D) After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

(3) The Secretary shall establish an advisory committee for the purpose of advising and making recommendations to him with respect to regulations proposed to be promulgated under paragraph (1)(A) and the approval or disapproval of petitions submitted under paragraph (2). The advisory committee shall be composed of nine members as follows:

(A) Three of the members shall be appointed from persons who are officers or employees of any State or local government or of the Federal Government.

(B) Two of the members shall be appointed from persons who are representative of interests of the device manufacturing industry; two of the members shall be appointed from persons who are representative of the interests of physicians and other health professionals; and two of the members shall be representative of the interests of the general public.

Members of the advisory committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business,

shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS-18 of the General Schedule, for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for persons in the Government service employed intermittently. The Secretary shall designate one of the members of the advisory committee to serve as its chairman. The Secretary shall furnish the advisory committee with clerical and other assistance. Section 14 of the Federal Advisory Committee Act shall not apply with respect to the duration of the advisory committee established under this paragraph.

(g) Exemption for devices for investigational use

(1) It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

(2)(A) The Secretary shall, within the one hundred and twenty-day period beginning on May 28, 1976, by regulation prescribe procedures and conditions under which devices intended for human use may upon application be granted an exemption from the requirements of section 352, 360, 360d, 360e, 360f, 360i, or 379e of this title or subsection (e) or (f) of this section or from any combination of such requirements to permit the investigational use of such devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices.

(B) The conditions prescribed pursuant to subparagraph (A) shall include the following:

(i) A requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such form and manner as the Secretary shall specify.

(ii) A requirement that the person applying for an exemption for a device assure the establishment and maintenance of such records, and the making of such reports to the Secretary of data obtained as a result of the investigational use of the device during the exemption, as the Secretary determines will enable him to assure compliance with such conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device.

(iii) Such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety.

(C) Procedures and conditions prescribed pursuant to subparagraph (A) for an exemption may appropriately vary depending on (i) the scope and duration of clinical testing to be conducted under such exemption, (ii) the number of human subjects that are to be involved in such testing, (iii) the need to permit changes to be made in the device subject to the exemption during test-

ing conducted in accordance with a clinical testing plan required under paragraph (3)(A), and (iv) whether the clinical testing of such device is for the purpose of developing data to obtain approval for the commercial distribution of such device.

(3) Procedures and conditions prescribed pursuant to paragraph (2)(A) shall require, as a condition to the exemption of any device to be the subject of testing involving human subjects, that the person applying for the exemption—

(A) submit a plan for any proposed clinical testing of the device and a report of prior investigations of the device (including, where appropriate, tests on animals) adequate to justify the proposed clinical testing—

(i) to the local institutional review committee which has been established in accordance with regulations of the Secretary to supervise clinical testing of devices in the facilities where the proposed clinical testing is to be conducted, or

(ii) to the Secretary, if—

(I) no such committee exists, or

(II) the Secretary finds that the process of review by such committee is inadequate (whether or not the plan for such testing has been approved by such committee),

for review for adequacy to justify the commencement of such testing; and, unless the plan and report are submitted to the Secretary, submit to the Secretary a summary of the plan and a report of prior investigations of the device (including, where appropriate, tests on animals);

(B) promptly notify the Secretary (under such circumstances and in such manner as the Secretary prescribes) of approval by a local institutional review committee of any clinical testing plan submitted to it in accordance with subparagraph (A);

(C) in the case of a device to be distributed to investigators for testing, obtain signed agreements from each of such investigators that any testing of the device involving human subjects will be under such investigator's supervision and in accordance with subparagraph (D) and submit such agreements to the Secretary; and

(D) assure that informed consent will be obtained from each human subject (or his representative) of proposed clinical testing involving such device, except where subject to such conditions as the Secretary may prescribe, the investigator conducting or supervising the proposed clinical testing of the device determines in writing that there exists a life threatening situation involving the human subject of such testing which necessitates the use of such device and it is not feasible to obtain informed consent from the subject and there is not sufficient time to obtain such consent from his representative.

The determination required by subparagraph (D) shall be concurred in by a licensed physician who is not involved in the testing of the human subject with respect to which such determination is made unless immediate use of the device is required to save the life of the human subject of such testing and there is not sufficient time to obtain such concurrence.

(4)(A) An application, submitted in accordance with the procedures prescribed by regulations under paragraph (2), for an exemption for a device (other than an exemption from section 360f of this title) shall be deemed approved on the thirtieth day after the submission of the application to the Secretary unless on or before such day the Secretary by order disapproves the application and notifies the applicant of the disapproval of the application.

(B) The Secretary may disapprove an application only if he finds that the investigation with respect to which the application is submitted does not conform to procedures and conditions prescribed under regulations under paragraph (2). Such a notification shall contain the order of disapproval and a complete statement of the reasons for the Secretary's disapproval of the application and afford the applicant opportunity for an informal hearing on the disapproval order.

(5) The Secretary may by order withdraw an exemption granted under this subsection for a device if the Secretary determines that the conditions applicable to the device under this subsection for such exemption are not met. Such an order may be issued only after opportunity for an informal hearing, except that such an order may be issued before the provision of an opportunity for an informal hearing if the Secretary determines that the continuation of testing under the exemption with respect to which the order is to be issued will result in an unreasonable risk to the public health.

(5)(A) Not later than 1 year after November 21, 1997, the Secretary shall by regulation establish, with respect to a device for which an exemption under this subsection is in effect, procedures and conditions that, without requiring an additional approval of an application for an exemption or the approval of a supplement to such an application, permit—

(i) developmental changes in the device (including manufacturing changes) that do not constitute a significant change in design or in basic principles of operation and that are made in response to information gathered during the course of an investigation; and

(ii) changes or modifications to clinical protocols that do not affect—

(I) the validity of data or information resulting from the completion of an approved protocol, or the relationship of likely patient risk to benefit relied upon to approve a protocol;

(II) the scientific soundness of an investigational plan submitted under paragraph (3)(A); or

(III) the rights, safety, or welfare of the human subjects involved in the investigation.

(B) Regulations under subparagraph (A) shall provide that a change or modification described in such subparagraph may be made if—

(i) the sponsor of the investigation determines, on the basis of credible information (as defined by the Secretary) that the applicable conditions under subparagraph (A) are met; and

(ii) the sponsor submits to the Secretary, not later than 5 days after making the change

or modification, a notice of the change or modification.

(7)(A) In the case of a person intending to investigate the safety or effectiveness of a class III device or any implantable device, the Secretary shall ensure that the person has an opportunity, prior to submitting an application to the Secretary or to an institutional review committee, to submit to the Secretary, for review, an investigational plan (including a clinical protocol). If the applicant submits a written request for a meeting with the Secretary regarding such review, the Secretary shall, not later than 30 days after receiving the request, meet with the applicant for the purpose of reaching agreement regarding the investigational plan (including a clinical protocol). The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan (including a clinical protocol) for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device.

(B) Any agreement regarding the parameters of an investigational plan (including a clinical protocol) that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Any such agreement shall not be changed, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (C) by the director of the office in which the device involved is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the device involved has been identified.

(C) A decision under subparagraph (B)(ii) by the director shall be in writing, and may be made only after the Secretary has provided to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the scientific issue involved.

(h) Release of information respecting safety and effectiveness

(1) The Secretary shall promulgate regulations under which a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the Secretary and which was the basis for—

(A) an order under section 360e(d)(1)(A) of this title approving an application for premarket approval for the device or denying approval of such an application or an order under section 360e(e) of this title withdrawing approval of such an application for the device,

(B) an order under section 360e(f)(6)(A) of this title revoking an approved protocol for the device, an order under section 360e(f)(6)(B) of this title declaring a protocol for the device completed or not completed, or an order under section 360e(f)(7) of this title revoking the approval of the device, or

(C) an order approving an application under subsection (g) of this section for an exemption for the device from section 360f of this title or

an order disapproving, or withdrawing approval of, an application for an exemption under such subsection for the device.

shall be made available to the public upon issuance of the order. Summaries of information made available pursuant to this paragraph respecting a device shall include information respecting any adverse effects on health of the device.

(2) The Secretary shall promulgate regulations under which each advisory committee established under section 360e(g)(2)(B) of this title shall make available to the public a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the advisory committee and which was the basis for its recommendation to the Secretary made pursuant to section 360e(g)(2)(A) of this title. A summary of information upon which such a recommendation is based shall be made available pursuant to this paragraph only after the issuance of the order with respect to which the recommendation was made and each summary shall include information respecting any adverse effect on health of the device subject to such order.

(3) Except as provided in paragraph (4), any information respecting a device which is made available pursuant to paragraph (1) or (2) of this subsection (A) may not be used to establish the safety or effectiveness of another device for purposes of this chapter by any person other than the person who submitted the information so made available, and (B) shall be made available subject to subsection (c) of this section.

(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 360e(c) of this title (including information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of a device, but excluding descriptions of methods of manufacture and product composition and other trade secrets) shall be available, 6 years after the application has been approved by the Secretary, for use by the Secretary in—

- (i) approving another device;
- (ii) determining whether a product development protocol has been completed, under section 360e of this title for another device;
- (iii) establishing a performance standard or special control under this chapter; or
- (iv) classifying or reclassifying another device under section 360c of this title and subsection (1)(2) of this section.

(B) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the agency actions described in subparagraph (A).

(i) Proceedings of advisory panels and committees

Each panel under section 360c of this title and each advisory committee established under section 360d(b)(5)(B) or 360e(g) of this title or under subsection (f) of this section shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and com-

mittee shall delete from any transcript made pursuant to this subsection information which under subsection (c) of this section is to be considered confidential.

(j) Traceability

Except as provided in section 360i(e) of this title, no regulation under this chapter may impose on a type or class of device requirements for the traceability of such type or class of device unless such requirements are necessary to assure the protection of the public health.

(k) Research and development

The Secretary may enter into contracts for research, testing, and demonstrations respecting devices and may obtain devices for research, testing, and demonstration purposes without regard to section 3324(a) and (b) of title 31 and section 6101 of title 41.

(l) Transitional provisions for devices considered as new drugs

(1) Any device intended for human use—

(A) for which on May 28, 1976 (hereinafter in this subsection referred to as the "enactment date") an approval of an application submitted under section 355(b) of this title was in effect;

(B) for which such an application was filed on or before the enactment date and with respect to which application no order of approval or refusing to approve had been issued on such date under subsection (c) or (d) of such section;

(C) for which on the enactment date an exemption under subsection (1) of such section was in effect;

(D) which is within a type of device described in subparagraph (A), (B), or (C) and is substantially equivalent to another device within that type;

(E) which the Secretary in a notice published in the Federal Register before the enactment date has declared to be a new drug subject to section 355 of this title; or

(F) with respect to which on the enactment date an action is pending in a United States court under section 332, 333, or 334 of this title for an alleged violation of a provision of section 331 of this title which enforces a requirement of section 355 of this title or for an alleged violation of section 355(a) of this title,

is classified in class III unless the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

(2) The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition. Except as provided in paragraph (3)(D)(ii), within one hundred and eighty days after the filing of a petition under this paragraph, the Secretary shall, after consultation with the appropriate panel under sec-

tion 360c of this title, by order either deny the petition or order the classification, in accordance with the criteria prescribed by section 360c(a)(1)(A) of this title or 360c(a)(1)(B) of this title, of the device in class I or class II.

(3)(A) In the case of a device which is described in paragraph (1)(A) and which is in class III—

(i) such device shall on the enactment date be considered a device with an approved application under section 360e of this title, and

(ii) the requirements applicable to such device before the enactment date under section 355 of this title shall continue to apply to such device until changed by the Secretary as authorized by this chapter.

(B) In the case of a device which is described in paragraph (1)(B) and which is in class III, an application for such device shall be considered as having been filed under section 360e of this title on the enactment date. The period in which the Secretary shall act on such application in accordance with section 360e(d)(1) of this title shall be one hundred and eighty days from the enactment date (or such greater period as the Secretary and the applicant may agree upon after the Secretary has made the finding required by section 360e(d)(1)(B)(i) of this title) less the number of days in the period beginning on the date an application for such device was filed under section 355 of this title and ending on the enactment date. After the expiration of such period such device is required, unless exempt under subsection (g) of this section, to have in effect an approved application under section 360e of this title.

(C) A device which is described in paragraph (1)(C) and which is in class III shall be considered a new drug until the expiration of the ninety-day period beginning on the date of the promulgation of regulations under subsection (g) of this section. After the expiration of such period such device is required, unless exempt under subsection (g) of this section, to have in effect an approved application under section 360e of this title.

(D)(i) Except as provided in clauses (ii) and (iii), a device which is described in subparagraph (D), (E), or (F) of paragraph (1) and which is in class III is required, unless exempt under subsection (g) of this section, to have on and after sixty days after the enactment date in effect an approved application under section 360e of this title.

(ii) If—

(I) a petition is filed under paragraph (2) for a device described in subparagraph (D), (E), or (F) of paragraph (1), or

(II) an application for premarket approval is filed under section 360e of this title for such a device,

within the sixty-day period beginning on the enactment date (or within such greater period as the Secretary, after making the finding required under section 360e(d)(1)(B) of this title, and the petitioner or applicant may agree upon), the Secretary shall act on such petition or application in accordance with paragraph (2) or section 360e of this title except that the period within which the Secretary must act on the petition or application shall be within the one hundred and

twenty-day period beginning on the date the petition or application is filed. If such a petition or application is filed within such sixty-day (or greater) period, clause (i) of this subparagraph shall not apply to such device before the expiration of such one hundred and twenty-day period, or if such petition is denied or such application is denied approval, before the date of such denial, whichever occurs first.

(iii) In the case of a device which is described in subparagraph (E) of paragraph (1), which the Secretary in a notice published in the Federal Register after March 31, 1976, declared to be a new drug subject to section 355 of this title, and which is in class III—

(i) the device shall, after eighteen months after the enactment date, have in effect an approved application under section 360e of this title unless exempt under subsection (g) of this section, and

(ii) the Secretary may, during the period beginning one hundred and eighty days after the enactment date and ending eighteen months after such date, restrict the use of the device to investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of such device, and to investigational use in accordance with the requirements applicable under regulations under subsection (g) of this section to investigational use of devices granted an exemption under such subsection.

If the requirements under subsection (g) of this section are made applicable to the investigational use of such a device, they shall be made applicable in such a manner that the device shall be made reasonably available to physicians meeting appropriate qualifications prescribed by the Secretary.

(4) Repealed. Pub. L. 105-115, title I, § 125(b)(2)(E), Nov. 21, 1997, 111 Stat. 2325.

(5)(A) Before December 1, 1991, the Secretary shall by order require manufacturers of devices described in paragraph (1), which are subject to revision of classification under subparagraph (B), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturers respecting the devices, including adverse safety or effectiveness information which has not been submitted under section 360i of this title. The Secretary may require a manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if such data are available to the manufacturer.

(B) Except as provided in subparagraph (C), after the issuance of an order under subparagraph (A) but before December 1, 1992, the Secretary shall publish a regulation in the Federal Register for each device which is classified in class III under paragraph (1) revising the classification of the device so that the device is classified into class I or class II, unless the regulation requires the device to remain in class III. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 360c(a) of this title. Before the publication of a regulation requiring a device to remain in class III or revising its classification, the Secretary shall publish a proposed regula-

tion respecting the classification of a device under this subparagraph and provide an opportunity for the submission of comments on any such regulation. No regulation under this subparagraph requiring a device to remain in class III or revising its classification may take effect before the expiration of 90 days from the date of the publication in the Federal Register of the proposed regulation.

(C) The Secretary may by notice published in the Federal Register extend the period prescribed by subparagraph (B) for a device for an additional period not to exceed 1 year.

(m) Humanitarian device exemption

(1) To the extent consistent with the protection of the public health and safety and with ethical standards, it is the purpose of this subsection to encourage the discovery and use of devices intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4,000 individuals in the United States.

(2) The Secretary may grant a request for an exemption from the effectiveness requirements of sections 360d and 360e of this title for a device for which the Secretary finds that—

(A) the device is designed to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States,

(B) the device would not be available to a person with a disease or condition referred to in subparagraph (A) unless the Secretary grants such an exemption and there is no comparable device, other than under this exemption, available to treat or diagnose such disease or condition, and

(C) the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The request shall be in the form of an application submitted to the Secretary and such application shall include the certification required under section 282(j)(5)(B) of title 42 (which shall not be considered an element of such application). Not later than 75 days after the date of the receipt of the application, the Secretary shall issue an order approving or denying the application.

(2) Except as provided in paragraph (8), no person granted an exemption under paragraph (2) with respect to a device may sell the device for an amount that exceeds the costs of research and development, fabrication, and distribution of the device.

(4) Devices granted an exemption under paragraph (2) may only be used—

(A) in facilities that have established, in accordance with regulations of the Secretary, a local institutional review committee to supervise clinical testing of devices in the facilities, and

(B) if, before the use of a device, an institutional review committee approves the use in the treatment or diagnosis of a disease or condition referred to in paragraph (2)(A), unless a

physician determines in an emergency situation that approval from a local institutional review committee can not be obtained in time to prevent serious harm or death to a patient.

In a case described in subparagraph (B) in which a physician uses a device without an approval from an institutional review committee, the physician shall, after the use of the device, notify the chairperson of the local institutional review committee of such use. Such notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use.

(5) The Secretary may require a person granted an exemption under paragraph (2) to demonstrate continued compliance with the requirements of this subsection if the Secretary believes such demonstration to be necessary to protect the public health, if the Secretary has reason to believe that the requirements of paragraph (6) are no longer met, or if the Secretary has reason to believe that the criteria for the exemption are no longer met. If the person granted an exemption under paragraph (2) fails to demonstrate continued compliance with the requirements of this subsection, the Secretary may suspend or withdraw the exemption from the effectiveness requirements of sections 360d and 360e of this title for a humanitarian device only after providing notice and an opportunity for an informal hearing.

(6)(A) Except as provided in subparagraph (D), the prohibition in paragraph (3) shall not apply with respect to a person granted an exemption under paragraph (2) if each of the following conditions apply:

(i)(I) The device with respect to which the exemption is granted is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs.

(II) The device was not previously approved under this subsection for the pediatric patients or the pediatric subpopulation described in subclause (I) prior to September 27, 2007.

(ii) During any calendar year, the number of such devices distributed during that year does not exceed the annual distribution number specified by the Secretary when the Secretary grants such exemption. The annual distribution number shall be based on the number of individuals affected by the disease or condition that such device is intended to treat, diagnose, or cure, and of that number, the number of individuals likely to use the device, and the number of devices reasonably necessary to treat such individuals. In no case shall the annual distribution number exceed the number identified in paragraph (2)(A).

(iii) Such person immediately notifies the Secretary if the number of such devices distributed during any calendar year exceeds the annual distribution number referred to in clause (ii).

(iv) The request for such exemption is submitted on or before October 1, 2012.

(B) The Secretary may inspect the records relating to the number of devices distributed dur-

log any calendar year of a person granted an exemption under paragraph (2) for which the prohibition in paragraph (3) does not apply.

(C) A person may petition the Secretary to modify the annual distribution number specified by the Secretary under subparagraph (A)(ii) with respect to a device if additional information on the number of individuals affected by the disease or condition arises, and the Secretary may modify such number but in no case shall the annual distribution number exceed the number identified in paragraph (2)(A).

(D) If a person notifies the Secretary, or the Secretary determines through an inspection under subparagraph (B), that the number of devices distributed during any calendar year exceeds the annual distribution number, as required under subparagraph (A)(iii), and modified under subparagraph (C), if applicable, then the prohibition in paragraph (3) shall apply with respect to such person for such device for any sales of such device after such notification.

(E)(i) In this subsection, the term "pediatric patients" means patients who are 21 years of age or younger at the time of the diagnosis or treatment.

(ii) In this subsection, the term "pediatric subpopulation" means 1 of the following populations:

- (I) Neonates.
- (II) Infants.
- (III) Children.
- (IV) Adolescents.

(7) The Secretary shall refer any report of an adverse event regarding a device for which the prohibition under paragraph (3) does not apply pursuant to paragraph (6)(A) that the Secretary receives to the Office of Pediatric Therapeutics, established under section 393a of this title. In considering the report, the Director of the Office of Pediatric Therapeutics, in consultation with experts in the Center for Devices and Radiological Health, shall provide for periodic review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of such committee regarding whether the Secretary should take action under this chapter in response to the report.

(8) The Secretary, acting through the Office of Pediatric Therapeutics and the Center for Devices and Radiological Health, shall provide for an annual review by the Pediatric Advisory Committee of all devices described in paragraph (6) to ensure that the exemption under paragraph (2) remains appropriate for the pediatric populations for which it is granted.

(n) Regulation of contact lenses as devices

(1) All contact lenses shall be deemed to be devices under section 321(h) of this title.

(2) Paragraph (1) shall not be construed as bearing on or being relevant to the question of whether any product other than a contact lens is a device as defined by section 321(h) of this title or a drug as defined by section 321(g) of this title.

(June 25, 1938, ch. 675, § 520, as added Pub. L. 94-295, § 2, May 28, 1976, 90 Stat. 565; amended Pub. L. 101-629, §§ 3(b)(2), 4(b)(2), 5(c)(2), 6(b)(2), 11, 14(a), 18(e), (f), Nov. 28, 1990, 104 Stat. 4514,

4516, 4518, 4519, 4522, 4524, 4529; Pub. L. 102-571, title I, § 107(10), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 105-115, title I, § 125(b)(2)(E), title II, §§ 201(a), 203, 216(a)(1), title IV, § 410(a), Nov. 21, 1997, 111 Stat. 2325, 2332, 2334, 2349, 2372; Pub. L. 109-96, § 1, Nov. 9, 2005, 119 Stat. 2119; Pub. L. 110-85, title III, § 303(a), title VIII, § 801(b)(3)(E), Sept. 27, 2007, 121 Stat. 860, 921.)

REFERENCES IN TEXT

Section 14 of the Federal Advisory Committee Act, referred to in subsec. (f)(3), is section 14 of Pub. L. 92-463, which is set out in the Appendix to Title 5, Government Organization and Employees.

CODIFICATION

In subsec. (k), "section 332(a) and (b) of title 31 and section 6101 of title 41" substituted for "sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 41 U.S.C. 5)" on authority of Pub. L. 97-259, § 4(b), Sept. 13, 1982, 96 Stat. 1067, which Act enacted Title 31, Money and Finance, and Pub. L. 111-350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

AMENDMENTS

2007—Subsec. (m)(2). Pub. L. 110-85, § 801(b)(3)(E), inserted before period at end of first sentence of concluding provisions "and such application shall include the certification required under section 282(j)(5)(B) of title 42 (which shall not be considered an element of such application)".

Subsec. (m)(3). Pub. L. 110-85, § 303(a)(1), substituted "Except as provided in paragraph (6), no" for "No".

Subsec. (m)(5). Pub. L. 110-85, § 303(a)(2), inserted ", if the Secretary has reason to believe that the requirements of paragraph (6) are no longer met," after "public health" and inserted at end "If the person granted an exemption under paragraph (2) fails to demonstrate continued compliance with the requirements of this subsection, the Secretary may suspend or withdraw the exemption from the effectiveness requirements of sections 360d and 360e of this title for a humanitarian device only after providing notice and an opportunity for an informal hearing."

Subsec. (m)(6) to (8). Pub. L. 110-85, § 303(a)(3), added pars. (6) to (8) and struck out former par. (6) which read as follows: "The Secretary may suspend or withdraw an exemption from the effectiveness requirements of sections 360d and 360e of this title for a humanitarian device only after providing notice and an opportunity for an informal hearing."

2005—Subsec. (n). Pub. L. 109-96 added subsec. (n).

1997—Subsec. (f)(1)(B)(iii). Pub. L. 105-115, § 410(a), added cl. (iii).

Subsec. (g)(6), (7). Pub. L. 105-115, § 201(a), added pars. (6) and (7).

Subsec. (h)(4). Pub. L. 105-115, § 216(a)(1), amended par. (4) generally. Prior to amendment, par. (4) related to premarket approval of devices.

Subsec. (i). Pub. L. 105-115, § 125(b)(2)(E), struck out "or antibiotic drugs" after "new drugs" in heading.

Subsec. (i)(4). Pub. L. 105-115, § 125(b)(2)(E), struck out par. (4) which read as follows: "Any device intended for human use which on the enactment date was subject to the requirements of section 357 of this title shall be subject to such requirements as follows:

"(A) In the case of such a device which is classified into class I, such requirements shall apply to such device until the effective date of the regulation classifying the device into such class.

"(B) In the case of such a device which is classified into class II, such requirements shall apply to such device until the effective date of a performance standard applicable to the device under section 360d of this title.

"(C) In the case of such a device which is classified into class III, such requirements shall apply to such device until the date on which the device is required

to have in effect an approved application under section 360e of this title."

Subsec. (m)(2). Pub. L. 105-115, §303(1), inserted at end. "The request shall be in the form of an application submitted to the Secretary. Not later than 75 days after the date of the receipt of the application, the Secretary shall issue an order approving or denying the application."

Subsec. (m)(4). Pub. L. 105-115, §303(2)(B), inserted at end. "In a case described in subparagraph (B) in which a physician uses a device without an approval from an institutional review committee, the physician shall, after the use of the device, notify the chairperson of the local institutional review committee of such use. Such notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use."

Subsec. (m)(4)(B). Pub. L. 105-115, §303(2)(A), inserted before period at end. "unless a physician determines in an emergency situation that approval from a local institutional review committee can not be obtained in time to prevent serious harm or death to a patient".

Subsec. (m)(5). Pub. L. 105-115, §203(3), amended par. (5) generally. Prior to amendment, par. (5) read as follows: "An exemption under paragraph (2) shall be for a term of 18 months and may only be initially granted in the 5-year period beginning on the date regulations under paragraph (6) take effect. The Secretary may extend such an exemption for a period of 18 months if the Secretary is able to make the findings set forth in paragraph (2) and if the applicant supplies information demonstrating compliance with paragraph (3). An exemption may be extended more than once and may be extended after the expiration of such 5-year period."

Subsec. (m)(6). Pub. L. 105-115, §203(4), amended par. (6) generally. Prior to amendment, par. (6) read as follows: "Within one year of November 28, 1990, the Secretary shall issue regulations to implement this subsection."

1992—Subsec. (g)(2)(A). Pub. L. 102-571 substituted "379e" for "378".

1990—Subsec. (c). Pub. L. 101-629, §11(1), substituted "from class III to class II or class I" for "under section 360c of this title (from class III to class II)" and inserted "(1) in accordance with subsection (b) of this section, and (2) after 'except'".

Subsec. (d)(1)(A). Pub. L. 101-629, §18(a), inserted "preproduction design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device)," after "manufacture."

Subsec. (b)(3). Pub. L. 101-629, §11(2)(A), substituted "Except as provided in paragraph (4), any" for "Any".

Subsec. (b)(4). Pub. L. 101-629, §11(2)(B), added par. (4).

Subsec. (i). Pub. L. 101-629, §8(b)(2), substituted "section 360d(b)(5)(B)" for "section 360d(g)(5)(B)".

Subsec. (j). Pub. L. 101-629, §3(b)(2), substituted "Except as provided in section 360(e) of this title, no" for "No".

Subsec. (l)(2). Pub. L. 101-629, §18(f), struck out "and after affording the petitioner an opportunity for an informal hearing" after "under this paragraph".

Pub. L. 101-629, §5(c)(2), substituted "The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer" for "The manufacturer".

Subsec. (l)(5). Pub. L. 101-629, §4(b)(2), added par. (5).

Subsec. (m). Pub. L. 101-629, §14(a), added subsec. (m).

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by sections 201(a), 203, 216(a)(1), and 410(a) of Pub. L. 105-115 effective 90 days after Nov. 31, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as a note under section 321 of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Section 14(b) of Pub. L. 101-629 provided that: "Subsection (m) of section 520 of the Federal Food, Drug,

and Cosmetic Act (21 U.S.C. 360)(m)), as added by the amendment made by subsection (a), shall take effect on the effective date of the regulations issued by the Secretary under paragraph (6) of such subsection."

GUIDANCE

Pub. L. 110-85, title III, §303(c), Sept. 27, 2007, 121 Stat. 362, provided that: "Not later than 180 days after the date of the enactment of this Act (Sept. 27, 2007), the Commissioner of Food and Drugs shall issue guidance for institutional review committees on how to evaluate requests for approval for devices for which a humanitarian device exemption under section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360)(m)(2)) has been granted."

Pub. L. 107-250, title II, §213, Oct. 26, 2002, 116 Stat. 1814, provided that: "Not later than 270 days after the date of the enactment of this Act (Oct. 26, 2002), the Secretary of Health and Human Services shall issue guidance on the following:

"(1) The type of information necessary to provide reasonable assurance of the safety and effectiveness of medical devices intended for use in pediatric populations.

"(2) Protections for pediatric subjects in clinical investigations of the safety or effectiveness of such devices."

REPORT ON HUMANITARIAN DEVICE EXEMPTIONS

Section 14(c) of Pub. L. 101-629 directed Secretary of Health and Human Services, within 4 years after issuance of regulations under 21 U.S.C. 360(m)(6), to report to Congress on types of devices exempted, an evaluation of effects of such section, and a recommendation on extension of the section.

REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 (title I, §101(c)(1)) of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

§360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

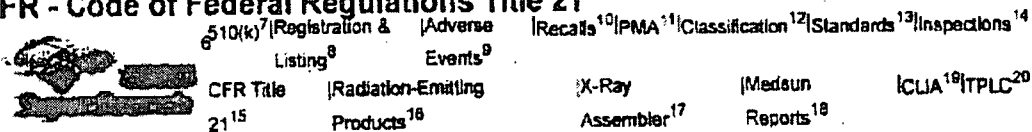
(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

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TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES
PART 801 -- LABELING

Subpart E--Exemptions From Adequate Directions for Use
Sec. 801.109 Prescription devices.

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

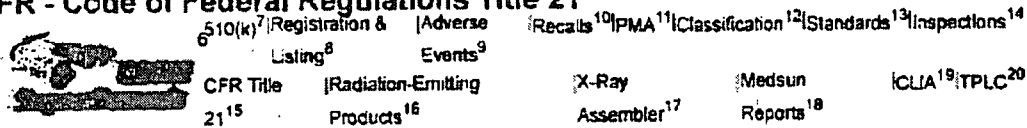
dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and 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, 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.

(d) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the device is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the device, that furnishes or purports to furnish information for use of the device contains adequate information for such 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 employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented. This information will not be required on so-called reminder--piece labeling which calls attention to the name of the device but does not include indications or other use information.

(e) All labeling, except labels and cartons, bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labeling.

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TITLE 21--FOOD AND DRUGS
 CHAPTER I--FOOD AND DRUG ADMINISTRATION
 DEPARTMENT OF HEALTH AND HUMAN SERVICES
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 PART 801 -- LABELING

Subpart C--Exemptions From Adequate Directions for Use
 Sec. 801.110 Retail exemption for prescription devices.

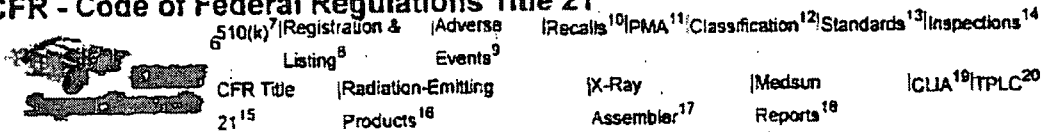
A device subject to 801.109 shall be exempt at the time of delivery to the ultimate purchaser or user from section 502(f)(1) of the act if it is delivered by a licensed practitioner in the course of his professional practice or upon a prescription or other order lawfully issued in the course of his professional practice, with labeling bearing the name and address of such licensed practitioner and the directions for use and cautionary statements, if any, contained in such order.

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TITLE 21--FOOD AND DRUGS
 CHAPTER I--FOOD AND DRUG ADMINISTRATION
 DEPARTMENT OF HEALTH AND HUMAN SERVICES
 SUBCHAPTER H--MEDICAL DEVICES
 PART 808 EXEMPTIONS FROM FEDERAL PREEMPTION
 OF STATE AND LOCAL MEDICAL DEVICE
 REQUIREMENTS

Subpart C--Listing of Specific State and Local Exemptions

Sec. 808.33 Arizona.

The following Arizona medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them exemptions from preemption under section 521(b) of the act:

(a) Arizona Revised Statutes, Chapter 17, sections 36-1901.7(s) and 36-1901.7(t).

(b) Arizona Code of Revised Regulations, Title 9, Article 3, sections R9-16-303 and R9-16-304.

[45 FR 67336, Oct. 10, 1980]

Sec. 808.55 California.

(a) The following California medical device requirements are enforceable notwithstanding section 521 of the act because the Food and Drug Administration exempted them from preemption under section 521(b) of the act: Business and Professions Code sections 3365 and 3365.6.

(b) The following California medical device requirements are preempted by section 521 of the act, and FDA has denied them an exemption from preemption:

(1) Sherman Food, Drug, and Cosmetic Law (Division 21 of the California Health and Safety Code), sections 26207, 26607, 26614, 26615, 26618, 26631, 26640, and 26641, to the extent that they apply to devices.

(2) Sherman Food, Drug, and Cosmetic Law, section 26463(m) to the extent that it applies to hearing aids.

(3) Business and Professions Code section 2541.3, to the extent that it requires adoption of American National Standards Institute standards Z-80.1 and Z-80.2.

[45 FR 67324, Oct. 10, 1980]

Sec. 808.57 Connecticut.

The following Connecticut medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act: Connecticut General Statutes, sections 20-403 and 20-404.

[45 FR 67336, Oct. 10, 1980]

Sec. 808.59 Florida.

The following Florida medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemption from preemption under section 521(b) of the act:

(a) Florida Statutes, section 468.135(5).

(b) Florida Administrative Code, section 10D-48.25(26).

[45 FR 67336, Oct. 10, 1980]

Sec. 808.61 Hawaii.

(a) The following Hawaii medical device requirements are enforceable notwithstanding section 521 of the act, because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act: Hawaii Revised Statutes, chapter 451A, 14.1, subsection (a) with respect to medical examination of a child 10 years of age or under, and subsection (c).

(b) The following Hawaii medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them exemption from preemption: Hawaii Revised Statutes, chapter 451A, 14.1, subsection (a) to the extent that it requires a written authorization by a physician and does not allow adults to waive this requirement for personal, as well as religious reasons, and subsection (b).

[50 FR 30699, July 29, 1985; 50 FR 32694, Aug. 14, 1985]

Sec. 808.67 Kentucky.

The following Kentucky medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Kentucky Revised Statutes, section 334.200(1).

[45 FR 67336, Oct. 10, 1980]

Sec. 808.69 Maine.

(a) The following Maine medical device requirement is enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted it from preemption under section 521(b) of the act: Maine Revised Statutes Annotated, Title 32, section 1658-C, on the condition that, in enforcing this requirement, Maine

apply the definition of "used hearing aid" in 801.420(a)(6) of this chapter.

(b) The following Maine medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Maine Revised Statutes Annotated, Title 32, section 1659-D and the last sentence of section 1658-E.

[45 FR 67336, Oct. 10, 1980]

Sec. 808.71 Massachusetts.

(a) The following Massachusetts medical device requirements are enforceable notwithstanding section 521 of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act:

(1) Massachusetts General Laws, Chapter 93, Section 72, to the extent that it requires a hearing test evaluation for a child under the age of 18.

(2) Massachusetts General Laws, Chapter 93, Section 74, except as provided in paragraph (6) of the Section, on the condition that, in enforcing this requirement, Massachusetts apply the definition of "used hearing aid" in 801.420(a)(6) of this chapter.

(b) The following Massachusetts medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them exemptions from preemption under section 521(b) of the act.

(1) Massachusetts General Laws, Chapter 93, Section 72, except as provided in paragraph (a) of this section.

(2) Massachusetts General Laws, Chapter 93, Section 74, to the extent that it requires that the sales receipt contain a statement that State law requires a medical examination and a hearing test evaluation before the sale of a hearing aid.

[45 FR 67326, Oct. 10, 1980]

Sec. 808.73 Minnesota.

The following Minnesota medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemption from preemption under section 521(b) of the act: Minnesota Statutes, sections 145.43 and 145.44.

[45 FR 67336, Oct. 10, 1980]

Sec. 808.74 Mississippi.

The following Mississippi medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Mississippi Code, section 73-14-3(g)(9).

[45 FR 67336, Oct. 10, 1980]

Sec. 808.77 Nebraska.

(a) The following Nebraska medical device requirement is enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted it from preemption under section 521(b)

of the act: Nebraska Revised Statutes, section 71-4712(2)(c)(vi).

(b) The following Nebraska medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Nebraska Revised Statutes, section 71-4712(2)(c)(vii).

[45 FR 67336, Oct. 10, 1980]

Sec. 808.80 New Jersey.

(a) The following New Jersey medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act:

(1) New Jersey Statutes Annotated, section 45:9A-23 on the condition that, in enforcing this requirement, New Jersey apply the definition of "used hearing aid" in 801.420(a)(6) of this chapter;

(2) New Jersey Statutes Annotated, sections 45:9A-24 and 45:9A-25;

(3) Chapter 3, Section 5 of the Rules and Regulations adopted pursuant to New Jersey Statutes Annotated 45:9A-1 et seq. except as provided in paragraph (b) of this section.

(b) The following New Jersey medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Chapter 3, Section 5 of the Rules and Regulations adopted pursuant to New Jersey Statutes Annotated 45:9A-1 et seq. to the extent that it requires testing to be conducted in an environment which meets or exceeds the American National Standards Institute S3.1 Standard.

[45 FR 67337, Oct. 10, 1980]

Sec. 809.81 New Mexico.

The following New Mexico medical device requirement is enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted it from preemption under section 521(b) of the act: New Mexico Statutes Annotated, section 67-36-16(F).

[45 FR 67337, Oct. 10, 1980]

Sec. 808.82 New York.

(a) The following New York medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act:

(1) General Business Law, Article 37, sections 784(3) and (4).

(2) Official Compilation of Codes, Rules and Regulations of the State of New York, Chapter V, Title 19, Subchapter G, section 191.10 and section 191.11(a) on the condition that, in enforcing these requirements, New York apply the definition of "used hearing aid" in 801.420(a)(6) of this chapter and section 191.11(b), (c), (d), and (e).

(b) The following New York medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemptions from preemption under section 521(b)

of the act:

- (1) General Business Law, Article 37, section 784.1.
 - (2) Official Compilation of Codes, Rules and Regulations of the State of New York, Chapter V, Title 19, Subchapter G, sections 191.6, 191.7, 191.9, and 191.9.
- [45 FR 67337, Oct. 10, 1980]

Sec. 808.35 Ohio.

(a) The following Ohio medical device requirement is enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted it from preemption under section 521(b) of the act: Ohio Revised Code, section 4747.09, the first two sentences with respect to disclosure of information to purchasers on the condition that, in enforcing these requirements, Ohio apply the definition of "used hearing aid" in 801.420(a)(6) of this chapter.

(b) The following Ohio medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Ohio Revised Code, section 4747.09, the last two sentences with respect to medical examination of children.

[45 FR 67337, Oct. 10, 1980]

Sec. 808.37 Oregon.

(a) The following Oregon medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act: Oregon Revised Statutes, section 694.036 on the condition that, in enforcing this requirement, Oregon apply the definition of "used hearing aid" in 801.420(a)(6) of this chapter.

(b) The following Oregon medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them exemptions from preemption under section 521(b) of the act: Oregon Revised Statutes, sections 694.136(6) and (7).

[45 FR 67337, Oct. 10, 1980, as amended at 53 FR 11252, Apr. 6, 1988]

Sec. 808.36 Pennsylvania.

(a) The following Pennsylvania medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act: 35 Purdon's Statutes 6700, section 504(4) on the condition that, in enforcing this requirement, Pennsylvania apply the definition of "used hearing aid" in 801.420(a)(6) of this chapter; section 506; and, section 507(2).

(b) The following Pennsylvania medical device requirement is preempted by section 521(a) of the act and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: 35 Purdon's Statutes 6700, section 402.

[45 FR 67326, Oct. 10, 1980]

Sec. 808.39 Rhode Island.

The following Rhode Island medical device requirements are preempted

by section 521(a) of the act, and the Food and Drug Administration has denied them an exemption from preemption under section 521(b) of the act: Rhode Island General Laws, Section 5-49-2.1, and Section 2.2, to the extent that Section 2.2 requires hearing aid dispensers to keep copies of the certificates of need.

[45 FR 67337, Oct. 10, 1980]

Sec. 808.93 Texas.

(a) The following Texas medical device requirement is enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted it from preemption under section 521(b) of the act: Vernon's Civil Statutes, Article 4566, section 14(b) on the condition that, in enforcing this requirement, Texas apply the definition of "used hearing aid" in 801.420(a)(6) of this chapter.

(b) The following Texas medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Vernon's Civil Statutes, Article 4566, section 14(d).

[45 FR 67337, Oct. 10, 1980]

Sec. 808.97 Washington.

(a) The following Washington medical device requirement is enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted it from preemption under section 521(b) of the act: Revised Code of Washington 18.35.110(2)(e) (i) and (iii) on the condition that it is enforced in addition to the applicable requirements of this chapter.

(b) The following Washington medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemption from preemption under section 521(b) of the act: Revised Code of Washington 18.35.110(2)(e) (ii).

[45 FR 67337, Oct. 10, 1980]

Sec. 808.98 West Virginia.

(a) The following West Virginia medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption: West Virginia Code, sections 30-26-14 (b) and (c) and section 30-26-15(a) on the condition that in enforcing section 30-26-15(a) West Virginia apply the definition of "used hearing aid" in 801.420(a)(6) of this chapter.

(b) The following West Virginia medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: West Virginia Code, section 30-26-14(a).

[45 FR 67337, Oct. 10, 1980, as amended at 53 FR 35314, Sept. 13, 1988]

Sec. 808.101 District of Columbia.

(a) The following District of Columbia medical device requirements are enforceable, notwithstanding section 521 of the act, because the

Food and Drug Administration has exempted them from preemption under section 521(b) of the act:

(1) Act 2-79, section 5, to the extent that it requires an audiological evaluation for children under the age of 18.

(2) Act 2-79, section 6, on the condition that in enforcing section 6(a)(5), the District of Columbia apply the definition of "used hearing aid" in 801.420(a)(6) of this chapter.

(b) The following District of Columbia medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Act 2-79, section 5, except as provided in paragraph (a) of this section.

[46 FR 59236, Dec. 4, 1981]

Authority: 21 U.S.C. 360j, 360k, 371.

Source: 43 FR 18665, May 2, 1978, unless otherwise noted.

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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

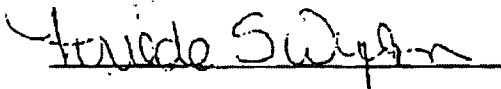
on the order or prescription of a physician, and (2) memorialize all such orders or prescriptions.

- (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.

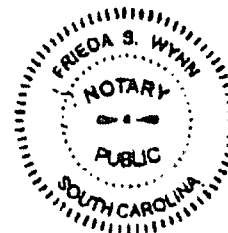
FURTHER AFFIANT SAYETH NOT.


Charles Trescott Ferguson

SWORN to and subscribed before me
this 26th day of August, 2013

 (L.S.)

Notary Public for South Carolina
My commission expires May 19, 2016



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 JOHN McCROSSON,
M.D. IN SUPPORT OF MOTION FOR
SUMMARY JUDGMENT

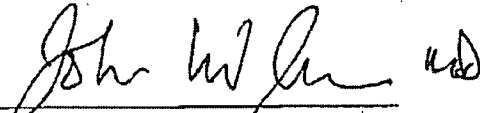
I, John McCrosson, M.D., being first duly sworn, state as follows:

1. I am a board certified orthopedic surgeon specializing in hip and knee joint replacements, and I practice at Roper St. Francis Hospital.
2. I am authorized to implant orthopedic hip and knee joint replacements into my patients who require them.
3. These orthopedic prosthetic devices are prescription devices and may only be sold by prescription.
4. I issue an oral order for the orthopedic prosthetic device I am going to implant into one of my patients during surgery, which is when I determine exactly what size and type of device the patient needs. I consider this oral order to be a prescription as required by law.
5. 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.

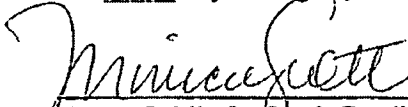
EXHIBIT C

6. A patient who requires a joint replacement will always be missing cartilage. Additionally during surgery, I remove more of the patient's joint to accommodate the orthopedic prosthetic device I am implanting. The device replaces the missing cartilage and joint of the patient.

FURTHER AFFIANT SAYETH NOT.


John McCrosson, M.D.

SWORN to and subscribed before me
this 28th day of August, 2013


_____(L.S.)
Notary Public for South Carolina
My commission expires 1.24.2023

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 BRETT M. BAKER,
M.D. IN SUPPORT OF MOTION FOR
SUMMARY JUDGMENT

I, Brett M. Baker, M.D., being first duly sworn, state as follows:

1. I am a board certified cardiologist specializing in the field of cardiovascular electrophysiology, and I practice at Roper St. Francis Hospital.

2. I am authorized to implant implantable cardioverter defibrillators ("ICDs") and pace makers (collectively the "Cardiac Devices") into my patients who require them.

3. The Cardiac Devices are prescription devices and may only be sold by prescription.

4. I issue an oral order for the Cardiac Devices that I implant during surgery, which is when I finally determine exactly what device, including the components and leads, the patient needs. I consider this oral order to be a prescription as required by law.

5. This prescription is then memorialized in writing at the conclusion of the surgery via a detailed report that is kept in my office as well as placed in the patient's medical records and sent to other physicians who are involved in the patient's care.

EXHIBIT D

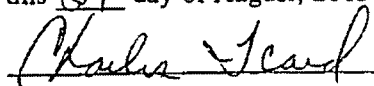
6. Many of my patients are experiencing some type of heart irregularity. The cause is most commonly that some portion of the patient's heart's electrical system has degenerated over time and that portions of the heart tissue or cells responsible for conduction of electrical signals to the heart have died off. The Cardiac Device replaces this missing cardiac tissue and restores the normal heart rhythm.

7. There are situations where a patient is born with a genetic defect of the heart (and thus heart cells are defective versus missing), but this represents less than 1% of my patients.

FURTHER AFFIANT SAYETH NOT.


Bret M. Baker, M.D.

SWORN to and subscribed before me
this 29 day of August, 2013

 (L.S.)

Notary Public for the State of South Carolina
My commission expires 8/12/2014

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 M. DAUD NAWABI,
M.D. IN SUPPORT OF MOTION FOR
SUMMARY JUDGMENT

I, M. Daud Nawabi, M.D., being first duly sworn, state as follows:

1. I am a board certified oncologist, and I practice in the areas of oncology and hematology at Roper St. Francis Hospital.
2. Whole blood is composed of four components: red blood cells, white blood cells, platelets and plasma.
3. 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.
4. 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.
5. 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.

EXHIBIT E

6. The blood proteins, which include, among other things, immunoglobulins and albumin, are then processed in a similar way to the red blood cells and platelets, which can include screening for infectious diseases, re-suspending in a buffer and adding a preservative.

7. A buffer is simply a liquid replacement for the liquid portion of plasma and is typically a solution made of water and salts.

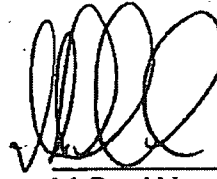
8. Nothing in the processing of the red blood cells, the platelets or the blood proteins extracted from the plasma in any way alters, modifies or changes their nature in any way.

9. The blood proteins are not synthetic, artificial or pharmaceutical. They are not manufactured but rather are created by the human body.

10. It is my understanding that the blood protein products at issue include the following: Gamunex, Octagam, Plasbumin, Albutein, Buminate, Flexbumin, Alburx and Albuminar. Gamunex and Octagam are both human immunoglobulin proteins, while the remaining products are albumin proteins.

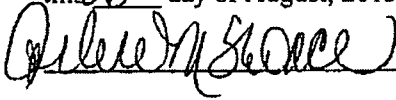
11. Sales of blood require the order of a physician.

FURTHER AFFLIANT SAYETH NOT.



M. Daud Nawabi, M.D.

SWORN to and subscribed before me
this 28th day of August, 2013



(L.S.)

Notary Public for the State of South Carolina
My commission expires 9/16/2015

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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EXHIBIT F

A. WILLIAM ROBERTS, JR., & ASSOCIATES (800) 743-1

Page 45

1 Q. Do you know what a blood product is?

2 A. I have a guess of what it might —

3 things it might include, but I, you know. . .

4 Q. Okay. And I have already asked whether

5 there was an official definition of that term and

6 you indicated that there was not; but 92-26 is

7 clearly about blood products, is it not?

8 A. It states blood products, yes.

9 Q. Yes. And even though there's a

10 discussion of whole blood, it's not really about

11 whole blood, is it?

12 A. Well, it states — the final conclusion,

13 as you said, talks about blood products.

14 Q. Tell me how the department uses this

15 decision. What do you draw from it and what, in

16 terms of policy, have you developed as a position by

17 the department based upon Commission Decision 92-26?

18 A. Well, I think the 92-26 is determining

19 that, again, that 43 — give you the right number

20 here, that 44-43-10 is not controlling and that the

21 definition of tangible personal property in 12-36-60

22 is controlling. So that's the first thing. Then I

23 think with the — which I believe were subsequent to

24 this.

25 Then with the Associated Medical case

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1 and with the more recent Home Medical case, that the

2 issue here is whether they were sold by

3 prescription, assuming that we're not dealing with

4 things that are used to treat cancer, leukemia,

5 lymphoma, and those — specifically ones that would

6 qualify. You know, that that might be another

7 issue. But as far as sold by prescription, that it

8 has to be something that requires a prescription,

9 it — excuse me, the prescription medicine, requires

10 a prescription and is actually sold by prescription.

11 Q. Okay.

12 A. And I think the department's position

13 with respect to this case deals with the issues that

14 hospitals do not need a prescription in order to

15 purchase blood products, you know, in order to do

16 that because hospitals are considered the user or

17 consumer under the statute, under the Sales Tax

18 Statute of anything that they buy, medicines, drugs

19 or equipment, and that they are — that based on

20 those two cases that the determination in this

21 particular issue that we're dealing with here today

22 is that, you know, they were not sold by

23 prescription and — or a prescription that was

24 required under the provisions of the Home Medical

25 case and the Associated Medical case.

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1 Q. Is blood subject to tax in South

2 Carolina?

3 A. I think the department stated its

4 position under department determination that it

5 would be unless it's used to treat certain diseases.

6 Q. Is blood being taxed now in South

7 Carolina?

8 A. That would be an issue, you know. As I

9 think I mentioned earlier, that the department/audit

10 division had made a determination as far as not

11 taxing certain levels of blood and blood — I don't

12 know whether you call it products or not, but

13 certain levels and taxing other levels of it and

14 that — and, obviously, it's been taxed because

15 you're claiming a refund here. So I mean, there's a

16 little bit of issues there.

17 Q. Well, my question was, do you know if

18 hospitals in the State of South Carolina are paying

19 sales tax on their purchases of blood, whole blood?

20 A. Whole blood? I don't know whether your

21 issue deals with blood or blood products.

22 Q. No. I'm just asking the question, do

23 you know of your knowledge whether hospitals in

24 South Carolina are paying sales tax or use tax on

25 their purchases of whole blood?

Page 48

1 A. I could not say one way or the other

2 because I don't deal with the hospitals, but —

3 Q. Okay. You don't know?

4 A. I don't know other than — unless part

5 of this refund deals with it. That would be the

6 only way I would know.

7 Q. Okay. Do you know if hospitals are

8 paying tax on blood products in South Carolina?

9 A. Again, because you're claiming a refund

10 in this case, that would be an issue there, you

11 know, on some hospitals. Now, whether all hospitals

12 are is another issue.

13 Q. So you don't know of your own personal

14 knowledge or your own professional knowledge whether

15 hospitals in South Carolina are paying sales tax or

16 use tax on blood products?

17 A. All I can answer is with respect to

18 whatever this — the refund case in this case

19 because I don't audit hospitals and I don't deal

20 with them.

21 Q. The issue in this case is blood

22 derivatives, what has been described as blood

23 derivatives. And do you know of your own knowledge

24 whether or not hospitals in South Carolina are

25 paying sales tax or use tax on their purchases of

1 blood derivatives?
 2 A. Obviously, in this case, one did.
 3 Whether others are, I don't know.
 4 Q. Is it the policy of the State of South
 5 Carolina to tax sales of whole blood?
 6 A. I believe that the policy, you know, as
 7 far as derivatives here, I think that's set forth.
 8 I think the same policy would probably apply there.
 9 Now, whether there's been an official policy issued
 10 on that, the closest thing you've got is this
 11 department determination.
 12 Q. You are the head of policy; is that
 13 correct?
 14 A. Yes.
 15 Q. Okay. Is the policy of the State of
 16 South Carolina to tax whole blood purchases by
 17 hospitals?
 18 A. What do you mean by policy?
 19 Q. Is it the official position promulgated
 20 by yourself and by the director of the department
 21 that hospitals are liable for the sales and use tax
 22 on their purchases of blood and that sellers of
 23 blood are required to collect the tax from the
 24 hospitals to whom they sell the blood?
 25 A. Well, there's been no official policy

1 document, no revenue ruling on that issue
 2 specifically. Now, whether — and there has been
 3 this issue here dealing with derivatives. And
 4 whether there has been issues dealing with how to
 5 handle this under audit as a result of this refund
 6 claim or anything else, any other results, you know,
 7 I don't know.
 8 Q. So Mr. McCormack, what you're saying is
 9 there is no policy?
 10 A. There's no official advisory opinion on
 11 blood, whole blood or blood products or blood
 12 derivatives.
 13 Q. And you are not aware whether or not
 14 hospitals are actually paying tax on their purchases
 15 of whole blood in the State of South Carolina?
 16 A. Since I don't audit the hospitals and
 17 have not been involved in discussing anything about
 18 hospital, other than this one dealing with this
 19 issue, I can't say one way or the other.
 20 Q. In your discussions and deliberations
 21 within the department with regard to this audit, is
 22 there a proposal at hand from anywhere in the
 23 department that you need to issue an administrative
 24 notice or other public notice with regard to the
 25 department's position on the taxation of blood?

1 A. Not that I'm aware of discussing on
 2 that. As we've mentioned earlier, usually when
 3 there's cases going on, we're not issuing any
 4 advisory opinions until those cases are resolved.
 5 So since this case is going on, we would not issue
 6 an advisory opinion until it's resolved.
 7 Q. Is the commissioner — I'm sorry, the
 8 director of the department aware of the position of
 9 the department with regard to the taxation of blood?
 10 A. That I can't say one way or the other.
 11 I have not discussed that with the new director.
 12 Q. You don't know one way or the other if
 13 he is aware?
 14 A. I just don't know one way or the other
 15 because I don't know whether litigation has
 16 discussed that.
 17 Q. You have never discussed it with him?
 18 A. No, not the — not this new director,
 19 no.
 20 Q. Did you discuss it with any of the old
 21 directors?
 22 A. The issue probably came up when the
 23 issue first arose with the director at the time. I
 24 believe it was Ray Stevens and so probably had some
 25 initial discussions with him, but I don't recall the

1 specifics of them right now.
 2 Q. And Mr. Stevens did not instruct you to
 3 issue any kind of administrative notice to the
 4 public with regard to the position of the
 5 department?
 6 A. Not that I recall, no. I mean, because
 7 again the refund —
 8 Q. But —
 9 A. The refund issue had come in and so,
 10 again, we don't issue advisory — formal advisory
 11 opinions when there's matters going on like that.
 12 Q. 92-26 was a commission decision in 1992;
 13 is that correct?
 14 A. Yes.
 15 Q. Okay. And since 1992, no policy
 16 statement has been issued discussing 92-26, has it?
 17 A. Not that I'm aware of, no.
 18 Q. Do you know if the legislature is aware
 19 of Commission Decision 92-26 and the position of the
 20 Department of Revenue with regard to this case?
 21 A. I could not tell you one way or the
 22 other. I don't — I try to keep up with the
 23 legislation that they're proposing, but I can't tell
 24 you whether they've proposed anything in recent
 25 years. I just don't recall one way or the other, so

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

CareAlliance Health) CIVIL ACTION NO:
Services d/b/a Roper St.) 12-ALJ-17-0405-CC
Francis Healthcare,)
Plaintiff,)
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

* * * * *

POST OFFICE BOX 21784
CHARLESTON, SOUTH CAROLINA 29413-1784

EXHIBIT G

Page 26	Page 28
1 Q. But this is Revenue Ruling 96-4, which 2 is issued by the South Carolina Department of 3 Revenue; is it not? 4 A. In my opinion, the purpose of this 5 Revenue ruling is to say that radioisotopes may 6 only be sold by prescription and so they were 7 exempt. 8 Q. Okay. And that is the position of the 9 South Carolina Department of Revenue? 10 A. Yes. 11 Q. Okay. That's all I have on that. 12 I want to -- one or two more questions 13 on that. If a hospital or a taxpayer is in 14 possession of radiopharmaceuticals without a 15 prescription, do you know if that's a violation of 16 law or regulation that is in any way actionable? 17 A. I do not know. 18 Q. Okay. You don't make any kind of 19 determination whether or not a taxpayer has 20 violated either Department of Pharmacy regulations 21 or other criminal statutes in the possession of 22 radiopharmaceuticals or other prescription 23 medicines, or do you? 24 MR. MARINELLI: Objection to the form. 25 THE WITNESS: No.	1 Q. Okay. And body parts are exempt from 2 sales and use tax? 3 A. Administratively, it's been the audit's 4 -- audit department's position that we have not 5 taxed body parts. 6 Q. Okay. And what is the authority for 7 that, for the administrative position of the 8 Department of Revenue? 9 A. I asked the question and they said this 10 is the way it's been done. 11 Q. Of whom did you ask the question? 12 A. I asked the -- my audit supervisor as 13 well as the district audit manager. 14 Q. And what was their response? 15 A. Administratively, in the past, audit 16 has taken -- the audit department has taken the 17 stance we do not tax body parts. 18 Q. Okay. But they didn't cite you a 19 statute or -- 20 A. No. 21 Q. -- a regulation or anything? 22 A. No. 23 Q. Could they possibly have been talking 24 about the Anatomical Gift Act? 25 A. Possibly.
Page 27	Page 29
1 BY MR. CARPENTER: 2 Q. You don't make that determination? 3 A. No. 4 Q. Okay. But it was your determination 5 that the radiopharmaceuticals were exempt under 6 96.4 and under the exemption statute in the sales 7 and tax use law? 8 A. Yes. 9 Q. Okay. 10 (PLP. EXH. 3, Copy of invoice, was 11 marked for identification.) 12 BY MR. CARPENTER: 13 Q. Ms. Buddin, I show you what has been 14 marked for identification as Plaintiff's Exhibit 3, 15 and ask you if you recognize that document. 16 A. I assume it's an invoice that I 17 reviewed as part of the audit -- or refund. 18 Q. It's a purchase by -- from -- by 19 Biomet. And do you know what your determination 20 was with regard to the items on that invoice? 21 A. By looking at the description and 22 seeing that it is ob cartilage, I exempted it. 23 Q. Can you tell us on what basis you 24 exempted that? 25 A. On the basis that it was a body part.	1 Q. I'm going to ask you to look at -- I 2 think we need the Anatomical Gift Act. I'm going 3 to ask you to take a look at Section 4443-10 of the 4 South Carolina Code, and ask you if you would just 5 read that provision out loud for us, if you would. 6 A. The implied warranties of 7 merchantability and fitness are not applicable to 8 the contract for the sale, procurement, processing, 9 distribution, or use of human tissues, including, 10 but not limited to, corneas, bones or organs, whole 11 blood, plasma, blood products, or blood 12 derivatives. Human tissue, whole blood, plasma, 13 blood products, and blood derivatives must not be 14 considered commodities subject to sale or barter, 15 and the transplanting, injecting, transfusing or 16 other transfer of these substances into the human 17 body are considered a medical service. 18 Q. Okay. Now, would you go back to 19 Exhibit 1.4, page 2, and read your -- 20 A. Reason For Refund Denied -- Denied or 21 Allowed, which one do you -- 22 Q. Allowed portion, please. 23 A. Reason For Refund Allowed. Code 24 Section 4443-10 reads -- what I just read. The 25 invoices provided by the taxpayer were reviewed in

8 (Pages 26 to 29)

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1 detail and it was determined that all invoices for 2 the purchase of human tissue and rib cartilage and 3 therefore exempt. These invoices were accrued as 4 a use tax by the taxpayer. 5 Q. Okay. I'm not clear. Did your 6 supervisors cite that particular provision to you 7 as the reason for exempting the rib cartilage? 8 A. Did they cite this? 9 Q. Did they tell you that was the 10 authority -- that was the basis for their 11 administrative decision -- their administrative 12 position? 13 A. I don't recall them saying what their 14 basis was. Again, what I remember them saying is, 15 audit has not taxed body parts. 16 Q. Okay. But you cited that provision? 17 A. But I am familiar with 4443-10, yes. 18 Q. And you cited it in your determination? 19 A. That is correct. 20 (PLF. EXH. 4, Copy of invoice, was 21 marked for identification.) 22 BY MR. CARPENTER: 23 Q. Go ahead. If you're refreshing 24 yourself with regard to that invoice, that's 25 precisely what I would like for you to do.	1 help you in making this determination? 2 A. Not that I know of. 3 Q. Okay. And would you have discussed 4 this determination with your supervisors in the 5 same manner that you discussed your other -- your 6 other decisions on taxability? 7 A. Yes, I assume so. I don't recall if I 8 specifically discussed this one particular drug, 9 but... 10 Q. Okay. And once again, from your 11 determination, why did you exempt Humate? 12 A. Again, I can't recall specifically what 13 it said on drugs.com, but I'm assuming it was human 14 -- mostly human plasma. 15 Q. Okay. And -- 16 A. And it looks like it's sold like in a 17 liquid form, in a vial. 18 Q. Okay. And would this have been pretty 19 much in the same line as the previous exhibits that 20 you looked at, where you determined -- where you 21 used the Anatomical Gift Act as at least a part of 22 your determination of taxability? 23 A. Yes. 24 (PLF. EXH. 5, Copy of chart, was marked 25 for identification.)
Page 31	Page 33
1 A. Okay. 2 Q. Okay. I show you what's been marked 3 for identification as Plaintiff's Exhibit Number 4, 4 and ask if you would tell me what that invoice is. 5 A. It's called Humate. 6 Q. Okay. Is the purchase of Humate by 7 Roper St. Francis Hospital, the taxpayer in this 8 case? 9 A. Yes, it is made to Roper, a purchase by 10 Roper. 11 Q. And would you tell me what your 12 disposition was with regard to the purchase on that 13 invoice? 14 A. Well, I had to find it to see, because 15 I honestly could not remember if it was taxable or 16 not, but according to my spreadsheet, I said that 17 it was exempt because it is made -- it is human 18 plasma. 19 Q. Okay. And how did you make that 20 determination that it was human plasma? 21 A. I went to drugs.com and read about 22 Humate. 23 Q. Okay. Is there an administrative 24 finding or a Revenue ruling or anything of that 25 sort issued by the Department of Revenue that would	1 BY MR. CARPENTER: 2 Q. Now, Ms. Buddin, I show you what's been 3 marked for identification as Plaintiff's Exhibit 5. 4 Can you describe what that is? 5 A. It appears to be a chart that was put 6 together, from what I was told, years ago to 7 provide guidance to the auditors as to the -- what 8 we would hold taxable or exempt. 9 Q. Do you know who put it together? 10 A. I don't remember the man's name, and I 11 don't believe he works for us anymore. 12 Q. Who told you that somebody put it 13 together? 14 A. I first saw this document when I was a 15 part of another hospital audit within two years of 16 when I was employed, and it was given to me by 17 another auditor in our office. 18 Q. And not by your supervisor? 19 A. No. 20 Q. Okay. Would it be fair to say that 21 this is a chart that lists whole blood at the top 22 and it lists four subcategories of blood and three 23 subcategories of plasma? 24 A. Yes. 25 Q. Okay. Now, on this chart, Plaintiff's

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1 Exhibit 5, there is written -- handwritten the 2 term, exempt, next to whole blood. The term, 3 exempt, is also written next to the four divisions 4 of whole blood. And then at the bottom there's a 5 term written in that says, taxable, under the three 6 subdivisions of plasma. Is that an accurate 7 description of Plaintiff's Exhibit 5? 8 A. Yes. 9 Q. Do you know who wrote those notes on 10 the paper? 11 A. No. 12 Q. Okay. What -- what do those notes tell 13 you with regard to your -- the taxability or 14 non-taxability of blood and its divisions as you -- 15 as you move down? 16 A. Whole blood is exempt. 17 Q. Okay. 18 A. Red blood cells, white blood cells, 19 platelets and plasma are exempt. Albumin, 20 globulin, and fibrinogen are taxable. 21 Q. And you have used this in other audits 22 of hospitals and health care systems, the 23 information on this Plaintiff's Exhibit 5? 24 A. I used it previously in one other 25 hospital audit.	1 were found in audits. 2 Q. Okay. Do you know if this is included 3 in any regulation that was issued by the Department 4 of Revenue? 5 A. I don't know. 6 Q. Is it issued in any other 7 administrative notice that goes out to taxpayers in 8 South Carolina to inform them of the position of 9 the Department? 10 A. I don't know. 11 Q. Is it in any statute that was adopted 12 by the Legislature, that you know of? 13 A. I don't know. 14 Q. Okay. Does it appear in the Anatomical 15 Gift Act? 16 A. No. 17 Q. Okay. Are there other instructional 18 charts, graphs or pieces of paper like this that 19 are used by auditors to determine if these items 20 are subject to sales tax? 21 A. I don't know. This is the only one 22 that I recall. 23 Q. Okay. And this was not part of any 24 manual or other document when you received it? Did 25 you receive it just as a single piece of paper?
Page 35	Page 37
1 Q. In one other audit. Okay. And you got 2 it from another auditor, so other auditors are 3 using it is that correct? 4 A. The auditor I got it from no longer 5 works for us, but at the time he was the auditor in 6 charge of the audit I was working assisting with. 7 Q. Do you mind telling us who that is? 8 A. Who? 9 Q. The auditor that is no longer working 10 for you. 11 A. Jack Thames. 12 Q. Jack? 13 A. Jack Thames, T-H-A-M-E-S. 14 Q. Okay. Thank you. 15 It is the policy of the Department of 16 Revenue to not tax whole blood; is that right? 17 MR. MARINELLI: Object to the form. 18 THE WITNESS: Yes. 19 BY MR. CARPENTER: 20 Q. Okay. Is this document the authority 21 for that policy, as far as you know? 22 A. I don't know if it's the authority. 23 Again, it's just the guidance that the Department 24 of Revenue or the audit division has taken as to 25 how we were going to handle these purchases if they	1 A. I had it as a single piece of paper 2 from the auditor from years ago. 3 Q. Okay. Has it ever been a subject of a 4 training course that you had as a member of the 5 Department of Revenue? 6 A. No. 7 Q. Okay. We are going to go through one 8 more and then take a short break. Plaintiff's 9 Exhibit 6. 10 (PLF. EXH. 6, Copy of invoice, was 11 marked for identification.) 12 BY MR. CARPENTER: 13 Q. Ms. Buddin, I show you what has been 14 marked for identification as Plaintiff's Exhibit 15 Number 6, and ask you if you recognize that 16 document. 17 A. I assume it's one of the invoices I 18 reviewed as part of the refund. 19 Q. Okay. Can you look at your 20 determination and tell me what your determination 21 was with regard to the purchase on Plaintiff's 22 Exhibit 6? 23 A. The product is called Gamunex and I 24 held it as taxable. 25 Q. Okay. Can you tell me why you held

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1 this purchase to be taxable? 2 A. Upon researching what the drug was, it 3 was determined that there was some human protein 4 and then it was a manufactured product. It took 5 other tangible stuff and it made a new product. 6 Q. Okay. And based upon that, you 7 determined that it was subject to sales tax? 8 A. It fell within the guidelines of the 9 taxable line almost in that -- that exhibit. It 10 wasn't whole blood and it wasn't plasma, red blood 11 cells, white blood cells, or platelets. 12 Q. But your decision with regard to 13 Gamunex in Plaintiff's Exhibit 6 was based upon 14 your use of the chart which is Plaintiff's Exhibit 15 5? 16 A. I based it upon the decision that it 17 really was a manufactured product. It was not 18 whole blood, plasma, white blood count, or red 19 blood count, or platelets. 20 Q. Can you tell me where in the tax code 21 those types of product are subjected to sales tax? 22 A. No, I can't. 23 Q. Do you know what a blood derivative is? 24 A. No, I don't. 25 Q. Do you know what a blood product is?	1 A. Not that I'm aware of. 2 Q. Okay. So when you made that 3 distinction, is this something that you discussed 4 with your supervisors? 5 A. Yes. 6 Q. Okay. And do all auditors in South 7 Carolina make that distinction? 8 A. I don't know. 9 Q. Okay. But your supervisors are aware 10 of the fact that you make it and you -- you base 11 your decisions on taxability on the research that 12 you just described to me from the website that you 13 mentioned? 14 A. On this particular drug, yes. 15 Q. Okay. Do you know what fractionated 16 plasma products are? 17 A. No. 18 Q. I'm going to show you Commission 19 Decision 92.26, and ask you if you recall -- or 20 what does that -- how does that decision inform 21 your actions with regard to the taxability of blood 22 and blood products? Are you familiar with 23 Commission Decision 92.26? 24 A. No. 25 Q. Okay. I believe you cited it in your
Page 39	Page 41
1 A. Not specifically, no. 2 Q. And you have some idea what whole blood 3 is, I'm sure. 4 A. Yes. 5 Q. Okay. How does a -- how does the blood 6 derivatives, blood products, how do they differ 7 from whole blood as far as -- as far as you would 8 determine in making your decisions on taxability? 9 A. The blood products, again, are -- 10 appear to be manufactured products. They take a 11 portion of a blood product or a blood protein and 12 they add additional material to it, and the end 13 result is a totally different product. Some of the 14 products that we looked at ended up being a powder 15 form and came in a package. 16 Q. Okay. 17 A. So it's totally different than what was 18 taken out of the body. It was a manufactured 19 product. 20 Q. Is there a regulation or an 21 administrative notice or something of that sort 22 issued by the Department that makes the 23 differentiation that you have just made between 24 whole blood and blood products and blood 25 derivatives?	1 findings with regard to -- to Gamunex. 2 A. Where would that be? 3 Q. I think it's on page 6 and 7, Exhibit 4 12. 5 A. Okay. 6 Q. Okay. You did cite that? 7 A. I did. 8 Q. Okay. If you recall, what does your -- 9 what is your understanding of the holding of the 10 Commission in Commission Decision 92-26? 11 A. It recognizes the sale of blood and 12 blood derivatives as tangible personal property 13 subject to sales and use tax. 14 Q. So Commission Decision 92-26 says blood 15 is subject to sales and use tax? 16 A. It says the sale of blood is the sale 17 of tangible personal property and that they are 18 medicines. 19 Q. Okay. Did Commission Decision 92-26 20 hold the items that were at issue in that case 21 taxable or nontaxable, as far as you recall? 22 A. Repeat the question. 23 Q. Did the Commission Decision 92-26 -- 24 and I'll tell you that at issue in that case were 25 blood products.

11 (Pages 38 to 41)

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ROA 563

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 Halfman 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 09:48AM >>>

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: 9/8/02 10:35AM
Subject: Re: Blood, Plasma...etc

When Bfort was open, we did the Hilton Head Hospital and were considering taxing the blood, plasma, etc purchases. I believe it was Steve Helman who came up with a Federal code section that prohibited the taxing of sale of blood, etc.

To answer your question, Bfort 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 09/08/02 09:48AM >>>

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

000049

From: James Watson
To: DONOVAN, TIM
Date: 9/8/02 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 09/08/02 09:48AM >>>

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



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.

<http://www.drugs.com/gamunex.html>

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Phone: 803 898-5619
Fax: 803 898-5686

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 ☒ 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 129
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 Reply

• 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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000053

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.

000054

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 statute, 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

000055

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 Department's 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.

000056

PO Box 125
Columbia, SC 29214
Phone: 803 898-6619
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:	

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Comments

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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



Sec. 274a. 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 121(b) of title 21.

To: Jan Crangle
From: Sandra Long
Fax: 803 898-5685

As promised.

Fin. nclia

From: JOHN SWEARINGEN
 To: CRANGLE, JAN
 Date: 3/8/03 10:13AM
 Subject: Fwd: Audit Supervisor Meeting

M

>>> 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. Tip's	Denise	Robby — <i>Sgt Aug 1985</i>
(4) Mtg 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

If you can't see this page or it doesn't seem to work properly, you need a new Flash Player from Macrom

Education Memo **Page Size** **Page Count**

General composition of blood.

S On top of the formed elements is the blood plasma. This straw-colored fluid makes up approximately 55% of the total blood volume.

C

R 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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L

End

Plasma Proteins

Types	% (by wt)	Functions
Albumins	80-85	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	18	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.

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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.

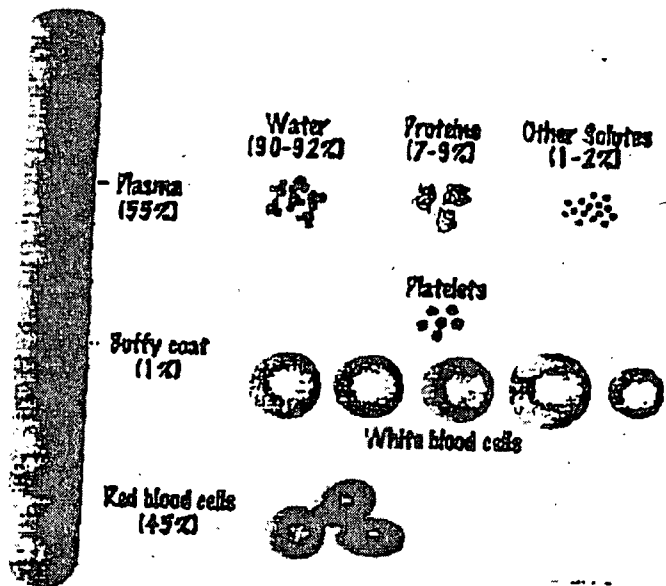
The bottom, red-colored layer is filled with red blood cells. Red blood cells normally occupy about 45% of the total blood volume (females = 37-48% & males = 45-52%).

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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000062

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Navigation Menu Page 9/26

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

Selected Non-protein Plasma Solutes

Nutrient	mg/dl	Nutrient	mg/dl
Glucose (dextrose)	70-110	HPAs	30-80
Amino acids	33-9	LPLs	52-189
Lipids (total)	450-850	Triglycerides	40-15
Cholesterol (total)	120-220	Phospholipids	8-12
Fatty acids	190-420	Nutrient	mg/dl
		Iron	50-150
Electrolytes		Electrolytes	
	meq/L		meq/L
Sodium (Na ⁺)	135-145	Chloride (Cl ⁻)	100-110
Potassium (K ⁺)	3.5-5.0	Bicarbonate (HCO ₃ ⁻)	23.1-27
Magnesium (Mg ²⁺)	1.2-2.1	Phosphate (HPO ₄ ²⁻)	104-21
		Sulfate (SO ₄ ²⁻)	0.8-1.2
Nitrogenous wastes		Nitrogenous wastes	
	mg/dl		mg/dl
Ammonia	0.02-0.08	Creatinine	0.8-1.0
Urea	8-25	Uric acid	1.5-8
Creatinine	0.1-0.8	Strubbin	0-1.0
Respiratory gases (O ₂ , CO ₂ , N ₂)		Close winds	

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10 : 634-000 (Received August 1959)

Tetanus Immune Globulin (Human)

BayTet™

**Solvent/Detergent Treated
250 Units.**

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[illegible][illegible]

The substances of interest in the United States have been demonstrated chemically from 1958 reported cases to 1967, and a second lot of 48 reported cases in 1967.⁴ The cases from 1968 listed undesignated lots of tablets found and investigated, including lots of tablets manufactured at foreign plants or foreign sources.

[illegible][illegible]

above are further evidence that parallel to a) the USSR's growing economic and technical priority under Secretary of Defense McNamara and that they did not use economic or technical aid as a lever to force other countries to accept the Soviet position on international issues of the Middle East, Cuba, and the Caribbean. The USSR's policy in the Middle East, Cuba, and the Caribbean was to use its economic and technical aid as a lever to force other countries to accept the Soviet position on international issues of the Middle East, Cuba, and the Caribbean. The USSR's policy in the Middle East, Cuba, and the Caribbean was to use its economic and technical aid as a lever to force other countries to accept the Soviet position on international issues of the Middle East, Cuba, and the Caribbean.

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of patients with a history of stroke, the study found that the use of a computerized decision support system (DSS) significantly improved the accuracy of the diagnosis. The DSS was designed to help physicians identify the most likely cause of a patient's symptoms based on a set of predefined rules. The results of the study showed that the DSS was able to correctly identify the cause of the patient's symptoms in 85% of cases, compared to 70% for the control group. This suggests that the DSS can be a valuable tool for improving the accuracy of medical diagnosis.

It is also indicated, although evidence of effectiveness is limited, that the use of the above-mentioned treatment is effective in the treatment of the above-mentioned condition.

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For more information, please contact the nearest U.S. Customs and Border Protection office. For more information, please contact the nearest U.S. Customs and Border Protection office.

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REMARKS: ~~THIS INFORMATION IS UNCLASSIFIED EXCEPT WHERE SHOWN OTHERWISE BY THE FOLLOWING~~

ALL INFORMATION CONTAINED HEREIN IS UNCLASSIFIED EXCEPT WHERE SHOWN OTHERWISE

12. The above information is correct and a history of prior systematic change recording following the withdrawal of the person is not shown.

It is not only the projected hostile situation but the need for adequate transportation equipment, say the critics.

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[P-P](#) [Pm-Pz](#) [Q-Q](#) [S-Sn](#) [So-Sz](#) [T-To](#) [Tt-Tz](#) [U-V](#) [W-Z](#) [Q-Z](#)

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

<http://www.nlm.nih.gov/medlineplus/druginfo/immunoglobulinintravenoushuman202641.htm> 8/7/2001

000066

- 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.

<http://www.nlm.nih.gov/medlineplus/druginfo/immuneoglobulinintravenoushuman202641.htm> 000087

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 consensus 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

8175801
000088

STATE OF SOUTH CAROLINA

ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a Roper	)	Civil Action No. 12-ALJ-17-0405-CC
St. Francis Healthcare,	)	
	)	
Petitioner,	)	
	)	<u>PETITIONER'S MEMORANDUM IN</u>
vs.	)	<u>OPPOSITION TO RESPONDENT'S</u>
	)	<u>MOTION FOR SUMMARY</u>
South Carolina Department of Revenue,	)	<u>JUDGMENT</u>
	)	
Respondent.	)	

Petitioner CareAlliance Health Services d/b/a Roper St. Francis Healthcare ("Petitioner") files this memorandum in opposition to Respondent South Carolina Department of Revenue's Motion for Summary Judgment (the "Motion").

I. Petitioner's Purchases of Prosthetic Devices Qualify as Exempt from Sales Tax as Prosthetics Sold by Prescription Pursuant to S.C. Code Ann. §12-36-2120(28).

In its summary judgment motion, Respondent South Carolina Department of Revenue ("SCDOR," the "Department" or "Respondent") asserts numerous arguments in support of its position that Petitioner's purchases of prosthetic devices do not qualify as exempt from sales tax as prosthetics sold by prescription pursuant to S.C. Code Ann. §12-36-2120(28). Petitioner incorporates herein by reference the arguments contained in its Motion for Summary Judgment that it meets all three requirements to qualify for the exemption and responds to the specific arguments raised in Respondent's Motion below.¹

¹ Petitioner would note that Respondent states the following in its Motion for Summary Judgment: "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 the 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." Motion at p. 2.

A. The Sale of the Prosthetic Devices at Issue from the Manufacturer to the Hospital is a Final Retail Sale, the Hospital is the Deemed Consumer and the Exemption Applies to this Final Retail Sale.

In its Motion, Respondent refers several times to the sales transaction between the hospital and the patient. Respondent states that this is the transaction for which the prescription was written as a physician cannot prescribe a prosthetic device for a hospital. Respondent appears to draw the erroneous conclusion that the Court should consider a subsequent transaction after the sale from the manufacturer to the hospital.

S.C. Code Section § 12-36-110 defines the term "retail sale" to include a sale of a prosthetic device to a hospital if furnished as part of the services rendered and states that these companies are "deemed to be the users or consumers of the property." In an advisory opinion regarding whether certain devices were exempt from sales tax, SCDOR explained as follows:

Because the items in question are furnished by hospitals as part of the services rendered by the hospitals, the hospitals are the users or consumers of the items. Therefore, based on Section 12-36-110(i) and Regulation #117-166, the sales in question are retail sales.

Having established that sales of ' . . . prosthetic devices . . . to hospitals' are retail sales, we must next look to the law to determine whether sales of any of the aforementioned items come within an exemption.

S.C. Rev. Ruling #98-9. Because a retail sale is a final sale, there is no subsequent sale from the hospital to the patient under South Carolina sales tax law and thus no subsequent sale for this Court to consider.

note 1. This action is a contested case hearing under S.C. Code Ann. §12-60-460 and involves Petitioner's claim for sales and use tax refund of certain taxes paid as supported by the invoices submitted by Petitioner and denied by Respondent. To the extent Respondent is attempting to reserve a right to re-litigate the issues in this case based on theories not presented to this Court, Petitioner will invoke the doctrines of res judicata and collateral estoppel at the appropriate time.

B. Sales to Hospitals May Qualify for Exemptions under the Sales Tax Exemption Statute.

Petitioner acknowledges and agrees with the premise stated by SCDOR in its Motion that the sales at issue are sales to hospitals for use in performing services and thus are retail sales and not wholesale sales. However, to the extent that SCDOR argues or implies that all sales to hospitals must be taxable, this is not the case as sales to hospitals clearly can be exempt. S.C. Rev. Ruling #98-9 (stating that once it is established that a sale to a hospital is a retail sale, then one must determine whether the items in question come within an exemption). In fact, SCDOR has already approved exemptions to Petitioner for the sale of diagnostic radioactive isotopes purchased by the hospital as medicines sold by prescription. Ex. A, Deposition of John P. McCormack ("McCormack Dep.") at 90:25 - 92:4. Thus, if Petitioner establishes that the sales of the prescription prosthetic devices at issue are sold by prescription pursuant to S.C. Code Ann. §12-36-2120(28), then the sales to the hospital will not be taxable.

C. The Devices at Issue Require a Prescription

Respondent appears to make a number of arguments in support of its position that the devices at issue do not require a prescription, including the following: (1) that hospitals and medical practitioners can legally purchase and possess the devices at issue "as they see fit to perform their medical services"; (2) that the oral order of a physician attaches to the patient's purchase of services and not the Petitioner's purchase of the device for use; and (3) that not all lawful orders of a physician constitute a prescription. Petitioner will address each of these arguments below.

1. Hospitals Cannot Legally Purchase the Devices at Issue Without a Prescription.

SCDOR argues that "... 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." Motion at p. 5. Respondent does not cite any law in support of this assertion. Petitioner assumes SCDOR may be referring to S.C. Code §40-43-60(H)² and the relevant regulations promulgated by the Food and Drug Administration ("FDA"); however, these laws provide only that a *medical practitioner* is not required to obtain a permit and may lawfully possess prescription devices used in their practice (see S.C. Code §40-43-60(H)) and that a prescription device may be purchased by or on the order of a physician (see 21 C.F.R. § 801.109); neither law provides that a *hospital* may purchase prescription devices without a prescription.³ To the contrary, the relevant federal regulations provide that prescription devices must be sold by or on the order of a physician (see 21 C.F.R. § 801.109), and the South Carolina Pharmacy Code even adopts this federal law on at least two occasions: (1) the definition of a device in S.C. Code Ann. § 40-43-30: "Federal law restricts this device for sale by or on the order of a physician" and (2) the restriction on the sale of devices set forth in S.C. Code Ann. § 40-43-86 (EE), which states: "Caution: Federal law restricts devices for sale by or on the order of a physician."

² The provision reads in full as follows: "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." S.C. Code Ann. §40-43-60(H).

³ As SCDOR correctly points out when it quotes Petitioner's expert, this distinction between hospitals and doctors makes sense—"if you're a - if you are handing a device to a doctor has asked you to sell the doctor a 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." Ex. B, Deposition of Mary Pendergast ("Pendergast Dep.") at 55:15- 56:1.

Respondent cites no law in support of its assertion that *hospitals* may purchase prescription medical devices without a prescription, and Petitioner submits that hospitals may not do so under the relevant state and federal law discussed herein. See *infra* §I(C)(3)); Motion for Summary Judgment at pp.7-12.

SCDOR then points to testimony by physician witnesses regarding the purchase or possession of certain prescription *drugs* by the *physicians* without a prescription as evidence that the *hospital* can purchase prescription *devices* without a prescription. This argument is flawed for several reasons. First, as previously discussed, the law allows physicians to possess and make purchases of prescription devices without a prescription as a prescription is implicit in their order of the device. Additionally, the law regarding the purchase of prescription drugs is entirely different from the law related to prescription devices, and as such how Roper physicians handle or purchase such drugs is irrelevant to the facts of this case. For example, a pharmacist is obviously licensed to purchase and inventory prescription drugs without a prescription. But a pharmacist is restricted from dispensing prescription drugs except upon a doctor's order or prescription. S.C. Code Ann. §40-43-30(46). There is no such counterpart under federal or state law as to prescription devices. Additionally, pharmacies do not actually purchase the prosthetic devices at issue in this matter, as such implantable prosthetic devices are ordered by hospitals directly from the manufacturer. See *Ex. C*, McCrosson Dep. at 9:25-11:16. SCDOR cites no law, and Petitioner is aware of none, that would allow a hospital to purchase prescription prosthetic devices without a doctor's order.

SCDOR then points to the testimony of one of the device manufacturers, Melanie Hutcherson with Zimmer, as supporting the proposition that hospitals are not required to provide written documentation of a physician's order and that patient-specific information is not sent, and, thus, there can be no prescription. Motion at p. 15-16. As Petitioner's FDA

regulation expert, Mary Pendergast, explained, manufacturers are not required to obtain a written order of a physician. Ex. B, Pendergast Dep. at 49:7-14. To comply with the relevant FDA regulations, the manufacturer is only required to sell devices on the order, which may be oral, from a physician. Id. The order may be memorialized in the hospital's records after the surgery by a variety of methods. Ex. B, Pendergast Dep. at 49:7-14. In addition, the manufacturers are not required to possess a copy of this memorialized order; they would simply need to obtain or otherwise provide evidence of the hospital's records if a regulatory body requested documentation. Id. at 51:17- 52:3; 54:14-20. The physician witnesses have stated that the sale to the hospital does not occur until after they issue their oral order during surgery for the prosthetic device. Affidavit of John McCrosson, MD ("McCrosson Aff.") at ¶4; Affidavit of Brett Baker, MD ("Baker Aff.") at ¶4 (attached to Petitioner's Motion for Summary Judgment as Ex. C and Ex. D respectively). Thus, the testimony of Ms. Hutcherson fails to support SCDOR's position.

Finally, SCDOR argues that if prescriptions were actually used in these transactions, there would have to be records of these prescriptions. In fact, there are such records. Both physicians testified that they issue oral orders to the manufacturer, which are memorialized in writing in numerous documents in the hospital's records. See McCrosson Aff. at ¶4-5; Baker Aff. at ¶4-5.⁴ As discussed in Petitioner's Motion for Summary Judgment, these orders fully comply with the law. See Petitioner's Motion for Summary Judgment at pp. 7-12.

⁴ While one physician witness agreed that he did not issue a written "prescription drug order" as defined in the Pharmacy Code, he also testified that that is only one method for issuing a prescription. Ex. C, McCrosson Dep. at 40:19-23.

2. The Exemption Statute Does Not Require the Purchaser of the Prosthetic Devices (the Hospital) to be the Patient into Whom the Device is Implanted.

SCDOR appears to be arguing that in order to qualify for the exemption, the prescription would have to be written for the hospital or that the purchaser must be the patient into whom the device is implanted. Motion at pp. 5-8 and 16-17. This reading is nonsensical, and the statute contains no such requirement. To read the statute in this way, the Court would need to add additional language thereto: that the device must be sold by prescription "to the patient into whom the device is implanted." Instead, the statute requires that the device be "sold by prescription." S.C. Code Ann. 12-36-2120(28). This Court should not re-write the statute to add a requirement that the Legislature did not see fit to add. State v. Leopard, 349 S.C. 467, 471, 563 S.E.2d 342, 344 (Ct. App. 2002) (holding that when the language of the statute is clear, "a court cannot rewrite the statute and inject matters into it which are not in the legislature's language. . . ."); Rosmer v. Pfizer, 263 F.3d 263 (4th Cir. 2001) (holding that when a statute is plain on its face, the court's inquiry is at an end).

3. The Lawful Orders for the Devices at Issue Constitute Prescriptions.

SCDOR asserts that 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 related to the hospital's transactions with the manufacturer." Motion at p. 8. SCDOR misunderstands Petitioner's position. As previously discussed and as set forth in its Motion for Summary Judgment, the physicians issue oral orders for the prescription devices at the time of surgery, the physicians consider these oral orders to be prescriptions, and these oral orders constitute prescriptions under the relevant federal law. See Motion for Summary Judgment at pp. 7-12.

Respondent then argues that the lawful orders of the physicians for the devices at issue are not prescriptions primarily because the orders are oral and not on a prescription pad. SCDOR wants the statute to read "prosthetic devices sold by WRITTEN prescription." The statute contains no such language. S.C. Code Ann. §12-36-2120(28)(a).⁵ SCDOR is attempting to add a requirement that is not even contained in its own Revenue Rulings. See S.C. Rev. Ruling 11-3. As previously stated, the Court should not add language to the statute but should instead interpret it as written. See State v. Leopard, 349 S.C. 467, 471, 563 S.E.2d 342, 344 (Ct. App. 2002) (holding that when the language of the statute is clear, "a court cannot rewrite the statute and inject matters into it which are not in the legislature's language. . . ."); Rosmer v. Pfizer, 263 F.3d 263 (4th Cir. 2001) (holding that when a statute is plain on its face, the court's inquiry is at an end).

SCDOR's bases its position that a written prescription is required primarily on its reading of definitions found in the South Carolina Pharmacy Code. First, Petitioner would note that the Pharmacy Code expressly states that the "definitions contained herein are "[f]or purposes of this chapter" (see S.C. Code Ann. §40-43-30), and the South Carolina Supreme Court has held that definitions contained in the Pharmacy Code do not apply in sales tax exemption cases. Home Medical Systems, Inc. v. S.C. Dept. of Rev., 382 S.C. 556, 677 S.E.2d 582 (2009). More importantly, as set forth in Petitioner's Motion for Summary Judgment, federal law preempts state law as to whether a prescription is required in order for a

⁵ Ironically, the legislature chose to include such language in S.C. Code Ann. §12-36-2120 (28)(c), clearly demonstrating both that a prescription can be in a form other than written (otherwise no need to clarify) and that the Legislature knows how to require that a prescription be in writing. Subsection c provides an exemption for disposable medical supplies such as bags, tubing, needles, and syringes, which are dispensed by a licensed pharmacist in accordance with an individual prescription written for the use of a human being by a licensed health care provider, which are used for the intravenous administration of a prescription drug or medicine, and which come into direct contact with the prescription drug or medicine.

hospital to purchase a prescription prosthetic device. See Petitioner's Motion for Summary Judgment at pp. 9-11. Unless the State of South Carolina applies to the FDA and obtains an exemption from the federal law requirements established in 21 U.S.C. § 360 et seq., it has no authority to modify, limit or expand restrictions placed on prosthetic devices implanted into human beings. See 21 C.F.R. §808; see also Pendergast Aff. at ¶ 6(b) and (c) (attached as Ex. A to Petitioner's Motion for Summary Judgment). South Carolina has not obtained such an exemption. 21 C.F.R. §801.109; Pendergast Aff. at ¶ 6(d). Accordingly, having declined to do so, South Carolina cannot now argue that the prescription devices at issue can be ordered in a manner not in keeping with those requirements.

Federal law provides that prescriptions may be written, oral or electronic (see Ex. B, Pendergast Dep. at 49:7-14), and SCDOR physicians have testified that their oral orders are prescriptions as required by law. McCrosson Aff. at ¶4; Baker Aff. at ¶4 (attached to Petitioner's Motion for Summary Judgment as Ex. C and Ex. D respectively). Common knowledge and general usage also support the fact that physicians often "call in" or otherwise electronically notify pharmacies to prescribe medications. Patients cannot go purchase the devices at issue directly, and thus it would make no sense for physicians to write a prescription to a pharmacy for the devices at issue. See Ex. C, McCrosson Dep. at 51:8- 52:4.

Even if one assumed that federal law did not preempt state law on this issue, SCDOR's arguments regarding the Pharmacy Code definitions are unpersuasive. First, the Pharmacy Code contains no requirement that a prescription be in writing and does not state or imply that an oral order of a physician is not a prescription. In fact, it expressly allows the prescribing practitioner to ". . . authorize his agent to transmit a prescription drug order orally or electronically to the pharmacy" S.C. Code Ann. §40-43-86(F)(6). Second, the Pharmacy Code does not define "sold by prescription" or a "prescription." Instead, the closest

term defined by the Pharmacy Code, which governs permitting and regulations related to pharmacies, is a "prescription drug order, which is defined as simply "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. . . ." See S.C. Code Ann. §40-43-30(7).⁶

SCDOR also points to S.C. Code Ann. §40-43-86(E), which provides that a prescription drug order should contain certain information and argues that the fact that the oral orders are not later transcribed to a document that complies with all of these items is evidence that the physicians are failing to comply with this regulation. The Legislature cannot have intended for prescriptions for devices to meet all these criteria as many of the requirements are non-sensical or simply not applicable to devices and would only apply to prescription drugs, such as number of refills, dosage form, instructions for use, strength, etc. And as Dr. McCrosson testified, this is only one way in which a doctor may give a prescription. Ex. C, McCrosson Dep. at 40:19-23.⁷ Thus, both the law and the facts of this case establish that the Pharmacy Code definition of a "prescription drug order," which is intended to be given by a physician to a pharmacy, and the requirements as to what must be contained in the same, are wholly inapplicable to this case.

Finally, SCDOR's narrow interpretation on what comprises a "prescription" would make it impossible for any prosthetic devices to be exempted. Pharmacies cannot sell these

⁶ Furthermore, SCDOR's own Revenue Ruling #11-3 cannot be read to require this as its example of an exempt sale is "*the sale of prescription lenses that replace a missing part of the eye . . . , as for example eyeglasses prescribed for a person whose natural lenses have been surgically removed.*" Eyeglasses would not require, *inter alia*, a number of refills, dosage form or instructions for use and yet the Department agrees their sale would be exempt.

⁷ SCDOR also relies on statements from Dr. Nawabi and Dr. McCrosson (blood products and cortisone/local anesthetics respectively) that they have kept various prescription drugs in inventory. As discussed in section I(C)(1) above, requirements and practices as to prescription drugs differ from those regarding prescription devices and thus this testimony is not relevant to the prosthetic devices at issue here.

devices to patients in the way that they sell prescription medicines. As the physicians testified, patients cannot buy these devices directly. See Ex. C, McCrosson Dep. at 51:8- 52:4. No prescription could be written for a prosthetic device that would meet the requirements of S.C. Code Ann. §40-43-86(E), which is clearly directed towards prescription drugs, as many of the requirements are simply inapplicable to devices (for example, number of re-fills, strength, dosage, etc.). To impose these rules on prosthetic devices would mean that they could never be exempt, which cannot be in accordance with legislative intent and would be inconsistent with SCDOR's own Revenue Ruling 11-3.

4. Home Medical and Associated Medical are Not Applicable to this Matter.

SCDOR also points to the Home Medical case as providing support for the proposition that not all lawful orders are prescriptions. In that case, the South Carolina Supreme Court held that Certificates of Medical Necessity ("CMNs") were not equivalent to prescriptions. However, the durable medical equipment at issue in Home Medical bears no factual resemblance to the implantable orthopedic and cardiac devices at issue in this case. Petitioner's position is in agreement with the ruling in Home Medical in so far as the Court determined that the durable medical equipment could not be considered to be *prosthetic devices* and thus were not exempt from tax in South Carolina. Obviously, the laws and regulations governing wheelchairs are and would be expected to be far different than those controlling the sale of implantable prosthetic devices. Home Medical did not address the question of whether implantable prosthetic devices sold on the oral prescription of a doctor qualified as devices sold by prescription, and, thus, Home Medical is simply not applicable to the facts of this case.

SCDOR also discusses Associated Medical Association v. S.C. Tax Comm'n., Unpub. Op. No. 97-UP-447 (August 26, 1997), an unpublished decision of the Court of Appeals and

correctly states that it "lacks precedential value" (see Motion at p. 7). As such, any reliance placed on the facts or holding in this case is misplaced as well. Whether the Department then uses the ruling to inform its further policy is only relevant in so far as the facts of Associated Medical bear on a determination of the issues in this case. At best, Associated Medical can be read to state that purchases of medicine by a "professional association" are not a sale "by prescription." However, in this case, sales of prescription medicines to a professional association of physicians are not at issue; only sales of prescription prosthetic devices to a hospital upon a doctor's order. Thus, Associated Medical is likewise not applicable to the facts in this case.

5. The Respondent is Due no Deference by the Court based upon its Long-Standing Interpretation of the Exemption Statute because the Interpretation has always been Recognized as Flawed.

Respondent's Motion states that while Associated Medical lacks precedential value, it should nevertheless be considered because it has been assimilated into SCDOR policy and thus its interpretation of the statute is a long-standing administrative practice. Motion at pp. 6-7. The Department's interpretation of the exemption statute was challenged as long ago as 1989 and found unwarranted by a court of competent jurisdiction. In fact, evidence from the record in that case establishes that the Department has long known that its statement that the term "sold by prescription" precluded sales to hospitals from the exemption was "not credible," and a South Carolina court told them so.

In Boykin v. South Carolina Tax Commission, Case Number 1989-CP-O200590, Aiken County Court of Common Pleas (a copy of which is attached hereto as Ex. D), Judge Timmerman made the following Conclusions of Law:

1. A work order is "subsumed" in the definition of the term prescription. See United States v. Patterson, 155 F.Supp. 669, (N.D. Ill. 1957), aff'd, 314 F.2d 491 (7th Cir. 1963).
2. Work authorizations issued by dentists for prosthetic devices are prescriptions for purposes of S.C. Code Ann. §12-35-550 (31) [now, §12-36-2120(28)(a)] as a matter of law.
3. "[N]o credible construction of the statute restricts in any manner the persons who are intended to benefit from the exemption."

Boykin, Case Number 1989-CP-O200590, at p. 2. The Department did not appeal the ruling in this case. The statute at issue in Boykin is the same statute under which this taxpayer has brought his claim in this case, and the Department's argument is the same as presented against Dr. Boykin. The evidence in this case is even more compelling in favor of the taxpayer than in Boykin.

Additionally, the evidence considered by the Court in Boykin included a letter from a member of the Tax Commission to a South Carolina senator which informed the Senate that while the exemption statute was originally intended to exempt only prescriptions ordered by individual patients from the drug sales tax, the wording actually used in the statute was actually much broader than that and would include sales to hospitals among others. Ex. E, Letter from H. Wayne Unger of the S.C. Tax Commission to Senator Rembert C. Dennis, dated June 19, 1974 and marked as Ex. C in the Court's records. The letter also informs Senator Dennis that the revenue estimate for the fiscal impact of the exemption should be increased in order to take into consideration that hospitals, doctors, nursing homes, etc. may take advantage of the exemption statute since it is broad enough to include sales to these entities. Where the Department has been on notice by a court of competent jurisdiction since 1989 that its interpretation of the statute is "not credible" and the Department has advised the Legislature that the statute can be read to include hospitals and that hospitals may indeed take advantage of

this wording such that the estimated revenue impact should be increased, the Department cannot claim that its interpretation of the exemption statute is due deference by this Court.

D. The Devices at Issue Were Actually Sold by Prescription

In heading C of its Motion, SCDOR correctly states that Petitioner must establish that the prosthetic devices at issue were actually sold by prescription. Motion at p. 20. SCDOR further states, with no authority, that this means that the Petitioner must "send" a prescription to the manufacturer. No such requirement is contained in the statute or even the Department regulations or rulings. All that is required is that the devices actually be sold by prescription. S.C. Code Ann. §12-36-2120 (28) and S.C. Rev. Ruling #11-3.

As set forth in its Motion for Summary Judgment and as previously argued herein, federal law requires that the prescription prosthetic devices at issue be sold only upon the order or prescription of a physician. 21 CFR § 801.109; see also Pendergast Aff. at ¶ 6(e) (attached to Petitioner's Amended Motion for Summary Judgment as Ex. A). 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. 21 CFR § 801.109; see also Pendergast Aff. at ¶ 6(e); see also 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").

The physicians in this case have stated that they issue oral orders to the manufacturer's representative for the devices at issue in the operating room at the time of the procedure when the specific type and size of device needed by their patients becomes known to them; that these oral orders constitute their prescriptions as required by law; and that the orders are then

memorialized in writing. McCrosson Aff. at ¶4-5; Baker Aff. at ¶4-5 (attached to Petitioner's Motion for Summary Judgment as Ex. C and Ex. D respectively); and Summary Judgment Motion at p. 11. In addition, Petitioner also purchases the Trauma Devices upon the orders of physicians. Ferguson Aff. at ¶3(c) (attached to Petitioner's Motion for Summary Judgment as Ex. B). Thus, the manufacturer makes the sale to the hospital specifically to fulfill the doctor's order. Nothing must be "sent" to the manufacturer. Instead the doctors simply tell the manufacturer's representative.

SCDOR also again makes the argument, again with no authority, that if a prescription exists, it is for the patient and not for the Petitioner and implies that this is not adequate. As previously stated, the prescription is for the patient but it is given to authorize the manufacturer to sell to the hospital for use in the patient. The statute contains no requirement that the prescription be used by the purchaser, and the Court should interpret the law as written and not add additional requirements. See State v. Leopard, 349 S.C. 467, 471, 563 S.E.2d 342, 344 (Ct. App. 2002); Rosmer v. Pfizer, 263 F.3d 263 (4th Cir. 2001).

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 the Sale of Blood and Products Derived from Blood are Sales of Services that are Excluded from the Sales and Use Tax.

As an initial matter, Petitioner would note that the basis for its position that the sales of certain products derived from blood are not taxable is one of *coverage* and not *exemption*. Petitioner asserts that these sales are not covered by the sales tax statute because they are sales of medical services and not sales of tangible personal property; it is not arguing that the sales qualify for an exemption from the sales tax statute. As such, the tax statute is to be interpreted in favor of the taxpayer and against the Department. Clark v. S.C. Tax Comm'n, 259 S.C.

161, 191 S.E.2d 23 (1972) (holding that "[r]evenue laws are generally construed in favor of the taxpayer and against the taxing authority"); Taylor v. Aiken County Assessor, 402 S.C. 559, 741 S.E.2d 31 (Ct. App. 2013) (same).

More specifically, as is discussed more fully in Petitioner's Motion for Summary Judgment, the sales and use tax statute in South Carolina generally taxes items of tangible personal property but does not tax the sale of services unless the service is specifically enumerated. See S.C. Code §12-36-910; §12-36-60; S.C. Code Reg. 117-308; S.C. Rev. Ruling 93-4. The Revised Uniform Anatomical Gift Act ("RUAGA") defines the sale of blood and its products or derivatives as the sale of a "medical service" and not a "commodity" for commercial purposes. S.C. Code Ann. § 44-43-10; see also Samson v. Greenville Hospital System, 297 S.C. 409, 377 S. E. 2d 311 (1989)(holding 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."). The sale of blood and products derived from blood are not specifically enumerated in the sales tax code as a service to be taxed. Therefore, because the sales of blood and products derived from blood are sales of medical services and are not specifically enumerated as taxable, these sales are excluded from coverage under the sales and use tax.

B. The Department's Arguments that Blood and Products Derived from Blood are Tangible Personal Property that is Subject to Sales and Use Tax are Unpersuasive.

SCDOR makes three primary arguments in its Motion for Summary Judgment as to why the products derived from blood at issue in this matter are taxable: (1) they do not qualify for a statutory exemption (Motion at p. 24-27); (2) RUAGA's definition of the sale of blood as

a sale of medical services in sales tax matters does not apply (Motion at p. 27-28); (3) even if RUAGA applies to the sales tax code, there is a "technological dilution" of the blood proteins at issue such that they are not covered by RUAGA (Motion at p. 28).

SCDOR's first argument that the blood proteins at issue do not qualify for an exemption may be ignored; as previously discussed, Petitioner is not arguing that these items qualify for an exemption. Instead, it asserts that the sales and use tax code does not cover these sales of services in the first place (see supra II(A)).

SCDOR's second argument, i.e. that the statute defining sales of blood products as sales of medical services cannot be applied to the tax code, is without merit. SCDOR argues that a 1992 Tax Commission Decision (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)) prevents the application of RUAGA to sales tax matters. In that unreported decision, the Tax Commission stated that although it had previously applied RUAGA in sales tax matters, it now found the better approach to be that RUAGA should not apply and stated that sales of blood and blood products were sales of tangible personal property.

First, the facts in this case are distinguishable from those in 92-26. The only items at issue in 92-26 were blood collection bags and labels used in the storage of blood and products derived from blood. These products are not mentioned in RUAGA and would not be covered thereunder. Blood proteins and blood products were not at issue in that decision. Consequently, Commission Decision 92-26 is distinguishable from the facts of this case.

Additionally, contrary to its assertions in its Motion, the Department has not adopted this decision in its policies and does not actually follow this unpublished decision in practice. While SCDOR states that it "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," it is clear that they, in fact, do have a policy of not taxing these items. The auditor in this matter testified that the Department gives the auditors a chart to provide guidance on these items. Ex. F, Deposition of Christine Buddin ("Buddin Dep.") at 33:2-8; Ex. G, Chart. The chart indicates that whole blood, red blood cells, white blood cells, plasma and platelets are not taxable while albumin, globulin and fibrinogen (all blood proteins) are taxable. Ex. F, Buddin Dep. at 33:2-8; 34:12-18- 35:18; Ex. G, Chart. In fact, in this same audit, the Department allowed Roper's requested refunds for Humate (a blood plasma product), human tissue and rib cartilage. See Ex. H, Refund Claim Documents. The Department correctly cited RUAGA as the basis for these exemptions. Id. Because 92-26 is unpublished, has not been adopted by the Department, is not followed by the Department and is distinguishable from the facts of this case, this decision is not binding, and this Court should give it no weight.⁸

Finally, SCDOR's third argument, i.e. that the blood proteins at issue are technologically diluted such that they would not be covered by S.C. Code Ann. §44-43-10, also fails. This argument reveals the real reason behind the Department's denial of the refund request for the blood proteins at issue when it exempts, with no questions asked, whole blood, red blood cells, white blood cells, plasma and platelets. It views the blood proteins as being "manufactured" products. Motion at pp. 26-28. SCDOR's summary of "facts" that support

⁸ As further support for its argument that the Legislature did not intend for RUAGA to apply to the sales tax code, SCDOR points to a new exemption-- S.C. Code Ann. §12-36-2120 (80)-- which under certain circumstances might exempt the items in question as "biologics." SCDOR claims this amendment would be superfluous if RUAGA already applied. However, this argument is unpersuasive as the exemption would not cover all of the items in question and it covers many other items that would not be exempt under RUAGA. More specifically it exempts all injectable medications no matter what their origin (i.e. non-human derived) and it only exempts injectable biologics when they are administered by a physician in the physician's office (versus items in this case which are sold to the hospital).

this theory contain not one citation to the testimony of a witness, a document or any other evidence. As such, these alleged facts should be ignored by the Court.

Moreover, most of these alleged facts are directly contradicted by the testimony of Dr. Daud Nawabi, the hematologist who is a witness in this case. As he explains, there is no factual or medical basis on which to distinguish the proteins derived from blood that are at issue in this case from the red blood cells, platelets and plasma that the Department agrees are exempt from taxation. They are derived from blood; they are not manufactured but are created by the human body; they are not synthetic, artificial or pharmaceutical; they are processed in a similar way to the red blood cells and platelets that the Department exempts from taxation; and 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. Aff. of M. Daud Nawabi, MD at ¶1-10 (attached to Petitioner's Motion for Summary Judgment as Ex. E).

In sum, the blood products at issue are sales of medical services that are excluded from taxation pursuant to RUAGA, and the Department's arguments to the contrary are not supported by the law, their own policies and practices or the facts in this case.

CONCLUSION

For the reasons set forth in Petitioner's Motion for Summary Judgment and above, Petitioner respectfully requests that this Court deny SCDOR's Partial Motion for Summary Judgment and grant Petitioner's Motion for Summary Judgment.

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Attorneys for CareAlliance Health Services d/b/a Roper St.
Francis Healthcare

Charleston, South Carolina
September 6, 2013

CERTIFICATE OF SERVICE

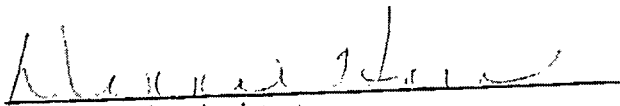
I, the undersigned Administrative Assistant of the law offices of Nelson Mullins Riley & Scarborough LLP, attorneys for CareAlliance Health Services d/b/a Roper St. Francis Healthcare, do hereby certify that I have served all counsel in this action with a copy of the pleading(s) hereinbelow specified by mailing a copy of the same by United States Mail, postage prepaid, to the following address(es):

Pleadings:

**PETITIONER'S MEMORANDUM IN OPPOSITION TO
RESPONDENT'S MOTION FOR SUMMARY JUDGMENT**

Counsel Served:

Adam N. Marinelli
Lauren Acquaviva
Counsel for Litigation
Office of General Counsel for Litigation
South Carolina Department of Revenue
301 Gervais Street (29201)
PO Box 12265
Columbia, SC 29211


Administrative Assistant

September 6, 2013

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

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

Petitioner,

vs. DOCKET NO. 12-ALI-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
Fast, Accurate & Friendly
Charleston, SC Hilton Head, SC Myrtle Beach, SC
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Columbia, SC Greenville, SC Charleston, NC
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JOHN McCORMACK,
being first duly sworn, testified as follows:

EXAMINATION

BY MR. CARPENTER:

Q. Mr. McCormack, I'm Ray Carpenter from the Law Firm of Raymond P. Carpenter & Associates out of Atlanta. This is Bryson Geer with the Law Firm of Nelson Mullins and that's Mr. Britt Dobbins with the Colonial Consulting Group. We're here to take your deposition today in the claim or the case of CareAlliance doing business as Roper/St. Francis Healthcare Systems.

This is a sales and use tax refund claim and we've asked you to come to answer some questions with regard to the conduct of your audit and with regard to issues about the sales and use tax. This deposition will be used for discovery, may be used at trial and for any and other all legal purposes for which a deposition can be used under the Rules of Civil Procedure here in South Carolina.

If you have any questions at any time, don't hesitate to ask. And if I ask a question that's not clear, don't hesitate to make me make it clear. If at any time we've gone longer than we need to go, you need a break or anything of that

APPEARANCES OF COUNSEL:

ATTORNEYS FOR THE PETITIONER
CAREALLIANCE HEALTH SERVICES
D/B/A ROPER/ST. FRANCIS MEDICAL
HEALTHCARE, INC.:

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SOUTH CAROLINA DEPARTMENT OF REVENUE:

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ALSO PRESENT:

Britt C. Dobbins

(INDEX AT REAR OF TRANSCRIPT)

sort, by all means let us know.

A. (Nodding head.)

Q. I'm going to be asking you a series of questions, like I said, with regard to the conduct of the audit, things of that sort, and just trying to develop the factual basis for the action by the department in this case.

Can you state your full name for the record, please?

A. John Patrick McCormack.

Q. Okay. Mr. McCormack, by whom are you employed?

A. The South Carolina Department of Revenue.

Q. And how long have you been so employed?

A. A little over 33 years.

Q. Okay. What is your current position?

A. I'm the senior administrator for policy within the office of general counsel, tax and regulatory services.

Q. Okay.

A. I had to think about it. We just reorganized last week, so I had to think of the new name.

MS. GEER: That's pretty good.

1 spacing and other items. And then (28)(2) medicine
2 and prosthetic devices sold by prescription,
3 prescription medicines used to prevent respiratory
4 syncytial virus, prescription medicines and
5 therapeutic radiopharmaceuticals used in the
6 treatment of rheumatoid arthritis, cancer, lymphoma,
7 leukemia, or related diseases, including
8 prescription medicines used to relieve the effects
9 of such treatment, free samples of prescription
10 medicine distributed by its manufacturer and any use
11 of these free samples.

12 Q. Okay. Those are exemptions from the
13 sale and use tax; correct?

14 A. This are two of the exemptions, yes.

15 Q. Yes. Okay.

16 (PLF. EXH. 8, SC Private Letter Ruling
17 #05-1, was marked for identification.)

18 BY MR. CARPENTER:

19 Q. Mr. McCormack, I show you what's been
20 marked for identification as Plaintiff's Exhibit 8.
21 Are you familiar with that revenue ruling?

22 A. Familiar with it. It's been a while
23 since I've read it; but, yeah, I'm familiar with it.

24 Q. Were you in the department at the time
25 that that was produced?

1 A. Yes.

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

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

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

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

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

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

21 Q. Okay. Thank you.

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

24 BY MR. CARPENTER:

25 Q. I show you what's been marked for

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

4 A. Yes.

5 Q. Okay. Can you tell me what the subject
6 of that ruling is?

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

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

11 A. States that the sale of radioactive
12 isotopes by nuclear pharmacies to hospitals are
13 exempt from the sale and uses tax per Code Section
14 12-36-2120(28)(a).

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

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

19 Q. Yes.

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

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

24 A. No. I think this is --

25 Q. Okay.

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

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

9 Are you familiar with the Food and Drug
10 Administration?

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

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

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

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

24 A. No.

25 Q. Okay. So you have no information on the

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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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EXHIBIT B

ROA 608

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46 1 doctor ordering the prescription use or administration 2 of these items or is he ordering the prescription sale 3 of these items? 4 A Doctors -- 5 Q Are you there? 6 A I'm -- I'm thinking because it's sort of -- 7 it's a confusing question. Let me put it that way. 8 Q Okay. 9 A A doctor orders a medical device for use for 10 a patient. 11 Q Of course. I agree. There is no 12 question -- and let me clarify, because I think this 13 is where the whole case is going to come down to. And 14 there's no question these are prescription devices. 15 The Department of Revenue would stipulate today that 16 these cannot be administered without the oversight of 17 a physician and his prescription for the 18 administration. 19 But the distinction between our two 20 positions is that there is a separate transaction that 21 takes place when the hospital as an institution is 22 buying these items from the manufacturer and that the	48 1 solely with Scott Ferguson and never hears from a 2 doctor, would that change your mind? 3 A Not if Scott Ferguson is acting at the 4 direction of the physician. I mean, picture a doctor 5 in a hospital. And he says to the nurse, give this 6 patient morphine. And the nurse goes and gets the 7 morphine and gives it to the patient. That's a 8 prescription order even though only the nurse goes to 9 get the morphine and gives it to the patient. 10 Q Would you look at Exhibit 1 again for me? 11 A Sure. 12 Q And read the fifth definition for me. 13 A Okay. Do you want me to read it? 14 Q No. No. No. Just read it to yourself. 15 Do you consider a chart order a 16 prescription? 17 A Well, this reads as though it is. It says 18 it's a "lawful order from a practitioner" -- so a 19 practitioner is usually meaning somebody who is 20 licensed to practice medicine in the state -- for a 21 "device for patients of a hospital," and then it says 22 "or such an order prepared by another person and
47 1 transaction between the patient and the hospital is a 2 separate transaction. 3 And this is probably falling in line with 4 the idiosyncratic nature of tax law, but in your mind 5 as an regulatory expert for the Federal Food and Drug 6 Administration, are these devices limited for the 7 legal sale by prescription or are they limited for 8 administration by prescription? 9 A They have to be sold by prescription. I 10 mean, picture a beauty parlor that calls and wants to 11 have a medical device for laser resurfacing of the 12 face as part of their cosmetics in the beauty parlor. 13 That type of medical device could not be sold by a 14 medical device company to that beauty parlor because 15 there is a prescription involved. The prescription 16 has to -- there has to be the prescription throughout 17 the process. 18 Q So -- 19 A And if a medical device company sells a 20 prescription device without having prescription, then 21 it's misbranding the device and that's illegal. 22 Q Now, if I told you that a manufacturer deals	49 1 signed by the practitioner," and it goes on to explain 2 "for a legitimate medical purpose." 3 So this is -- this is similar to federal 4 law, although federal law doesn't require a signature. 5 You know, it could be purely electronic or purely oral 6 or written. 7 Q So in your mind as a federal regulator, any 8 kind of correspondence from a doctor, whether it be 9 out of his mouth or in writing, in any format 10 whatsoever, that's what you consider a prescription? 11 A Yes. It has to be memorialized somehow. 12 And a hospital has to keep a record of it -- of the 13 medical devices used in the hospital by prescription, 14 but it can be oral, written, or electronic. 15 Q Would you look at Exhibit 2 for me? 16 A Okay. 17 Q And Exhibits 3 and 9 and 10? 18 A Okay. Just let me line these up here. 19 please. 20 Q Sure. 21 A Okay. I have them all lined up. 22 Q Okay. Before we get to these individual

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50 1 documents, does the FDA itself regulate prescriptions 2 or do state boards of pharmacy or departments of 3 health do that? 4 A The -- that's a difficult question to 5 answer. Generally speaking, the FDA does not 6 interfere with what the FDA calls the practice of 7 medicine. So generally speaking, the FDA does not say 8 to a doctor or a licensed healthcare practitioner, no, 9 you may not prescribe that drug to that patient. 10 That's a really bad idea. 11 Generally speaking, the FDA stays out of 12 that. 13 Q No. I meant in regards to the actual format 14 of what a prescription is. Do they regulate what is 15 required in that memorialization? 16 A Oh, I see what you're saying. The federal 17 government regulates the form only in one instance 18 that I'm aware of, and that's the Drug Enforcement 19 Agency has certain requirements for what a 20 prescription has to look like and be like for 21 schedule II and III controlled substances, things like 22 fentanyl, morphine, or that sort of thing.	52 1 what you're doing and you're not selling it to beauty 2 parlors. Walk me through your tracking system to make 3 sure that this has had an order of a physician. 4 Q If I represented to you that South Carolina 5 law distinguishes between an order of a physician and 6 an actual prescription, would you have any reason to 7 disbelieve me? 8 A No, I don't have any reason to believe or 9 disbelieve you. The federal law doesn't make that 10 distinction. 11 Q If there is a distinction between a 12 prescription and a chart order or basically the order 13 of a physician, would that change your expert opinion 14 in this matter? 15 A Change my expert opinion about what? 16 Q That these sales to hospitals require 17 prescriptions. 18 A No. I -- federal law demands that Zimmer 19 have a prescription before it sells it, and so you 20 have to ask the question then how is Zimmer getting 21 the prescription, where and when and from whom. 22 Q Exactly.
51 1 But the FDA, no, it's just basically the 2 order of the physician and the memorialization of that 3 order can take a variety of means. 4 Q Okay. I guess I'm confused about what you 5 said earlier, but so long as a doctor is involved in 6 the process, a hospital or a group of doctors in their 7 private practice can basically order anything they 8 want at will and you consider that to be by 9 prescription: is that right? 10 A Well, "anything they want at will," that's a 11 little broad. 12 Q Let me clarify it for you. They could keep 13 a stock of inventory, you know, a room full of 14 hundreds of these medical devices if they wanted to. 15 Would you consider that to be purchased by 16 prescription? 17 A Yes. The way the FDA looks at it is there 18 has to be -- because every -- when the FDA goes and 19 inspects a device manufacture -- let's use Zimmer. 20 Zimmer can only sell prescription devices by or on the 21 order of a physician. So the FDA will say -- they go 22 to Zimmer and they say, okay, let's make sure that's	53 1 A And to use the -- 2 Q Look at Exhibit 3 for me. 3 A Okay. 4 Q If I told you that that is the only document 5 that Zimmer or any of these manufacturers received 6 from the hospital, would you say that they're selling 7 these things illegally? 8 A I just have to take a minute and look at it. 9 Q Sure. And identify it for the record for 10 me. 11 A It's McKesson and it's PO number 805129, PO 12 date December 4, 2012. 13 Q Does that look like a purchase order to you? 14 A It's describing -- purchase order? Maybe PO 15 is purchase order. It looks like Zimmer is selling or 16 shipping -- that's the vender -- is shipping to Roper 17 Hospital. It's hard to read. Bill only Dr. McKesson. 18 so it's basically shipping to Dr. McKesson through the 19 hospital. And it's some kind of metal -- I think it 20 says tibia. 21 Q So this purchase order for a knee 22 replacement is the only document that Zimmer

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54 1 received -- if I represented that to you -- obviously, 2 I mean, there's no way for you to know that. But if 3 that is the only document they received, do you think 4 that satisfies the federal requirement that these 5 things are sold by prescription? 6 A Well, it does name a -- it does name a 7 physician on here. And I'm sure -- I mean, Zimmer 8 would have to prove up to the FDA that it was sold by 9 prescription, so they would have to trace it from the 10 time it left its plant to the knee and making sure 11 that all along the way it was done appropriately and 12 that it was given to a patient properly on a doctor's 13 order. 14 Q How would Zimmer prove that with one 15 document? 16 A Well, it would have to go -- then it would 17 have to go -- if the FDA was really saying to Zimmer, 18 prove it up, they would have to go to the hospital, 19 they'd have to get the hospital records and, you know, 20 so on and so forth. 21 Q But in your mind, that purchase order 22 qualifies as a prescription?	56 1 is prescribing, is wanting. 2 Q Do prescriptions require patient data? 3 A Do they require patient data? Only -- 4 Q Let's take the heart valve, for example. In 5 your mind, if they order hundreds of heart valves to 6 keep in inventory, do you still consider that a 7 prescription even though they are not meant for any 8 particular patient yet? 9 A Yes, because at the end of the day there's 10 got to be a prescription and it's got to be kept in a 11 little box or file at the hospital. 12 Q And so if South Carolina law dictates that a 13 prescription have very specific patient information, 14 would that change your mind? 15 A Well, it's hard to describe. I mean, from a 16 federal perspective, it doesn't quite matter what 17 South Carolina says about a prescription. 18 Q Well, I think a South Carolina judge would 19 not like to hear that. 20 A Well, I know, but -- I'm sorry, but like the 21 FDA, you've got regulations about what pharmacies can 22 compound and you've probably been reading all of this
55 1 A Yes. Using the industry standards, it's got 2 a physician's name on it, and a hospital. 3 Q So in your mind, selling it to a doctor is 4 the same thing as a sale by prescription? 5 A Well, a doctor -- well, I mean, yes, if you 6 think it about, because it's the doctor who is making 7 the decision. A prescription is a memorialization of 8 a decision made by a doctor. 9 Q Okay. Go back to Exhibit 7 for me, please. 10 A Okay. Just a second. Okay. 11 Q If selling it to a physician is the same 12 thing as a sale by prescription, why would there be 13 the distinction then in subsection (a)(2) for it to be 14 sold only to or on the order of? 15 A Well, I mean, it's very practical. If 16 you're a -- if you are handing a device to a doctor 17 because the doctor has asked you to sell the doctor 18 the device, that is an implicit -- the sale is an 19 implicit order saying, give me this. And so you only 20 need a prescription or other order if it isn't being 21 sold directly to the doctor because then you have to 22 memorialize that that's what the doctor is asking for.	57 1 information about the pharmacies that were compounding 2 and have had to take all of these drugs off the 3 market. 4 Well, the State of South Carolina's 5 compounding law is more lenient or permits more 6 compounding than the FDA would feel comfortable with. 7 So that's all I mean is that there doesn't have to be 8 identity between state and federal law. In other 9 words, something could meet federal law and not meet 10 your technical requirements. 11 Q But you testified earlier, though, that the 12 FDA did not regulate what a prescription should look 13 like; is that right? 14 A As long as -- right. It's an order of a 15 physician that ultimately has to be memorialized so 16 that it's traceable so that you can determine whether 17 or not somebody is violating the labeling and 18 misbranding laws. 19 Q And could you point me to the law or federal 20 regulation that says that? 21 A Yes, I can. If you look at section 21 USC 22 331, and you look at (a), (b), (c) and (k), they're

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

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

* * * * *

VIDEOTAPED	JOHN MCCROSSON, M.D.
DEPOSITION OF:	
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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EXHIBIT C

Electronically signed by Denise Lauder (301-268-293-2597)

b2d71412-c841-4d90-be9e-1ca5a647

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1 (DFT. EXH. 11, Copy of definition, was
2 marked for identification.)
3 (DFT. EXH. 12, Copy of definition, was
4 marked for identification.)
5 (DFT. EXH. 13, Copy of definition, was
6 marked for identification.)
7 (DFT. EXH. 14, Copy of definition, was
8 marked for identification.)
9 THE VIDEOGRAPHER: The date today is
10 June 13, 2013, the time is 4:02. This is the video
11 deposition of Dr. John McCrosson in the matter of
12 CareAlliance Health Services d/b/a Roper St.
13 Francis Healthcare vs. South Carolina Department of
14 Revenue, the State of South Carolina Administrative
15 Court, Civil Action Number 12 ALJ 17 0405 CC.
16 This deposition is being held at Roper
17 Hospital located at 125 Dougherty Street in
18 Charleston, South Carolina.
19 Will Counsel please identify themselves
20 for the record?
21 MR. CARPENTER: I'm Raymond P.
22 Carpenter representing CareAlliance doing business
23 as Roper St. Francis Hospital.
24 MS. GEER: Bryson Geer also
25 representing CareAlliance doing business as Roper

Page 7

1 Hospital.
2 MR. MARINELLI: Adam Marinelli
3 representing the South Carolina Department of
4 Revenue.
5 MS. ACQUAVIVA: And Lauren Acquaviva
6 also representing the Department of Revenue.
7 THE VIDEOGRAPHER: Please swear in the
8 witness.
9 JOHN MCCROSSON, M.D.,
10 being first duly sworn, testified as follows:
11 DIRECT EXAMINATION
12 BY MR. CARPENTER:
13 Q. Would you state your full name for the
14 record?
15 A. John Joseph McCrosson.
16 Q. Okay. Dr. McCrosson, by whom are you
17 employed?
18 A. Roper St. Francis Physician Partners.
19 Q. And are you a physician?
20 A. Yes.
21 Q. Okay. And what is your area of
22 specialization?
23 A. Orthopedic surgery, hip and knee
24 replacements.
25 Q. Can you describe what you do in that

Page 8

1 area of specialization?
2 A. I replace hip and knees, that's
3 90 percent of my practice.
4 Q. Okay. Are you board certified in this
5 area or any area?
6 A. Board certified in orthopedic surgery.
7 There's no special certification beyond that for
8 hip and knee replacement.
9 Q. Okay. Tell us about your educational
10 background.
11 A. I went to college at Emory University
12 in Atlanta, then medical school and residency at
13 the Medical University of South Carolina here in
14 Charleston, and a one-year fellowship in adult
15 reconstructive surgery in New York City, Insall
16 Scott Kelly Institute.
17 Q. How long have you been employed by
18 Roper St. Francis?
19 A. Since 2007, so five and a half or six
20 years.
21 Q. Approximately, how many of the hip -
22 heat - knee and hip surgeries do you perform
23 during a week, month, year?
24 A. I usually perform about 12 per week, 40
25 to 50, sometimes more, in a month, and over 500 a

Page 9

1 year for the last few years. And I've been in
2 practice since 2000, I've just been employed since
3 2007. Before that I was in private practice.
4 Q. I see. Doctor, I'm going to ask you a
5 series of questions with regard to the nature of
6 your practice, how you order prosthetic devices,
7 things of that sort, what happens in your office
8 during that process. Let's begin by talking about
9 when a patient presents themselves for knee or hip
10 replacement. Can you describe the procedure that
11 you follow in your office to determine the course
12 of treatment for that patient?
13 A. Yes. I examine the patient, along with
14 my physician assistant, and we do a history,
15 physical, review X-rays, sometimes MRIs, CAT scans,
16 other types of radiologic studies, sometimes other
17 lab tests. Oftentimes we are seeing patients that
18 have previously seen orthopedic surgeons or other
19 doctors that refer the patient to us. We review
20 that prior medical record and any correspondence
21 from those doctors.
22 And then once we determine that the
23 patient probably is a good candidate for joint
24 replacement surgery, we talk to the patient about
25 that, or any other treatment options that may be

3 (Pages 6 to 9)

Page 10	Page 12
1 appropriate for that patient. Then at that point I 2 walk out of the exam room, tell my medical 3 assistant -- there are two actually that are out 4 there -- that the patient is a candidate for 5 whatever procedure it is, and fill out a 6 preoperative planning sheet. 7 For 90 percent of the patients, that's 8 all the same type of thing. We're saying it's a 9 right knee, left knee, hip, et cetera, revision, et 10 cetera. And 90 percent of the time it's the 11 standard types of implants that I want to have 12 available for the operation that I always use on a 13 customary basis, and to the out-of-the-ordinary 14 situation, I mark that on the sheet, including if 15 the surgery may take longer than usual, for 16 scheduling purposes, and give that sheet to my 17 medical assistant. 18 She then goes into the room, gives the 19 patient a book that is published here in the 20 hospital about hip or knee replacement, tells them 21 to go to the joint replacement class. I have a 22 video in my office where I'm giving more frequently 23 answered -- frequently asked questions answers, et 24 cetera, for more information for the patient. 25 Pam then -- after giving them the book,	1 hospital, tells them which implants that we want to 2 have available and it goes from there. 3 Q. With regard to the implants, do you 4 discuss the type of implant with the patient? In 5 other words, do you and the patient come to some 6 kind of joint decision on that or how do you make 7 that decision? 8 A. Yes. Some patients want to know more 9 details than others, but in every exam room we have 10 models of the implants that we use. Most patients 11 have already looked at those models. Usually while 12 we're talking to them about the surgery, we're 13 showing them the model. Some patients are 14 interested in the specifics of if it's metal, 15 plastic, ceramic, who made it, and at that point we 16 talk about what would be the best option for them. 17 And of course I have my go-to favorite 18 implants that I'm most accustomed to using that I 19 get good results with. That's generally what I 20 use. I usually explain to the patient, if that's 21 appropriate for them, that that's why I will be 22 using it, because it works well for me. And I hope 23 that answers your question. 24 Q. Yeah, but at the end of the day, who 25 makes that decision, is it you or the patient?
Page 11	Page 13
1 telling them about the class, how to watch the 2 videos online or on DVD, then instructs the patient 3 on what they need to do prior to surgery. She 4 tells them to avoid certain injections that may 5 affect their immune system prior to surgery, what 6 medicines to stop, and tells them that they'll get 7 another call from a preop nurse from the hospital 8 two weeks prior to surgery about doing routine 9 preoperative labs and, again, going over 10 medications and maybe stopping more medications. 11 She tells the patients that they need 12 to have a preoperative clearance from their primary 13 care doctor so that we're not missing anything 14 medical; being specialized in hip and knee 15 replacement, we want to make sure we get a letter 16 from their primary doctor and sometimes a 17 cardiologist or other specialist, depending on the 18 situation. 19 And, finally, she tells the patient to 20 take some antibiotics prior to surgery, apply some 21 in their nose and to do an antibiotic bath several 22 days prior to surgery. She then does a posting 23 slip for the operating room where she takes what I 24 did on my piece of paper, puts it into a computer 25 format so she can electronically send it to the	1 A. I make the decision for the implant. 2 Q. Okay. When you make a decision to 3 treat a patient with a specific device, how do you 4 then identify that device and order that device? 5 A. I start with that preop posting slip. 6 If it's the standard stuff, I just put, right total 7 knee, and I have the standard things. There's 8 always -- the supplier, the Zimmer representative 9 that I work with, is in the operating room every 10 time I operate. And that information is 11 communicated, by the way, to him. 12 He knows the types of procedures for -- 13 on any given date so that he'll have -- he'll bring 14 the implant assortment that we'll need to make it 15 through the day. Because if we do eight surgeries 16 in a day, he needs to have multiple in case several 17 patients all require the same size, et cetera. 18 Q. Let's go back to -- to right after 19 we've met with the patient and you've made a 20 determination that the patient is a candidate for 21 hip or knee replacement. Now you're going to order 22 the device. Do you -- how do you communicate that 23 and with whom do you communicate at that time? 24 A. I communicate that with Pam usually or 25 Jennine, one of my two medical assistants.

4 (Pages 10 to 13)

Page 38	Page 40
1 or what does it tell you?	1 MR. CARPENTER: Thank you. And --
2 A. Well, on the day of surgery, after I	2 just go crazy.
3 called out the sizes that I want to use, the -- not	3 (Petitioner's Exhibit 5, Box, was
4 only did the nurse put that in the computer, but	4 marked for identification.)
5 the Zimmer rep put it into his iPad so that he	5 BY MR. CARPENTER:
6 could charge the hospital. And surgery in this	6 Q. Dr. McCrosson, I show you what has been
7 case was December 17, 2007, and the Zimmer rep sent	7 marked for identification Petitioner's 5, and ask
8 a bill to Roper Hospital two days later -- one day	8 you if you are familiar with that item.
9 later, on December 18th, 2007, for the devices that	9 A. Yes.
10 we had used the day before.	10 Q. Okay. Can you tell us what it is?
11 Q. Okay. So the document shows that the	11 A. It's a box that holds one implantable
12 surgery occurred prior to the date of the invoice?	12 device of a -- part of a knee replacement.
13 A. That's correct.	13 Q. Okay. And on what occasion do you see
14 Q. And are you listed as the doctor on	14 that -- that item?
15 this invoice who performed the surgery?	15 A. Every Monday and Tuesday. Except
16 A. Yes.	16 Christmas and holidays.
17 Q. Okay. Let's go to 4.	17 Q. And what's occurring when you see that
18 (Petitioner's Exhibit 4, Copy of	18 item?
19 letter, was marked for identification.)	19 A. Yeah. This is -- right after I call
20 BY MR. CARPENTER:	20 out the sizes, the Zimmer rep picks this up off the
21 Q. Dr. McCrosson, I show you what has been	21 cart where he has potential likely sizes and pulls
22 marked for identification as Petitioner's	22 off the wrapper which are hermetically sealed, he
23 Exhibit 4. And I'll tell you that it's a FDA	23 begins to open it, and then the inside part is
24 premarket approval letter to a manufacturer. Once	24 finished opening by the nurses and the nurse hands
25 again I call your attention to the description of	25 it to the sterile field.

Page 39	Page 41
1 the item in this letter and ask you if you're	1 Q. And you would use that in the treatment
2 familiar with that item.	2 of the patient that's in the operating room?
3 A. Yes. It says the Zimmer NexGen LPS	3 A. That's right. The circulating nurse
4 knee.	4 gives it to the scrub nurse, or tech, that's
5 Q. Is it related to the same item in the	5 another hospital staff member that is assisting me
6 previous exhibit?	6 in surgery, sterile. That's why they're called
7 A. Yes.	7 scrubbed. And then that nurse sometimes may apply
8 Q. All right.	8 some cement to it or get it ready for me and then
9 A. That's a similar model, same	9 hands it to me and I put it in the patient.
10 manufacturer.	10 So from the time it's out of the box
11 Q. And just for purposes of the record,	11 and in the patient is just, you know, less than a
12 would you read in the second paragraph just the	12 minute oftentimes.
13 first and second lines of that -- of that document?	13 Q. I call your attention to the writing on
14 A. The sale, distribution, and use of this	14 the box. Can you tell us if there's any
15 device are restricted to prescription use, in	15 descriptive information on the box that -- that is
16 accordance with 21 CFR 801.19, within the meaning	16 related to Plaintiff's 5 and 6?
17 of section 520(e) of the Federal Food, Drug, and	17 A. Yes. There's an RX only on the box.
18 Cosmetic Act.	18 Q. And what does that tell you?
19 Q. What does that tell you as far as your	19 A. It's a prescription only device.
20 practice is concerned?	20 MS. GEER: Did you say Exhibits 5 and
21 MR. MARINELLI: Objection; calls for a	21 6?
22 legal conclusion.	22 MR. CARPENTER: I did say 5 and 6. 4
23 THE WITNESS: It tells me that this	23 and -- yeah, that was 5. This is 5? I'm sorry,
24 device can be only sold or distributed by	24 Exhibits 3 and --
25 prescription.	25 THE WITNESS: Somehow I knew what you

11 (Pages 38 to 41)

Page 50	Page 52
1 record? 2 A. This is The American Heritage College 3 Dictionary. 4 Q. And can you read the highlighted 5 definition? 6 A. Prescription, a written order, 7 especially by a physician, for the preparation and 8 administration of a medicine or other treatment. 9 Q. And can you fit what you do in the 10 operating room into that definition, other than it 11 being written? 12 A. Not so much. I mean, it's the same 13 situation as the last couple of ones. 14 Q. Are you not ordering the administration 15 of a treatment in the operating room? 16 A. Yeah. Oh, yeah, I'm sorry. I got 17 caught up on medicine on that one too. Yeah. 18 Yeah, I'm ordering a treatment. 19 Q. Okay. And I will hand you what's been 20 marked as Defendant's Exhibit 5. 21 A. This is the Concise Oxford American 22 Dictionary, and following along with our pattern, 23 prescription, an instruction written by a medical 24 practitioner that authorizes a patient to be 25 provided a medicine or treatment.	1 Q. Can you read the highlighted 2 definition? 3 A. Order, to give a prescription for. 4 Q. And the next page, the next highlighted 5 definition? 6 A. Prescription, a written direction for 7 the preparation, compounding, and administration of 8 a medicine. 9 Q. And can you fit what you do in the 10 operating room into that definition? 11 A. Maybe so, but just using the word, 12 medicine, there -- and preparation, compounding, 13 administering a medicine, on its face is not 14 talking about replacing a body part like I'm doing 15 in the operating room, but it kind of is in there. 16 Q. Okay. And this is Defendant's Exhibit 17 8. Can you identify that dictionary for the 18 record? First identify the first page for the 19 record. 20 A. Oh, The American Heritage Dictionary. 21 Q. And can you read that definition for 22 the record? 23 A. Prescription, a written instruction by 24 a physician for the preparation and administration 25 of a medicine.
Page 51	Page 53
1 Q. And could you fit what you do in the 2 operating room into that definition? 3 A. Yes. 4 Q. Okay. Now to the medical dictionaries. 5 I'm handing you Defendant's Exhibit 6. Can you 6 identify what dictionary that is from? 7 A. Stedman's Medical Dictionary for the 8 Health Profession and Nursing. 9 Q. Is that something that you've used 10 before? 11 A. I probably did 20 years ago. 12 Q. And can you read the highlighted 13 definition? 14 A. A written formula for the preparation 15 and administration of any remedy. 16 Q. And, again, could you fit what you do 17 in the operating room into that definition? 18 A. Yes. 19 Q. Okay. Defendant's Exhibit 7. Can you 20 identify where that comes from? 21 A. Oh, this is Merriam-Webster's Medical 22 Desk Dictionary. 23 Q. Do you or have you used that dictionary 24 before? 25 A. I don't think so. I may have.	1 Q. And, again, could you fit into that 2 definition? 3 A. Same type of thing, using the word, 4 medicine. Maybe it -- maybe it -- I don't 5 understand why you would try to make it fit, 6 though. 7 Q. Well, it was your testimony that a 8 prescription is defined as a doctor's order, 9 correct? 10 A. Yes. 11 Q. Okay. So this is the last one, 12 Defendant's Exhibit 9. 13 A. But this doesn't mean what I said is 14 not true. There are a lot of different definitions 15 for things. I don't understand why -- 16 Q. And we're going through those 17 definitions. So can you identify where that comes 18 from for the record? 19 A. Why aren't we reading them all then? 20 Why are we just reading the highlighted ones? 21 Q. Dr. McCrosson, I'm asking the 22 questions. Can you please answer them for me? 23 A. Prescription, an order for medicine, 24 therapy, or therapeutic device given by a properly 25 authorized person, which ultimately goes to a

14 (Pages 50 to 53)

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ROA 616

STATE OF SOUTH CAROLINA)

COUNTY OF AIKEN)

DR. WILLIAM J. BOYKIN,
PLAINTIFF.

-vs-

THE SOUTH CAROLINA TAX COMMISSION,
DEFENDANT

IN THE COURT OF COMMON PLEAS

Case No. 89-CP-82-590

ORDER

This is an action maintained by the Plaintiff pursuant to S.C. Code Ann. Section 12-47-440 (1976 and Cum. Supp. 1988) to require the South Carolina Tax Commission to refund use taxes paid by the Plaintiff for the years 1985 through 1988. Now before the Court are cross motions for summary judgment. The Court has before it all pleadings in this case, including a stipulation of mutually agreed facts. A hearing on the parties' respective motions was heard on November 15, 1989.

Findings of Fact

Based upon the stipulation of the parties, I find that there is no dispute regarding the existence of the following material facts. Plaintiff is a citizen and resident of the City of Aiken, South Carolina, and is a dentist duly licensed to practice in South Carolina. During the years 1985 through 1988, he purchased from out of state various items which constitute prosthetic devices within the meaning of S.C. Code Ann. Section 12-35-550(31), and upon which he paid South Carolina use taxes on August 25 and October 13, 1988, in the amounts of \$429.77 and \$3,868.93, respectively. The prosthetic devices were sold to Plaintiff pursuant to written work authorizations issued by Plaintiff and were used by Plaintiff in providing dental services to his patients.

Plaintiff timely filed for a refund of the above-mentioned use taxes, which claim was denied; Plaintiff then appealed the denial of his refund claim to the Commission. The Commission upheld the denial, resulting in the Plaintiff's filing of the present lawsuit.

Conclusions of Law

Based upon the foregoing facts, the Court concludes that this case presents only issues of law for decision. The Court further concludes that there being no dispute as to any material fact, the Plaintiff is entitled to judgment as a matter of law. The legal grounds for the Court's conclusion are as follows:

In his complaint before this Court, Plaintiff cited as grounds for refund that such items were exempt from sales and use taxes pursuant to S.C. Code Ann. Section 12-35-550(31), which states in relevant part that "[t]here are exempted from the provisions of this article, and from the computation of the amount of the tax levied, assessed, or payable under this article, the following: ... (31) Gross proceeds from the sale of medicine and prosthetic devices sold by prescription. ..." Although the above exemption relates only to the sales tax, S.C. Code Ann. Section 12-35-820(2) provides an

11-2-89 - 17

James L. ...
P. 301/2001

11-2-89

MBT/h

EXHIBIT D

exemption from use tax to all tangible property exempted from the sales tax. Therefore, the exemption of Section 12-35-550(31) applies to both the sales tax and the use tax.

Plaintiff maintains that the exemption is applicable on its face, since the parties have stipulated all relevant facts and, furthermore, since a "work authorization" is subsumed in the definition of prescription. See United States v. Patterson, 155 F.Supp. 669, 673 (N.D.M. 1957), aff'd, 314 F.2d 491 (7th Cir. 1963). Defendant maintains that the "work Authorization" issued is not a "prescription" as required by the exemption statute. To so hold would emasculate the statute and deny its purpose, since Defendant can point to only a single prosthetic device (i.e., eyeglasses for cataract patients) which would be subject to the exemption under its interpretation. This would deny the plain language of the statute and the intent of the Legislature to exempt an entire class of items constituting prosthetic devices. See Etiwan Fertilizer Co. v. South Carolina Tax Comm'n, 217 S.C. 354 80 S.E.2d 682 (1950). (If the terms are clear and unambiguous, they must be taken in their plain, ordinary sense, unless it fairly appears from context that the Legislature intended to use such terms in a technical or peculiar sense.) The Court therefore holds that work authorizations issued by dentists for prosthetic devices are prescriptions for purposes of Section 12-35-550(31) as a matter of law.

Defendant's second argument involves the proposition that to be exempt a prosthetic device must be sold by prescription directly to a patient. The Court can find no basis in the statute to support this view. The language of the tax exemption statute must be given its plain, ordinary meaning and must be strictly construed against the exemption being claimed. John D. Hollingsworth on Wheels, Inc. v. Greenville County Treasurer, S.C. 314, 278 S.E.2d 340 (1981). The Court finds, however, that no credible construction of the statute restricts in any manner the persons who are intended to benefit from the exemption.

Based upon the foregoing, it is hereby

A. ORDERED that Plaintiff's motion for summary judgment be, and the same hereby is, GRANTED.

B. It is ORDERED further that judgment be, and the same hereby is, GRANTED, in favor of Plaintiff for refunds in the amounts of \$429.77 and \$3,868.93, together with pre-judgment and post-judgment interest at the maximum legal rates and court costs as allowed by law.

C. It is ORDERED further that the Clerk is to enter judgment pursuant hereto on the Judgment Roll forthwith.

D. It is ORDERED further that Defendant's Motion for Summary Judgment be, and the same hereby, is DENIED.

Done and Ordered in chambers this 23 day of Nov, 1989, at Lexington, South Carolina.

George Bell Timmerman, Jr.
Presiding Judge
Second Judicial District

2 #2 - 2 pages

MBT/

COMMON PLEAS COURT

CASE NO. 89-CP-02-590

NO. J. R. 78,070

Dr. William J. Boykin

VS

The S. C. Tax Commission

PLAINTIFF(S)

DEFENDANT (S)

- ☐ Jury verdict This action came before the court for a trial by jury. The issues have been tried and the jury has rendered its verdict.
- ☒ Decision by court. This action came to trial or hearing before the court. The issues have been tried or heard and a decision has been rendered.
- ☐ Action Dismissed ☐ Rule 40 (c) (3), SCRPC ☐ Rule 12 (b), SCRPC
☐ Settled ☐ Vol. nonsuit ☐ Other, Explain _____

IT IS ORDERED AND ADJUDGED: ☒ See attached order
☐ Statement of Judgment by Court

Dated at Aiken, South Carolina, this 27th day of Nov, 1988

Clerk of Court

Deputy Clerk

This judgment/order was ~~entered~~/filed on the 27th day of Nov, 1989, and a copy mailed first class this 27th day of Nov, 1989 to attorneys of record or to parties (when appearing pro se) as follows:

Robert Young, Esquire

P. O. Box 12525

Columbia, S. C. 29211-2525

Attorney (s) for Plaintiff (s)

Ray N. Stevens, Deputy Attorney Gen.

Joe L. Allen, Chief Deputy Attorney Gen.

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Columbia, S. C. 29214-0125

Attorney (s) for Defendant (s)

State of South Carolina
South Carolina Tax Commission

ROBERT C. WASSON
CHAIRMAN



WYATT E. GURMAN
M. WAYNE ONGER, JR.
ROBERT C. WASSON
COMMISSIONERS

June 19, 1974

Senator Rembert C. Dennis
State House
Columbia, S. C.

Re: Part II, Section 5, 1974-75 Appropriation Bill
Exemption Proceeds from Sale of Drugs from the Sales Tax

Dear Senator Dennis:

By letter
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 tax. It appears, however, that in preparing the wording of same the [redacted] is much broader in scope and would include all drugs sold to hospitals, doctors, nursing homes, etc.

The initial estimate given to the House when the amendment was proposed from the floor was a \$2,000,000 loss in revenue. This was based upon the assumption that the exemption would be restricted to individual taxpayers. It appears, however, that because of the broad terms of the Section that there would be a loss of revenue of approximately \$6,000,000. The Section is drawn up to provide for an effective date of February 1, 1975. By doing this, it, of course, would result in a substantial lessening of the loss in revenue of the first fiscal year of its enactment. We estimate that if the Bill goes through as written, there would be a loss in revenue of \$2,000,000.

EXHIBIT C

EXHIBIT E

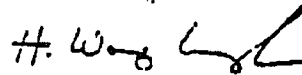
Senator Rembert C. Dennis

June 19, 1974

the first fiscal year and \$6,000,000 for every year thereafter..
If the amendment as prepared and attached hereto is substituted,
we estimate that there would be a loss in revenue for the first fiscal
year of \$666,667 and \$2,000,000 for all subsequent fiscal years.

Thanking you, I am

Sincerely,



H. Wayne Unger, Jr.

HWUJR/cs

Enclosure

**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

**RESPONDENT'S REPLY TO
PETITIONER'S MOTION
FOR SUMMARY JUDGMENT**

TO: RAYMOND CARPENTER, ESQ., JOHN VON LEHE, ESQ., AND BRYSON
M. GEER, ESQ., ATTORNEYS FOR THE PETITIONER.

Pursuant to Rule 56(e), SCRCP, and ALC Rule 19(A), the undersigned, as attorneys for the Respondent, South Carolina Department of Revenue (Department), respond to Petitioner's Amended Motion for Summary Judgment as follows, and contend that the Department remains 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. However, approximately \$3.1 million of the refund claims were based on the incorrect 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," and 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 these 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, and that 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 both parties filed motions for summary judgment.

Legal Analysis

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

¹The 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 of 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.

²The 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.

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 Analysis of the Prescription Requirements for Surgical Implants is Without Merit.

The Petitioner's entire motion for summary judgment is based upon two fundamentally flawed assertions. First, it attempts to conflate the transaction between doctor and patient with the actual taxable transaction at issue, which is between the

hospital and manufacturer. The former is a sale of a medical service, and the latter a sale of tangible personal property between corporate entities. Second, the Petitioner erroneously believes that any involvement of a medical doctor, either directly or indirectly, in the chain of custody of the devices at issue constitutes a prescription. Surprisingly, this claim is directly refuted by Petitioner's own repeated use of the phrase "prescription or other order" that is found in 21 C.F.R. § 801.109, which clearly distinguishes a prescription as a legal term specifically set apart. Both of these assertions – the conflation of the two transactions and the blurring of the term "prescription" – are unsupported by the law, jurisprudence, and long standing administrative practice of the Department, as will be shown below.

A. This is Not "A Case of Novel Impression."

Petitioner attempts to distinguish Home Medical Systems, Inc. v. South Carolina Dep't of Revenue, 382 S.C. 556, 677 S.E.2d 582 (2009), as inapplicable to the case at bar. This flawed logic is based upon two aspects of that case – that the devices at issue in Home Medical were not surgical implants, but rather various positive airway pressure breathing devices; that it involved a Certificate of Medical Necessity which is not at issue here. (Petr.'s Amended Mem. Supp. Summ. J. 8.) First, the court's discussion of the definition of a prosthetic, which replaces a missing body part as opposed to a function, is directly applicable to the Class B devices at issue here. Second, the Petitioner glosses over the portion of Home Medical involving over-the-counter enteral nutritional formulas prescribed by doctors. As discussed at length in the Department's Motion for Summary Judgment at page 6, the Home Medical ruling affirmed the long standing policy of the Department when it held that those nutritional formulas were not exempt as medicines

sold by prescription, since "[i]n order for this exemption to be applicable . . . the sale must require a prescription and the [medicine or] device must actually be sold by prescription" Id. at 564 (citing S.C. Rev. Rul. #03-02 (2003) (emphasis added)). The South Carolina Supreme Court agreed with the Department's position that simply because a doctor or hospital chooses to write a prescription for something, (ostensibly, this is often done for insurance purposes), that act does not automatically create an exempt transaction. Furthermore, Home Medical directly contradicts the Petitioner's claims that the involvement of doctors in any way creates a transaction that is sold by prescription.

This is evidenced by the fact that the court found that Certificates of Medical Necessity³ (CMNs) are not equivalent to a prescription despite the fact that a CMN contains patient specific information and a detailed lawful order from a doctor for a specific type of treatment. Id. at 566. That holding unequivocally demonstrates that not all lawful orders of a physician constitute a prescription, contrary to the claims of the Petitioner. As such, the case at bar is anything but a novel case of first impression. The prescription exemption has been administered by the Department since its inception with the same requirements expressly affirmed in Home Medical. The Petitioner's contention that the ruling in Home Medical does not apply to the issues in this case stretches the bounds of jurisprudential interpretation to absurdity.

³A CMN is a standard form used by Medicaid and Medicare that contains patient specific information. See Exhibit A to Respondent's Mot. For Sum. J.; see also Home Med., 382 S.C. at 566, 677 S.E.2d at 588.

B. The Sales Transactions at Issue Do Not Meet the Four Requirements to be Exempt from Sales and Use Tax.

1. The Devices at Issue are Classified as "Prescription Devices" Only with Regards to Administration to Patients, Not the Purchase by Medical Practitioners.

The Petitioner misunderstands and mischaracterizes the Department's position concerning the classification of the devices at issue as "prescription devices." The Department agrees that the devices at issue fall under the province of 21 CFR § 801.109 in that they are exempt from the labeling requirements of 21 U.S.C. § 352(f).⁴ Pursuant to 21 CFR § 801.109, a device does not need adequate directions for use if it is being sold only to a physician; however, the devices do require a prescription to be sold directly to a patient. To that extent, the devices at issue in this case would be considered "prescription devices," but, as discussed at length in the Department's Motion for Summary Judgment on pp. 12-20, a physician does not need a prescription to purchase or possess said devices by virtue of his/her medical license. To that extent, the federal classification for these devices does not create an absolutist requirement that a prescription is used in every transaction, and the Petitioner's reliance on 21 CFR 801.109 is misplaced.

2. The Sales Transactions at Issue Do Not Require a Prescription.

The Petitioner asserts that 21 CFR § 801.109 mandates that "a sale to a hospital . . . 'requires' the order of a physician to avoid harm to the public" Petr.'s Amended Mem. Supp. Summ. J. 10. This assertion is flawed. Unequivocally, 21 CFR § 801.109 does not state that a sale to a hospital requires the order of a physician. In fact, 21 CFR § 801.109 only discusses is an exemption from the labeling requirements of 21 U.S.C. §

⁴21 U.S.C. § 352(f) requires that the labels for prescription drugs and devices bear adequate directions for use.

352(f). As discussed at length in the Department's Motion for Summary Judgment, the sale of prosthetic devices to a hospital does not require a prescription. See Respondent's Mot. for Summ. J. 12-20. By virtue of its facility license, a hospital can purchase prosthetic devices without a prescription.

Not only is the Petitioner's reliance on 21 CFR § 801.109 misplaced with regard to determining whether a prescription is required in a sales transaction between a hospital and a manufacturer, but the Petitioner's reliance on 21 U.S.C. § 360j(e)(1) to assert that "[t]he 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" is also misguided. Petr.'s Amended Mem. Supp. Summ. J. 10. The Petitioner asserts that "[t]he State of South Carolina has no authority to modify, limit or expand restrictions placed on prosthetic devices . . . without specific authority from the FDA." Petr.'s Amended Mem. Supp. Summ. J. 10. This assertion is incorrect. State requirements are pre-empted under the Medical Device Amendments (MDA) of the Federal Food, Drug, and Cosmetic Act (FDCA) only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. Riegel v. Medtronic, Inc., 552 U.S. 312, 330, 128 S. Ct. 999, 1011, (2008). 21 U.S.C. § 360k(a) provides:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(emphasis added). No aspect of the regulations promulgated by South Carolina's medical and pharmacy boards as they relate to the practice of medicine, affect the labeling and misbranding requirements of the FDA. Furthermore, even the FDA itself openly defers to the states in regards to the regulation of prescriptions. The FDA's own website states, "[e]ach state has laws and regulations that dictate who can write a prescription for a medical device in that state. FDA defers to the states on determining who can write a valid prescription." See Exhibit A (emphasis added). Moreover, the lack of preemption of any State regulation concerning the practice of medicine is expressly noted in the relevant FDA regulation, which states:

(3) Section [360k] does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense, or sell devices.

21 C.F.R. § 808.1 (emphasis added). Therefore, states are only prohibited from passing legislation that relates to the safety or effectiveness of the device and that is different or in addition to federal law. States are not prohibited from regulating pharmacy practice or the practice of medicine, nor are states prohibited from using their own definitions when interpreting their own tax exemption statutes. In that regard, the Petitioner's attempt to make 21 CFR § 801.109 the only relevant regulation in this case is inappropriate.

3. The Devices at Issue Were Not Actually Sold by Prescription.

The Petitioner asserts that a prescription is used when the doctor simply calls out what device he or she 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 shown at length on pp. 8-9 of the Department's Motion for Summary Judgment, and (2) the transaction at issue is not between the operating doctor and sales representative, but between the Petitioner and the manufacturer.

Even 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 the Petitioner. The doctor-patient transaction, however, is not the transaction at issue in this case. As previously explained, a prescription can only be written for a patient once a doctor-patient relationship has been established, and a doctor-patient relationship simply cannot ever be formed with a hospital. To that extent, the Petitioner's 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. As a result, a prescription is not actually being used by the Petitioner when it purchases the devices from the manufacturer.

4. The Class B Prosthetic Devices Do Not Replace a Missing Part of the Body.

As discussed in footnote 3 of the Department's Motion for Summary Judgment, this issue will be rendered moot should the court rule in favor of the Department on the prescription issue; however, this issue is one of fact and is not ripe for Summary Judgment. Despite the Petitioner's cursory interpretation of the testimony of its witness, Dr. Baker, the determination as to whether or not these electrical cardiac devices replace a missing part or perform a missing function has not yet been shown. Dr. Baker's testimony was primarily based on speculation and estimates, with physical removal of nervous tissue only being surgically performed in 5-10% of his practice. Exhibit B.

Baker Dep. 15:2-17:11. Furthermore, his questionable belief that the definition of prosthetic, which "replaces a missing body part," can be evaluated on a cellular level is a question of fact for this Court. Id. at 21:9-22:6. Additionally, Dr. Baker testified that he believed a part could be construed as missing despite the fact that nervous tissue in the heart actually becomes fibrotic and is simply no longer functioning. Id. at 17:18-18:16. These questions of fact present significant challenges that must be explored at trial should these cross-motions be denied.

II. The Sale of Manufactured Plasma Derivatives are Not Exempt from Sales and Use Tax.

With respect to brevity for the sake of this return, the plasma derived medicines issue is discussed at length on pp. 25-28 of the Department's Motion for Summary Judgment; however, it should be reiterated that there is no express exemption for blood and blood products for the tax years at issue. Furthermore, the Petitioner's reliance upon Title 44 and the Revised Uniform Anatomical Gift Act ("RUAGA") is unfounded. While the RUAGA clearly defines the "transplanting, injection, transfusion, or other transfer of these substances into the human body" as medical services, the sale of manufactured plasma derived medicines between corporate entities does not fall into that category of enumerated services. And as noted previously, the RUAGA does not contemplate taxation and is not controlling in that regard. Title 12, which defines tangible personal property subject to the sales and use tax, applies to the transactions at issue.

The Petitioner also relies upon Samson v. Greenville Hospital System, 297 S.C. 409, 377 S.E.2d 311 (1989), a case involving whole blood and products liability claims, as a basis to claim that the hospital's purchases of these manufactured protein-based

medicines should be considered services. This assertion is unfounded. First, the underlying premise of the RUAGA is the encouragement of a readily available supply of blood and human tissue. Samson was decided on that premise as well. The fallacy of applying that logic to the pharmaceutical products at issue here (which carry unnatural brand names like Gammunex, Octagam, and Albuminar) is that these products are subjected to a complex sterilization process during their manufacturing and would be free of any viral or bacterial threats that would give rise to the possible torts blocked by the RUAGA. Furthermore, the purchaser in the taxable transaction at issue is a corporate hospital, not a patient. As the Petitioner itself stated on page 16 of its Motion, "[t]he 'true object' of the purchaser is to obtain the treatment of a licensed physician and not the tangible blood, blood product or blood derivative." That is precisely the reason that patients in the hospitals are not charged sales tax on their bills for receiving injections of Gammunex or Octagam, as they are receiving medical services. The Petitioner's purchases, however, are not considered services. As previously explained, S.C. Code Ann. § 12-36-110 (2000) clearly defines the terms "sale at retail" and "retail sale" to include:

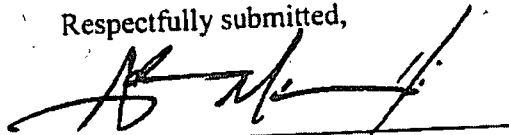
(i) sales of drugs, prosthetic devices, and other supplies to hospitals, infirmaries, sanitariums, nursing homes, and similar institutions, medical doctors, dentists, optometrists, and veterinarians, if furnished to their patients as a part of the service rendered. These institutions, companies, and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

These protein based medicines clearly fall under the scope of the sales and use tax code sections, as the purchase by the hospital is made in anticipation of providing services. Such purchases, however, are not themselves considered a service.

Finally, the Petitioner attempts to undermine the authority provided in Tax Commission Decision #92-26, referring to it as an "unreported, unadopted, and otherwise unacknowledged opinion." See Petr's Amended Mot. For Summ. J. at 16. This assertion is erroneous and should be disregarded by this Court. First, no Tax Commission decisions are published in a reporter and the Petitioner's attempt to brand this particular decision as unreported is disingenuous at best. Second, S.C. Code Ann. § 1-30-95 (2005) clearly states that the Tax Commission and all its duties, property, and rights are expressly incorporated into and administered as part of the Department of Revenue. All decisions issued by the former S.C. Tax Commission have been adopted by the Department as part of its long standing practice, until policy or law alters those decisions. Finally, this opinion has clearly been acknowledged by the Department as it is cited at length in its Motion for Summary Judgment at page 25 and was provided to the Petitioner multiple times during the audit stages as explanatory justification for the denial of the tax exemption. Tax Commission Decision #92-26 recognized that Title 44 was not controlling with regard to tax matters and pursuant to Title 12 blood and blood products fit within the definition of tangible personal property. Finally, construction of a statute by those charged with execution thereof is entitled to the most respectful consideration by the court, and should not be overruled without cogent reasons. See Faile v. South Carolina Employment Sec. Comm'n, 267 S.C. 536, 230 S.E.2d 219 (1976). Therefore, the Petitioner's argument for no deference is invalid. To that extent, with the absence of any express exemption, these items should be subject to sales and use tax.

THEREFORE, by the undersigned counsel as attorneys for the Respondent, the Department respectfully requests that this Court grant its Motion for Partial Summary Judgment for the lack of a genuine issue of material fact under Rule 56(c), SCRPC.

Respectfully submitted,



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Columbia, South Carolina
September 6, 2013

PROOF OF SERVICE

I, Jean M. O'Connor, do hereby certify that I have caused to be mailed postage pre-paid, a copy of the Respondent's Reply to Petitioner's Motion for Summary Judgment in re: Roper/St. Frances Medical Healthcare, Inc., v. South Carolina Department of Revenue, Docket No. 12-ALJ-17-0405-CC to the Raymond Carpenter, Esquire, 625 Colonial Park Drive, Suite 201, Roswell, GA 30075, John C von Lehe, Jr., Esquire and Bryson M. Geer, Esquire, 151 Meeting Street, Sixth Floor, Charleston, SC 29401 this 6th day of September 2013.

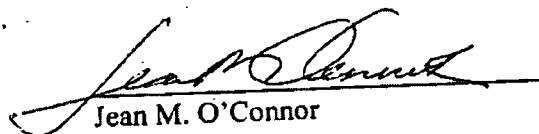

Jean M. O'Connor

EXHIBIT A

[Home](#) [About FDA](#) [Transparency](#) [FDA Basics](#)

About FDA

Who can write a prescription for a medical device?

Each state has laws and regulations that dictate who can write a prescription for a medical device in that state. FDA defers to the states on determining who can write a valid prescription.

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If you would like to ask a specific question, please visit our "[Contact Us](#)²¹" page for more information about how to contact FDA.

Please note that any information you submit may become public or subject to release under the Freedom of Information Act (FOIA). For more information, read about our privacy policies²² and the FOIA²³.

Page Last Updated: 12/30/2009

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19. </AboutFDA/Transparency/Basics/ucm194430.htm>
20. </AboutFDA/Transparency/Basics/ucm194424.htm>
21. </AboutFDA/ContactFDA/default.htm>
22. </AboutFDA/AboutThisWebsite/WebsitePolicies/default.htm>
23. </RegulatoryInformation/FOI/default.htm>

EXHIBIT B

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

CareAlliance Health	)	CIVIL ACTION NO:
Services d/b/a Roper St.	)	12-ALJ-17-0405-CC
Francis Healthcare,	)	
	)	
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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ROA 640

A P P E A R A N C E S

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ROA 641

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ROA 642

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 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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ROA 643

1 A. Uh-huh.

2 Q. You do. So how often have you either
3 seen done or done yourself the removal of a sinus
4 node?

5 A. Of a sinus node? I would say probably
6 maybe ten times.

7 Q. Ten times?

8 A. AV node probably 400.

9 Q. Okay. And that would be since you
10 finished school or since your residency?

11 A. Right.

12 Q. Okay. And how many surgeries have you
13 done since you completed your education?

14 A. So -- and we're talking specifically
15 ICDs and pacemakers? Because I do other things; I
16 do these ablation procedures.

17 Q. Total how many surgeries have you done?
18 We'll start there.

19 A. Okay. So I would say -- and we
20 typically group these as procedures as opposed to
21 surgeries because the ablations are invasive but
22 they're not -- they're not considered a surgery per
23 se. But I would say probably around 3,000, maybe
24 three to 4,000 probably.

25 Q. And how many pacemaker and ICD

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ROA 644

1 surgeries or procedures have you done?

2 A. I do about -- probably about 200 a
3 year.

4 Q. Okay. And is that just since you've
5 had your practice, about 200 a year?

6 A. Well, since I came here. So '99.

7 Q. Okay.

8 A. Right. And I probably did close to 200
9 during the course of my fellowship.

10 Q. Okay. And the pacemaker and ICD
11 procedures, are they done in a hospital or are they
12 done in your office?

13 A. In a hospital.

14 Q. Do you do any procedures in your
15 office?

16 A. We do not, no. We see patients in
17 follow-up.

18 Q. Okay. Can you give me a percentage of
19 how often a sinus node is removed in relation to a
20 pacemaker or ICD implant?

21 A. The sinus node?

22 Q. Uh-huh.

23 A. Okay. I would say, you know, 1 percent
24 or less.

25 Q. Okay. And what about --

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ROA 645

1 A. And so you're saying removing it,
2 either surgically or cauterizing it or something to
3 destroy it?

4 Q. Yes, I guess. Taking it out or getting
5 rid of it in some way, shape or form.

6 A. That would be the answer.

7 Q. Is the AV node the other one?

8 A. Yes.

9 Q. What about that one?

10 A. I would say that is probably between, I
11 don't know, perhaps 5 to 10 percent of my practice.

12 Q. Okay. Do you consider pacemakers and
13 ICDs to be artificial devices?

14 A. I mean, I guess I would consider
15 anything, you know, man-made to be artificial, I
16 guess.

17 Q. And do either the pacemaker or ICD
18 replace a missing body part?

19 A. They typically replace heart cells that
20 are dead, frankly. I mean, the reason why a sinus
21 node doesn't work, the reason why a person has the
22 slow heart rate is because, frankly, cells of the
23 sinus node complex, those cells that are along that
24 ridge that we talked about, are gone. They have
25 died off.

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ROA 646

1 So essentially when -- you know,
2 typically, a person is born or when they're in the
3 prime of their life, there's no issues with slow
4 heart rate. And, remember, it's more than just the
5 sinus node too. It could be anyplace along the
6 conduction system. So a person could have a
7 perfect -- a sufficiently functional sinus node,
8 but they might have had -- they might have lost
9 their left bundle branch or they might have lost
10 their AV node.

11 And, again, those are things that can
12 -- essentially, they age and the cells die and
13 they're replaced by sometimes fibrous tissue or
14 scar, and so you end up with a situation where, you
15 know, to keep the heart going, you have to put in a
16 device.

17 Q. So when you say, lost, you mean the
18 cells die?

19 A. Correct.

20 Q. Okay. So anything where the cells die,
21 you consider missing, like the whole part is
22 missing?

23 A. Well, you know, I think that -- let's
24 put it this way. A lot of these patients, if they
25 didn't have these devices in, they would die. I

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ROA 647

1 going to need and these are the leads that I would
2 like you to have with you.

3 And so they'll, you know, meet us
4 before the procedure and we'll -- we'll put a
5 device in.

6 Q. Do you write the patient a prescription
7 for a pacemaker or IDC?

8 A. No, I do not.

9 Q. I want to get into more of the missing
10 nodes and cells and things like that when they're
11 not working properly. How often in your -- since
12 you've been here, do you see that either nodes,
13 cells, parts of the heart, anything that would call
14 for a pacemaker or ICD, are just there but not
15 working properly?

16 A. I would say that, you know, if you were
17 to look on the cellular level, there's always
18 something missing. You know, if people have a full
19 complement of cells, then, frankly, except in the
20 situation where you have these genetic disorders
21 that are inherited, there's something missing.

22 Now, sometimes you have the complete
23 absence of any of those cells and you have a
24 situation -- and then sometimes you have a
25 situation where a critical mass of those cells is

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ROA 648

1 lost.

2 Q. Okay.

3 A. And so it can be a question of degree,
4 but on the cellular level, there would be something
5 missing in virtually all of these patients, except
6 for the genetically predisposed individuals.

7 Q. How often would you say that there's a
8 100 percent absence of cells?

9 A. I think that in -- we're talking about
10 a number of different areas in the heart, so I
11 think they -- I would say that I would have to
12 answer that question a slightly different way,
13 saying that I think that probably -- if you look at
14 the devices we're talking about, I think that
15 potentially a large percentage of those people are
16 completely dependent upon the device to live.

17 So if that device were to suddenly
18 fail, they would have a life-ending or
19 life-threatening experience. So that loss of
20 tissue is -- is extensive to that point that that
21 device is -- I think, you know, the problem with
22 your question is we're talking about different
23 areas of the heart. And so to say, you know,
24 completely every single cell from a particular area
25 of the heart's electrical system is gone, I think

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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 26th day of June, 2013 at Charleston, Charleston County, South Carolina.

Denise Lauder

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



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ROA 650

FILED

SEP 20 2013

STATE OF SOUTH CAROLINA

ADMINISTRATIVE LAW COURT

SC ADMIN. LAW COURT

CareAlliance Health Services d/b/a Roper	)	Civil Action No. / 12-ALJ-17-0405-CC
St. Francis Healthcare,	)	
	)	
Petitioner,	)	<u>REPLY TO RESPONDENT'S</u>
	)	<u>RESPONSE TO PETITIONER'S</u>
vs.	)	<u>AMENDED MOTION FOR</u>
	)	<u>SUMMARY JUDGMENT</u>
South Carolina Department of Revenue,	)	
	)	
Respondent.	)	

Petitioner files this Reply in support of its Amended Motion for Summary Judgment and in response to Respondent's Response to that motion. In the interest of judicial economy, Petitioner hereby incorporates the arguments made in its Memorandum in Opposition to SCDOR's Motion for Summary Judgment herein as many of the issues raised in SCDOR's Response to Petitioner's Motion for Summary are addressed therein. Petitioner will briefly address below the few remaining issues raised by SCDOR's Response that have not previously been fully addressed.

I. Petitioner's Analysis of the Prescription Requirements for Surgical Implants is Consistent with the Law.

In Respondent's Response to Petitioner's Amended Motion for Summary Judgment, it states as follows:

The Petitioner's entire motion is based on two fundamentally flawed assertions. First, it attempts to conflate the transaction between doctor and patient with the actual taxable transaction at issue, which is between the hospital and the manufacturer. The former is a sale of a medical service, and the latter a sale of tangible personal property between corporate entities. Second, the Petitioner erroneously believes that any involvement of a

medical doctor, either directly or indirectly, in the chain of custody of the devices at issue constitutes a prescription."

Response at pp. 3-4. These assertions are without merit.

First, as explained in detail in Petitioner's Memorandum in Opposition to SCDOR's Motion for Summary Judgment, Petitioner is NOT attempting to "conflate" the sale from the manufacturer with the service provided by the physician. See Memorandum in Opposition at p. 2. The taxpayer's position is and always has been that there is one sale- the sale to the hospital, which the law defines as a retail sale. Id. The prescription is clearly for the patient, but it is the prescription that authorizes the sale to be made to the hospital. This is identical to the transaction that occurs when a physician gives a prescription to a patient to take to a pharmacy thereby allowing the pharmacy to sell to the patient. The prescription is not for the benefit of the pharmacy, rather it is to authorize the pharmacy to make the sale. There is simply no requirement under the law that the prescription at issue be for the benefit of the hospital as SCDOR suggests.

Second, Respondent's characterization of Petitioner's position as being that any involvement either directly or indirectly by a physician in the chain of custody of the devices at issue constitutes a prescription is not accurate. Rather, Petitioner's position is that a physician issues an oral order for each device at issue in this matter during surgery (which is supported by the physician's testimony in the record), and that these oral orders constitute prescriptions under the relevant FDA regulations and the law (which is also supported by the physician's testimony as well as the law). See Petitioner's Amended Motion for Summary Judgment at pp. 11-12.

SCDOR makes several additional arguments in its Response to Petitioner's Amended Motion for Summary Judgment, which Petitioner will now address. First, SCDOR argues that

the use of the language "prescription or other order of such practitioner" in CFR §801.109 shows that an order cannot be a prescription. SCDOR's reading of this federal regulation is not persuasive. A clear reading of the regulation, which is confirmed by the physicians' testimony in the case, is that a doctor's order is synonymous or interchangeable with a prescription in this context. See Petitioner's Amended Motion for Summary Judgment at Ex. C, McCrosson Aff. at ¶4 (wherein Dr. McCrosson states that his oral orders constitute a prescription as required by law) and Ex. D, Baker Aff. at ¶4 (wherein Dr. Baker states the same); Petitioner's Memorandum in Opposition to SCDOR's Motion for Summary Judgment at Ex. B, Dep. of Mary Pendergast at 49:7-14 (wherein expert on FDA regulations testifies that the oral order of a physician is a prescription).

Respondent also states that Petitioner fails to distinguish Home Medical Systems, Inc. v. S.C. Dept. of Rev., 382 S.C. 556, 677 S.E.2d 582 (2009) from the facts of this case and asserts that it controls the outcome of this matter. Response at pp. 4-5. Petitioner does not disagree with much of what SCDOR says about Home Medical. For example, Petitioner agrees that simply because a physician writes a prescription for a device, that does not make it a prescription device. The FDA is the only body that may classify a device as a prescription one. See Petitioner's Amended Motion for Summary Judgment at pp. 10-11. So although a physician could write a patient a prescription for the items at issue in Home Medical, Advil or even jumping jacks, non-prescription items are not thereby converted into prescription items. Unlike the items in Home Medical, however, there is no dispute in this case that the devices at issue are prescription devices.¹ Home Medical is simply not relevant as it does not address the

¹ The Department states that it agrees that the devices at issue would be considered prescription devices. Response at p. 6. It then further explains that a physician does not need a prescription to purchase prescription prosthetic devices. On this latter point, Petitioner would again note that the Department's

issue in this case of whether the orders of physicians (again, for what all parties agree are prescription devices) constitute prescriptions. As previously stated, FDA law provides and the expert regarding FDA regulations and the physicians who have testified in this case state that the oral orders of physicians at issue constitute prescriptions, and SCDOR has presented no evidence, testimony or controlling law to the contrary.

Next SCDOR states that the FDA regulations do not require that a hospital have a prescription in order to purchase a prescription device and can purchase them pursuant to its facility license. Response at p. 7. SCDOR cites no law in support of this proposition (see Response at p. 7) in its Response, and the only law cited in its Motion for Summary Judgment (to which the Response refers) is the South Carolina statute that provides that nothing in the Pharmacy Code "shall be construed to require a permit of or to prevent a *licensed practitioner* from *possessing or administering* drugs or devices . . . in the regular course of professional practice." S.C. Code Ann. § 40-43-60(H). This statute addresses only *possession* and *administration* by *physicians* not the *purchase* of devices by *hospitals*, and the SCDOR's misreading of the statute is contrary to federal law and to the testimony of Petitioner's expert on FDA regulations. See Petitioner's Amended Motion for Summary at pp. 9-11 and Petitioner's Memorandum in Opposition to Respondent's Motion for Summary Judgment at pp. 4-6.

SCDOR also argues that South Carolina is at liberty to regulate the pharmacy practice within the State and to use its own definitions in interpreting its tax laws. See Response at pp. 7-8. Petitioner agrees that the State of South Carolina may pass laws to regulate the pharmacy practice within the State so long as such laws are not "different from" the requirements

continued focus on whether a physician needs a prescription to purchase items is irrelevant. The sales at issue in this case are to a hospital not to doctors, and, unlike prescription medicines that may be purchased under a hospital pharmacy license to be dispensed later upon a prescription, the law requires that a hospital have a doctor's order before it can purchase prescription devices.

imposed by federal law. 21 U.S.C. §360k(a). Because federal law requires that a hospital have a prescription, any law enacted by a State to the contrary would be "different from" the federal regulations and thus preempted. Additionally, although the State of South Carolina can define a prescription in its Pharmacy Code as it wishes so long as it is consistent with federal law, such definitions do not apply to the tax code. Home Medical Systems, Inc. v. S.C. Dept. of Rev., 382 S.C. 556, 677 S.E.2d 582 (2009) (holding that definitions in the Pharmacy Code do not apply in sales tax exemption cases).

Finally, while SCDOR does not appear to challenge that the orthopedic prosthetic devices at issue replace a missing part of the body (Response at pp. 9-10), it does attempt to argue that the cardiac devices may not replace a missing part of the body and asserts that this is a factual issue. Id. However, it offers no evidence or testimony in support of this argument or that would refute the only medical testimony in the record on this issue, which is the testimony of a cardiologist who testifies unequivocally 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. Amended Motion for Summary Judgment at Ex. D, Baker Aff. at ¶6. Thus, Petitioner would submit that there is no factual dispute on this issue.

II. The Sale of Blood and Products Derived from Blood is a Sale of a Service Excluded from the Sales and Use Tax Statute.

SCDOR's response to Petitioner's position on products derived from blood (i.e. that the sale of such products is excluded from sales and use tax) is not supported by the law or the facts in this case. The Department attempts to read the Revised Uniform Anatomical Gift Act

("RUAGA") as only defining "transplanting, injection, transfusion, or other transfer of these substances into the human body" as a service and argues that it does not address the sale of such substances. Response at p. 10. This selective reading ignores the heart of the statute, which states in full: "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. Thus, RUAGA clearly defines the sale of products derived from blood as the sale of a medical service. Id.

The Department also argues that the premise behind RUAGA as well as the Samson v. Greenville Hospital System, 297 S.C. 409, 377 S. E. 2d 311 (1989) case cited by Petitioner in its motion (which also finds the sale of blood and blood products to be the sale of a medical service) is to encourage "a readily available supply of blood and human tissue." Response at p. 11. It then claims that the blood proteins at issue "are subjected to a complex sterilization process during their manufacturing and would be free of any viral or bacterial threats that would give rise to the possible torts blocked by RUAGA." Response at p. 11. SCDOR cites not one shred of evidence in the record to support this statement, and, in fact, the only testimony in the case from Petitioner's hematologist clarifies if not directly contradicts this statement. First, Dr. Nawabi testified that the blood proteins are not "manufactured" as SCDOR claims but are created by the human body. See Petitioner's Amended Motion for Summary Judgment at Ex. E, Nawabi Aff. at ¶9. Additionally, he testified that to the extent that the blood proteins are processed in a similar way to blood, plasma and red blood cells (including screening for infectious diseases), all of which the Department considers exempt. Id. at ¶6.

The Department then argues that the blood proteins at issue have "unnatural brand names" like Albuminar (which is an albumin protein). Response at p. 11. Interestingly, the Department did not have a similar issue with and, in fact, approved the tax excluded status of Humate, a plasma product also with a brand name and included in Petitioner's refund claim, and it provides no substantive explanation as to the relevance of a blood product having a brand name.

SCDOR also attempts to mount a "long-standing administrative construction" argument based on Tax Commission Decision 92-26. Response at p. 12. In other words, the Department appears to be arguing that it has long interpreted the blood proteins at issue not to be excluded from tax and that it has long considered blood and blood products to be tangible personal property. Id. This argument is contradicted by the depositions of the SCDOR witnesses in the case as well as the internal communication within the Department produced in discovery, both of which indicate that there has been considerable discussion within the Department concerning whether sales of products derived from blood are subject to tax. More specifically, 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. See Petitioner's Amended Motion for Summary Judgment at 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. Id. at Ex. G, Deposition of Christine Buddin ("Buddin Dep.") at 28:1-25 and 32:10- 34:25 and 37:19- 40:5. At various times, hospitals in some areas of the state were paying the tax while others were not. See Petitioner's Amended

Motion for Summary Judgment at Ex. H, E-mail Correspondence, Bates-stamped 000048-000068.

Additionally, the Department concedes that it does not currently tax whole blood, red blood cells, platelets or plasma (see e.g. id. at Ex. G, Buddin Dep. at 34:12-25), but there appears to be no basis in medicine or the law for it to distinguish blood proteins derived from plasma from the other blood products. If the Department's position is that blood, plasma, red blood cells, etc. are tangible personal property, then these items should be taxable and yet the Department currently excludes such items. Simply put, there is no long-standing administrative policy on the blood proteins at issue, and the current policy is inconsistent and arbitrary with no basis in law or fact. Thus, the Court should give no weight or deference to the Department's policies or supposed long-standing construction of the statutes at issue.

Finally, it is important to remember that the taxation of the blood proteins in question is one of imposition of the tax or coverage and not of exemption. As such the imposition statute should be narrowly construed against the imposition of the tax and liberally construed in favor of the taxpayer. Clark v. S.C. Tax Comm'n, 259 S.C. 161, 191 S.E.2d 23 (1972) (holding that "[r]evenue laws are generally construed in favor of the taxpayer and against the taxing authority"); Taylor v. Aiken County Assessor, 402 S.C. 559, 741 S.E.2d 31 (Ct. App. 2013) (same). When this standard is applied, it is clear that the blood proteins at issue are excluded from coverage of the sales and use tax.

CONCLUSION

For the reasons set forth in Petitioner's Motion for Summary Judgment, in its Response to SCDOR's Motion for Summary Judgment and in this Reply, Petitioner respectfully requests that the Court grant its Motion and deny Respondent's Motion.

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Charleston, South Carolina
September 20, 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:

REPLY TO RESPONDENT'S RESPONSE TO
PETITIONER'S AMENDED MOTION FOR SUMMARY
JUDGMENT

Counsel Served:

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September 20, 2013

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SC ADMIN. LAW COURT

CareAlliance Health Services d/b/a Roper) Civil Action No. 12-ALJ-17-0405-CC
St. Francis Healthcare,)
)
Petitioner,)
)
MOTION TO EXCLUDE AFFIDAVIT
OF STEVEN SILVERMAN AND
MEMORANDUM IN SUPPORT
vs.)
)
South Carolina Department of Revenue,)
)
Respondent.)
)

1

STATEMENT OF APPLICABLE FACTS

There is no scheduling order in this case, but the parties have engaged in full discovery, including the duty and opportunity to name experts. On March 11, 2013, in response to SCDOR's Interrogatory #3, Roper identified Mary K. Pendergast, a former Deputy Commissioner and Senior Advisor to the Commissioner of the Federal Food and Drug Administration ("FDA"), as its expert on the FDA regulations at issue in this case. On January 11, 2013, SCDOR answered Roper's Interrogatory #3, which requested identification of all expert witnesses. SCDOR did not identify any regulatory experts. Although SCDOR has previously expressed a desire in this case to procure testimony from an expert from the FDA, it has never supplemented its discovery answers naming any such experts because SCDOR had difficulty in obtaining any testimony from the FDA and because apparently Mr. Silverman is either not willing or unable to appear for a deposition or as a witness at trial. He is only willing to provide a written statement that is not subject to cross-examination.

The parties filed cross-motions for summary judgment on August 26, 2013. SCDOR did not submit any affidavits in support of its motion. The trial of this matter was originally set for the week of September 30, 2013. On September 17, 2013, this Court postponed the trial and scheduled a hearing on the parties' cross motions for summary judgment for October 1, 2013. On September 24, 2013, one week before the scheduled hearing, SCDOR filed the Affidavit of Steven Silverman "in support of the Respondent's Motion for Summary Judgment and in Opposition to the Affidavits of Mary K. Pendergast and Charles Prescott Ferguson." Ex. A, Letter from Adam Marinelli to Judge Robinson dated September 24, 2013; Ex. B, Affidavit of Steven Silverman ("Silverman Aff.").

Roper immediately notified this Court by letter on September 25, 2013 of its intention to move to exclude Mr. Silverman's Affidavit as untimely and prejudicial. In a response letter the same day, SCDOR argued that it had timely filed the affidavit under SCRCP 56(c); that Roper had been on notice since early in the discovery process of SCDOR's intention to seek such testimony; that the FDA only provides written testimony in declaratory format and thus the Department had no option to name a possible FDA witness in discovery; and that the South Carolina Rules of Civil Procedure do not require that a party be given the opportunity to depose an opposing party's declarants of affidavits prepared for a motion for summary judgment. Ex. C, Letter dated September 25, 2013 from Adam Marinelli to Judge Robinson.

LEGAL ANALYSIS AND ARGUMENT

SCDOR should be precluded from using Steven Silverman's Affidavit in the hearing on cross motions for summary judgment because it is untimely under the rules, highly prejudicial, and would violate Roper's due process rights. Over the course of over nine months of discovery and preparation for trial, SCDOR had an ongoing duty to supplement interrogatory answers to disclose witnesses. See SCRCP 33(b). A trial court has discretion to determine whether a sanction is warranted for a violation of Rule 33(b)'s continuing duty to disclose information. Jenkins v. Few, 391 S.C. 209, 219, 705 S.E.2d 457, 462 (S.C. Ct. App. 2010), *cert. granted, and dismissed as improvidently granted*, 400 S.C. 32, 732 S.E.2d 892 (2012). Before excluding a witness as a sanction for violating the continuing duty to disclose information under Rule 33, the trial court should ascertain (1) the type of witness involved, (2) the content of the evidence, (3) the explanation for the failure to name the witness in answer to

the interrogatory, (4) the importance of the witness's testimony, and (5) the degree of surprise to the other party. Id. (citing Bensch v. Davidson, 354 S.C. 173, 580 S.E. 2d 128 (2003)).¹

Petitioner will address elements (1) (type of witness), (2) (content of evidence) and (4) (importance of testimony) first. In this case, the witness at issue is an expert from the FDA who purports to provide written testimony containing opinions that relate to issues in dispute, including the application of FDA regulations regarding the sale of prescription devices. However, the affidavit does not even state that it applies to the items that are at issue in the case, namely *Type II* and *Type III* prescription *prosthetic* devices. Instead, it only states that it relates to "prescription devices". See Ex. B, Silverman Aff. at ¶¶6-7. It is true that the pharmacy of a properly licensed health care facility, through its pharmacist, can order prescription devices that may only be dispensed upon prescription. However, no such items are at issue in this case. Thus, while an FDA expert could provide testimony that is relevant to the case, Mr. Silverman's affidavit does not directly address the prescription prosthetic devices at issue in this case, which by law can only be sold by prescription.

As to element (3) (the explanation for not naming the witness), SCDOR's explanation as to why it did not name Mr. Silverman as a witness is basically that he is not a witness. He is either not willing or unable to submit to a deposition or to be a witness at the trial of this case. The Department wishes to have this Court rely on the statements of a witness who has not and will not be cross-examined and whose testimony would not be admissible at a trial on

¹ In Jenkins, the Court of Appeals noted that similar factors were outlined in Jumper v. Hawkins, 348 S.C. 142, 558 S.E.2d 911 (Ct. App. 2001), and that the Jumper factors were applied in a number of subsequent cases. However, those cases all dealt with challenges to experts named after the pre-trial scheduling order deadline. The court then declined to apply Jumper and concluded the Bensch factors were more appropriate on the issue of expert exclusion because the ongoing duty to supplement interrogatories was implicated instead. Jenkins, 391 S.C. at 219, 705 S.E.2d at 462. That is also the circumstance in this dispute because there was no pre-trial scheduling order.

this matter as it is clearly hearsay. Petitioner will address the prejudice and due process concerns of this below. Upon information and belief, SCDOR has been attempting to obtain testimony from the FDA for quite some time, and so this is not a case where the witness's name was known but improperly withheld; however Petitioner would note that current employees of the FDA are not the only source of expert testimony on these matters, as evidenced by the fact that Roper timely named its own expert witness on the FDA regulations at issue here in a timely manner, and she has been made available to SCDOR for deposition and was deposed. In fact, SCDOR has deposed all witnesses whose affidavits are being offered in support of Roper's motion for summary judgment, and it had ample opportunity to question them. When a party learns that its first choice for an expert witness will not be available in a timely manner, the alternative to waiting until the eve of trial or dispositive motions hearing to name one (or as in this case, submit an affidavit), is to find another witness.

As to element 5 (degree of surprise to opposing party), the degree of surprise to Roper is high, and allowing this affidavit to be considered by the Court would be highly prejudicial to Roper and would violate its due process rights. While Roper knew that SCDOR wanted to secure the testimony of someone from the FDA, it had no idea who the witness would be or what their testimony would be. It cannot be considered fair notice of a witness where no name is given and no summary of the substance of the witness's testimony is provided.

Additionally, the fact that Mr. Silverman cannot be cross-examined (either prior to the hearing or prior to trial) is highly prejudicial to Roper and would clearly result in a violation of Roper's due process rights.² It is a fundamental principle of law that "[d]ue process requires

²The lack of opportunity to cross examine the witness is a clear factor supporting exclusion. See Jenkins, 391 S.C. at 219, 705 S.E.2d at 462 ("the trial court found the degree of surprise and prejudice . . . was low because . . . Few's counsel had the opportunity to cross-examine" the expert).

(1) adequate notice; (2) adequate opportunity for a hearing; (3) the right to introduce evidence; and (4) the right to confront and cross-examine witnesses." In re Vora, 354 S.C. 590, 595, 582 S.E.2d 413, 416 (2003); see also Brown v. South Carolina State Bd. of Educ., 301 S.C. 326, 329, 391 S.E.2d 866, 867 (1990) citing Goldberg v. Kelly, 397 U.S. 254, 90 S.Ct. 1011, 25 L.E.2d 287 (1970); South Carolina Dep't of Social Serv. v. Holden, 319 S.C. 72, 459 S.E.2d 846 (1995) (right to confrontation applies in civil context). Confrontation includes the right to be physically present during the presentation of testimony. See State v. Shuler, 344 S.C. 604, 545 S.E.2d 805 (2001). Therefore, because Roper would be precluded from cross-examining this expert, and his testimony is offered as to central issues in the case, Roper's due process rights would be violated by the admission of Mr. Silverman's affidavit. Roper is also prejudiced by this late submission in terms of preparing for the hearing and obtaining rebuttal affidavits.

Finally, as a procedural matter, the affidavit should be excluded as untimely because it was not filed with SCDOR's motion for summary judgment. See SCRPC 6(d) ("When a motion is to be supported by affidavit, the affidavit shall be served with the motion"). To the extent SCDOR relies on Rule 56 to argue that it could file such an affidavit within 2 days prior to the hearing, that Rule applies to affidavits offered for the purpose of rebutting the opposing party's claim that there are no genuine issues of fact. It does not permit the late filing of affidavits in support of a party's own motion. "The adverse party may serve *opposing affidavits* not later than two days before the hearing." SCRCP 56(c). Therefore, even if this Court is inclined to admit Mr. Silverman's affidavit, SCDOR should be limited to offering that testimony as a shield in response to Roper's motion for summary judgment, and not a sword on behalf of its own motion for summary judgment.

CONCLUSION

For the above-stated reasons, Roper respectfully requests that this Court exclude the Affidavit of Steven Silverman filed in support of SCDOR's Motion for Summary Judgment. In the alternative, Roper would request that it be given the opportunity to file responsive affidavit(s).

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September 27, 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:

**MOTION TO EXCLUDE AFFIDAVIT OF STEVEN
SILVERMAN AND MEMORANDUM IN SUPPORT**

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Donna Horn
Administrative Assistant

August 27, 2013

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SC ADMIN. LAW COURT

September 24, 2013

The Honorable Shirley G. Robinson
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Edgar A. Brown Bldg.
1205 Pendleton St., Ste. 224
Columbia, SC 29201

Re: CareAlliance Health Services d/b/a Roper St. Francis Healthcare v.
South Carolina Department of Revenue
Docket No.: 12-ALJ-17-0405-CC

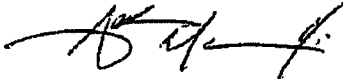
Dear Judge Robinson:

Enclosed for filing in the above-referenced matter is the Affidavit of Steven D. Silverman, Director of the Office of Compliance, Center for Devices and Radiological Health, United States Food and Drug Administration, in support of the Respondent's Motion for Summary Judgment and in opposition to the Affidavits of Mary K. Pendergast and Charles Prescott Ferguson.

Also enclosed is a Proof of Service. Should you have any questions or if any issues arise, do not hesitate to contact me.

With kind regards,

OFFICE OF GENERAL COUNSEL FOR LITIGATION



Adam N. Marinelli
Counsel for Litigation

ANM:jmo

Enclosures

c: John C. von Lehe, Jr., Esquire
Bryson M. Geer, Esquire
Raymond Carpenter, Esquire

EXHIBIT A

FILED

SEP 24 2013

SC ADMIN. LAW COURT

AFFIDAVIT OF STEVEN D. SILVERMAN, J.D.

Steven D. Silverman, J.D., being first duly sworn, deposes and says:

1. I am the Director, Office of Compliance, Center for Devices and Radiological Health ("CDRH"), United States Food and Drug Administration ("FDA"). My office is located at 10903 New Hampshire Avenue, Silver Spring, Maryland. I have been in this position for approximately three years. As Director of the Office of Compliance, I oversee a staff of regulatory personnel who ensure that medical devices regulated by FDA comply with the relevant provisions in the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations. Among other things, my position requires that I personally review, interpret, and apply the Act and its regulations as they pertain to medical devices and to parties involved in investigating, developing, manufacturing, producing, and distributing medical devices. This affidavit is based on my personal knowledge and information obtained by me in my official capacity.

2. The statements in this affidavit are made in response to a request from the State of South Carolina, Department of Revenue, Office of General Counsel for Litigation, in connection with the *CareAlliance Health Services d/b/a Roper/St. Francis Medical Healthcare, Inc. v. SC Dept. of Revenue*, 12-ALJ-17-0405-CC (S.C. Admin. Ct.) case.

3. I have been authorized by the Commissioner of Food and Drugs' designee to give testimony in this matter.

EXHIBIT B

4. Under FDA's regulations, a "prescription device" is 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." 21 C.F.R. § 801.109.

5. FDA can require by regulation that a device be a prescription device. See 21 U.S.C. § 360j(e)(1)(A) ("The Secretary may by regulation require that a device be restricted to sale, distribution or use only upon the written or oral authorization of a practitioner licensed by law to administer or use such device"). FDA can also require that a device be a prescription device in its order approving an application for premarket approval ("PMA") for a specific device under 21 U.S.C. § 360e(d)(1)(B)(ii) ("An order approving [a PMA] for a device may require as a condition to such approval that the sale and distribution of the device be restricted" as provided for in 21 U.S.C. § 360j(e)). A third way a device could become a prescription device is through FDA's clearance of a premarket notification under 21 U.S.C. § 360(k) for a device indicated for prescription use.

6. The Act deems a device to be misbranded unless its labeling bears adequate directions for its use. 21 U.S.C. § 352(f)(1). FDA's regulations exempt prescription devices from such labeling requirement when, among other things, the device is "[i]n 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,*" and the device "*[i]s to be sold only to or on the prescription or order of such practitioner for use in the course of his*

professional practice." 21 C.F.R. § 801.109(a) (emphases added). 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 or pursuant to a prescription or order of a physician.

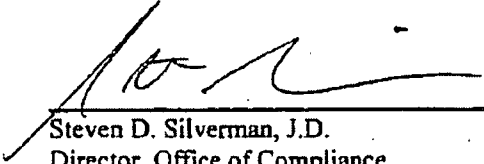
7. There is nothing in the Act or its regulations that prohibits device manufacturers from selling prescription devices to properly-licensed healthcare facilities that do not have patient-specific physician orders for such devices at the time of purchase by the healthcare facility, to be stored in inventory by the facility for ultimate distribution to or use on a patient by a licensed practitioner or pursuant to a prescription or other order from a licensed practitioner. To prohibit 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 (e.g., infusion pumps, ventilators, cardiac pace makers, and dialysis equipment) in their inventory for immediate access to render care to their patients.

Executed this 23rd day of September, 2013.

FILED

SEP 24 2013

SC ADMIN. LAW COURT

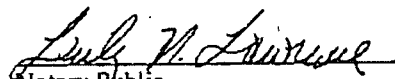


Steven D. Silverman, J.D.
Director, Office of Compliance
Center for Devices and Radiological Health
United States Food and Drug Administration

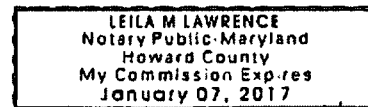
State of Maryland)
County of Montgomery) ss:

I, Leila M. Lawrence, a Notary Public for said County and
State, do hereby certify that Steven D. Silverman, J.D., personally appeared before me this day
and acknowledged the due execution of the foregoing instrument.

Witness my hand and official seal, this the 23rd day of September,
2013.


Notary Public

My commission expires January 07, 2017



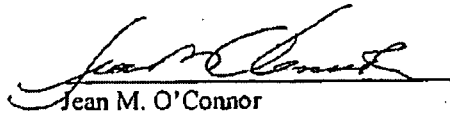
FILED

SEP 24 2013

PROOF OF SERVICE

SC ADMIN. LAW COURT

I, Jean M. O'Connor, do hereby certify that I have caused to be mailed postage pre-paid, a copy of the Affidavit of Steven D. Silverman, Director of the Office of Compliance, Center for Devices and Radiological Health, United States Food and Drug Administration in support of Respondent's Motion for Summary Judgment and in opposition to the Affidavits of Mary K. Pendergast and Charles Prescott Ferguson in re: Roper/St. Frances Medical Healthcare, Inc., v. South Carolina Department of Revenue, Docket No. 12-ALJ-17-0405-CC to the Raymond Carpenter, Esquire, 625 Colonial Park Drive, Suite 201, Roswell, GA 30075, John C von Lehe, Jr., Esquire and Bryson M. Geer, Esquire, 151 Meeting Street, Sixth Floor, Charleston, SC 29401 this 24th day of September 2013.


Jean M. O'Connor

State of South Carolina
Department of Revenue
Office of General Counsel, Tax & Regulatory Services
300A Outlet Point Blvd., (29210); P.O. Box 12265, Columbia, South Carolina 29211
Telephone (803) 898-5130 Telecopier (803) 898-5147

September 25, 2013

The Honorable Shirley G. Robinson
Administrative Law Court
Edgar A. Brown Bldg.
1205 Pendleton St., Ste. 224
Columbia, SC 29201

Re: CareAlliance Health Services d/b/a Roper St. Francis Healthcare v.
South Carolina Department of Revenue
Docket No.: 12-ALJ-17-0405-CC

Dear Judge Robinson:

The Department is in receipt of the Petitioner's Reply to Respondent's Response to Petitioner's Amended Motion for Summary Judgment, and the letter concerning the possible objections to the Department's filing of Steven Silverman's sworn Affidavit. This letter shall address both in kind.

The Department objects to the inclusion of Petitioner's Reply to the record of this case, as it is untimely – both under ALC Rule 19(A) and the scheduling order that was in place for this case. Rule 19(A), in pertinent part, states that "[a]ny party may file a written reply within five (5) days of the filing of a response, unless otherwise ordered by the administrative law judge." Here, the Department's Response to Petitioner's Amended Motion for Summary Judgment was filed on September 6, 2013. A reply, pursuant to the rule, would have been due no later than September 13, 2013. This reply was untimely filed by the Petitioner approximately ten days past that date. Moreover, the email sent by your law clerk on June 26, 2013 clearly stated that "Judge Robinson is asking that all pretrial motions be made no later than Monday, August 26, 2013 and that the written responses to the pretrial motion(s) be filed no later than Friday, September 6, 2013." The Department respectfully posits that this most recent Reply is therefore untimely and should be disregarded by this Court.

As to the letter regarding the Department's filing of Steven Silverman's affidavit, the noted objections presented by the Petitioner are without merit. Rule 56(c) SCRPC unequivocally states that "The adverse party may serve opposing affidavits not later than two days before the hearing." See also Jernigan v. King, 312 S.C. 331, 440 S.E.2d 379 (Ct. App. 1993). This affidavit was filed a week prior to the scheduled hearing, and was therefore timely.

Furthermore, the Petitioner has had notice of pending written testimony from the U.S. Food and Drug Administration ("FDA") since the beginning of the discovery process in this case. In fact, the procurement of such testimony was one of the stated grounds for the Department's request for continuance on June 20, 2013.

EXHIBIT C

In addition, it is the policy of the FDA to only provide written testimony in declaratory format unless under exigent circumstances, and thus the Department had no option to name a possible FDA witness in discovery. Finally, the South Carolina Rules of Civil Procedure do not impose a duty upon an adverse party to allow opposing counsel an opportunity to depose declarants in affidavits prepared for a motion for summary judgment. As such, the Petitioner's objections should be disregarded and the affidavit should remain filed and part of the record.

Should this Court require anything further regarding these matters, do not hesitate to contact me at your convenience at MarineA@sctax.org or (803) 898-5153.

With kind regards,

OFFICE OF GENERAL COUNSEL FOR LITIGATION



Adam N. Marinelli
Counsel for Litigation

ANM:jmo

Enclosures

c: John C. von Lehe, Jr., Esquire
Bryson M. Geer, Esquire
Raymond Carpenter, Esquire

**STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT**

Roper/St. Francis Medical	)	DOCKET NO. 12-ALJ-17-0405-CC
Healthcare, Inc.,	)	
	)	
Petitioner,	)	RESPONDENT'S RESPONSE
	)	TO PETITIONER'S MOTION TO
v.	)	EXCLUDE STEVEN
	)	SILVERMAN'S AFFIDAVIT
South Carolina Department of	)	
Revenue,	)	
	)	
Respondent.	)	
	)	

COMES NOW, the Respondent, South Carolina Department of Revenue (Department), who would respond to Petitioner's Motion to Exclude Steven Silverman's Affidavit and Memorandum in Support, which was filed on Friday, September 27, 2013, in the above captioned matter. It is the position of the Department that Steven Silverman's Affidavit was filed timely with proper notice, in accordance with Rules 6(d) and 56(c) of the South Carolina Rules of Civil Procedure, and the only prejudicial aspect of its filing towards the Petitioner is the illuminating effects of its content upon the validity of Petitioner's case.

Statement of Facts

The Department's attempts to acquire an official written declaration from the U.S. Food and Drug Administration ("FDA") began in late 2012. Ms. Lauren DiPaola, Testimony Specialist for the Office of Policy and Risk Management, was assigned to the Department's requests in June of 2013. See Email from Lauren DiPaola to Adam

Marinelli attaching Subpoena request for testimony, dated June 7, 2013, attached as Exhibit A. The Subpoena sent to the FDA requested deposition testimony, as the Department was attempting to secure a federal witness that could have been named for discovery purposes. During a conference call with the Office of Chief Counsel for the FDA, acquiring a witness for deposition testimony was informally denied. Attorneys for the FDA, claiming that any attempts to enforce the Subpoena would be met with invocations of sovereign immunity, informed the Department that only a written declaration would be possible. On September 20, 2013, the Department was issued a letter from the Director of the Office of Enforcement and Import Operations and the Office of Regulatory Affairs at the FDA, authorizing Steven Silverman, the Director of the Office of Compliance for the Center for Devices and Radiological Health, to issue a written declaration on the question posed in Exhibit A (which had been forwarded to his desk on June 20, 2013). See Letter from Armondo Zamora to Adam Marinelli dated September 20, 2013, attached as Exhibit B. That question was "whether or not a doctor or hospital can legally purchase and possess Class II and Class III regulated devices prior to their use or administration on a patient without writing a prescription." See Exhibit A. The Department received a sworn affidavit from Steven Silverman late in the afternoon on September 23, 2013. See Email from Marci Norton to Adam Marinelli, dated September 23, 2013, attached as Exhibit C. The sworn Affidavit of Steven Silverman was then timely filed by the Department on the morning of September 24, 2013, one week before the scheduled hearing in this matter.

The most interesting fact pertaining to the acquisition of this affidavit is that the request was made impartially pursuant to 21 C.F.R 20.1, with an objective question

posed, and was answered impartially by the federal agency charged with regulating all of the devices at issue in this case. The Petitioner, had they wished to complete the same request in the name of due diligence, could have done so and would have been given the same answers. Once the Department received the letter from the Petitioner on September 25, 2013 objecting to the filing of Mr. Silverman's sworn Affidavit, the request to secure deposition testimony with the FDA was again renewed in good faith. Marci Norton, the attorney in the Office of Chief Counsel assigned to the Department's requests, responded in an email, denying the request again. See email from Marci Norton to Adam Marinelli dated September 26, 2013 attached as Exhibit D.

Legal Analysis

The Department's use of Steven Silverman's sworn Affidavit should not be precluded in the hearing on cross-motions for Summary Judgment in this case, as it was timely filed, is not prejudicial, and does not violate any due process rights. With respect to brevity, the Petitioner's three arguments regarding these points will be addressed below.

I. The Sworn Affidavit of Steven Silverman was filed timely.

The Petitioner's attempt to characterize the Silverman Affidavit as untimely is simply incorrect and can be dealt with swiftly. This Affidavit was filed in opposition to Mary K. Pendergast's and Charles Prescott Ferguson's Affidavits, as stated clearly in the cover letter filed with it. The Rules of Civil Procedure plainly state that opposing affidavits may be filed within two (2) days of the hearing. Rule 56(c), SCRCF. Steven Silverman's Affidavit was filed a week before the hearing date and was therefore timely.

II. There is No Prejudicial Effect in the Filing of Steven Silverman's Affidavit.

The Petitioner is correct in that there is no scheduling order in place for this case; thus, the ongoing duty to supplement witnesses is governed under the Rules of Civil Procedure. Rule 33(b), SCRCP states that "[i]nterrogatories shall be deemed to continue from the time of service until the time of trial of the action" As we have not yet reached the eve of trial, the Department's duty to supplement its witness list remains ongoing, but no breach of that duty has occurred. As discussed above, the Department is unable to secure live testimony at this stage from Mr. Silverman; therefore the Department has no witness to supplement to its responses to Petitioner's Standard Interrogatories.

To that extent, the Petitioner's reliance upon Jenkins v. Few, 391 S.C. 209 (2010) is misplaced, as it has no application to a challenge to an opposing affidavit. The Jenkins decision determined there was no prejudice when a named fact witness was called as an expert at trial unannounced. The Department has not named a new expert witness on the eve of trial, but merely has filed an affidavit in opposition to Petitioner's own paid expert's written declarations. The identity of the declarant was unknown to the Department until September 23, 2013; and absolutely no information was withheld from the Petitioner during discovery. Furthermore, no duty exists to provide an opportunity to depose a declarant in an opposing affidavit for a motion for summary judgment in the Rules of Civil Procedure, and the Petitioner's claims of prejudice on that basis are

erroneous. More importantly, calling for sanctions for discovery abuse on that basis is patently absurd.

Once informed by the FDA's legal counsel that any attempt to enforce a Subpoena for testimony would be met with sovereign immunity, the Department abandoned the hope of providing a witness from the FDA. At the very least, the Affidavit's use at trial would be viably admissible as impeachment evidence against the Petitioner's named expert. No duty to disclose impeachment evidence exists, nor is there a duty to provide an opportunity to depose a person in that regard. The Department has not failed to comply with any of the rules of discovery, and the Petitioner's challenge to the filing of this opposing affidavit is simply an attempt to hide the immutable truth of this case – that the FDA does not require prescriptions for the purchase of devices by hospitals. The Department is unaware of any precedent in case law that would support a finding of prejudice for having one's argument shown to be invalid.

At this point, a direct quote from the Petitioner's Motion to Exclude must be addressed:

When a party learns that its first choice for an expert witness will not be available in a timely manner, the alternative to waiting until the eve of trial or dispositive motions hearing to name one (or as in this case, submit and affidavit), is to find another witness.

Petr.'s Mot. To Exclude at 5. The aspersions cast there are completely unfounded, and the legal assertions are even further distanced from reality. To repeat – Steven Silverman is not a new named witness, expert or layperson, for the Department. The Department did not hide this Affidavit, like some smoking gun to be used with the element of surprise. It's laughable to entertain the thought, when the Petitioner admits that it was on

notice of the Department's attempt to acquire this testimony from the beginning. The Affidavit and identity of the declarant was provided to opposing counsel within fifteen hours of receipt by the Department. Furthermore, as stated above, the Petitioner could have made the exact same requests from the FDA and chose not to do so. Instead, they hired a paid consultant who once worked at the FDA. Nothing precluded the Petitioner from seeking answers to the questions central to this case from the FDA, and to now claim prejudice when that agency has impartially issued a sworn affidavit declaring the Petitioner's position to be incorrect lacks any merit.

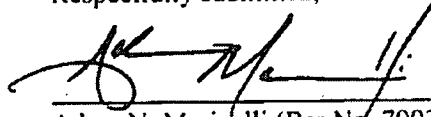
III. No Due Process Rights of the Petitioner have been Violated.

The Petitioner's claims of violations of due process are unfounded. The Affidavit was filed within the time limitations of Rules 6(b) and 56(c) of the South Carolina Rules of Civil Procedure, therefore no notice requirements have been breached by the Department. Furthermore, the Department has not proffered Mr. Silverman as a new witness, thus no duty to provide an opportunity to depose him has ever existed. To that extent, implications of the Confrontation Clause are misplaced by the Petitioner. Steven Silverman is not a personally interested party in the outcome of this litigation. He was not paid by the Department. He is the Director of the very division that enforces the federal regulations the Petitioner has attempted to invoke, and the Petitioner was well within their rights to request a declaration from the FDA themselves. No violation of due process rights exist simply because the Department sought that request, and the Petitioner does not like the answer.

Conclusion

The Affidavit of Steven Silverman should remain a filed part of the record in this case, and the Department respectfully requests that the Petitioner's Motion to Exclude should be denied.

Respectfully submitted,



Adam N. Marinelli (Bar No. 79031)
Counsel for Litigation
Lauren Acquaviva (Bar No. 100528)
Counsel for Litigation
Milton G. Kimpson (Bar No. 7917)
Chief of Litigation
P.O. Box 12265
Columbia, SC 29211
803-898-5153 (Telephone)
803-898-5147 (Fax)
Attorneys for the Department of Revenue
MarineA@sctax.org

Columbia, South Carolina
September 30, 2013

EXHIBIT "A"

Adam Marinelli

From: DiPaola, Lauren <Lauren.Dipaola@fda.hhs.gov>
Sent: Friday, June 07, 2013 10:58 AM
To: Adam Marinelli
Subject: Re: Scan from a Xerox WorkCentre

Thanks Adam, I will be in touch next week:
Lauren DiPaola
P: (301) 796-3910
F: (301) 827-3631

----- Original Message -----

From: Adam Marinelli [mailto:MarineA@sctax.org]
Sent: Thursday, June 06, 2013 02:11 PM
To: DiPaola, Lauren
Cc: Lauren Acquaviva <AcquavL@sctax.org>
Subject: FW: Scan from a Xerox WorkCentre

Ms. DiPaola,

Thank you for contacting me today regarding our case involving FDA regulated prescription devices. As we discussed, the crux of the case is the question - whether or not a doctor or hospital can legally purchase and possess Class II and Class III regulated devices prior to their use or administration on a patient without writing a prescription.

Per our conversation, I have attached the subpoena which was sent to the Clerk of Court in Rockville, but apparently the address on the website was incorrect. I look forward to hearing back from you, and I cannot tell you how much we appreciate the help.

With kind regards,

Adam N. Marinelli, Esq.

Counsel for Litigation
South Carolina Department of Revenue
300A Outlet Pointe Blvd.
P.O. Box 12265
Columbia, SC 29211
(803) 898-5153

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

SUBPOENA

To: **U.S. Food and Drug Administration**

Office of Regional Operations
Division of Federal-State Relations
12420 Parklawn Drive,
Rm. 3033 Rockville, MD 20857

YOU ARE COMMANDED TO:

Appear and testify at the taking of a deposition in the above-captioned case at the place, date and time shown below, regarding the following:

1. The U.S. Food and Drug Administration's (FDA) applicable laws and regulations pertaining to prescription devices;
2. The sale (not the use, administration, dispensing, etc.) of an orthopedic surgical implant from a manufacturer to a hospital and/or physician, and whether that sale requires a prescription; and,
3. The record-keeping requirements the FDA imposes upon manufacturers and/or hospitals and/or physicians for the sale (not the use, administration, dispensing, etc.) of an orthopedic surgical implant.

Date and Location of Deposition:

Thursday, June 20, 2013

Date

By telephone or TBD

Location

10:00 a.m. EST

Time of Appearance

Party Requesting Subpoena:

Lauren Acquaviva, Esq.

Name

South Carolina Department of Revenue
P.O. Box 12265
Columbia, SC 29201

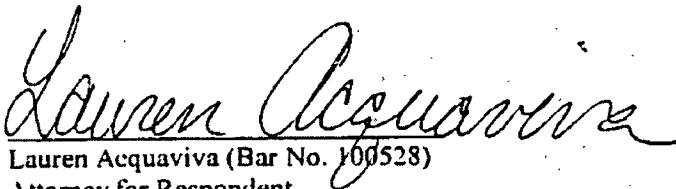
Address

803-898-5110

Telephone

ANY SUBPOENAED ORGANIZATION NOT A PARTY TO THIS IS HEREBY DIRECTED TO RULE 30(b)(6), SOUTH CAROLINA RULES OF CIVIL PROCEDURE, TO FILE A DESIGNATION WITH THE COURT SPECIFYING ONE OR MORE OFFICERS, DIRECTORS, OR MANAGING AGENTS, OR OTHER PERSONS WHO CONSENT TO TESTIFY ON ITS BEHALF, SHALL SET FORTH, FOR EACH PERSON DESIGNATED, THE MATTERS ON WHICH HE WILL TESTIFY OR PRODUCE DOCUMENTS OR THINGS. THE PERSON SO DESIGNATED SHALL TESTIFY AS TO MATTERS KNOWN OR REASONABLY AVAILABLE TO THE ORGANIZATION.

I CERTIFY THAT THIS SUBPOENA IS ISSUED IN COMPLIANCE WITH RULE 22(A), RULES OF PROCEDURE FOR THE ADMINISTRATIVE LAW COURT.



Lauren Acquaviva (Bar No. 100528)

Attorney for Respondent

South Carolina Department of Revenue

P.O. Box 12265

Columbia, SC 29211

803-898-5110

AcquavL@sctax.org

Date of Issue: May 29, 2013

Rule 45, South Carolina Rules of Civil Procedure, Parts (c) and (d):

(c) Protection of Persons Subject to Subpoenas.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction, which may include, but is not limited to, lost earnings and a reasonable attorney's fee.

(2)(A) A person commanded to produce and permit inspection and copying of designated electronically stored information, books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial. A party or an attorney responsible for the issuance and service of a subpoena for production of books, papers and documents without a deposition shall provide to another party copies of documents so produced upon written request. The party requesting copies shall pay the reasonable costs of reproduction.

(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection and copying may, within 14 days after service of the subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to inspection or copying of any or all of the designated materials or of the premises—or to producing electronically stored information in the form or forms requested. If objection is made, the party serving the subpoena shall not be entitled to inspect and copy the materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time in the court that issued the subpoena for an order to compel the production. Such an order to compel production shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection and copying commanded.

(3)(A) On timely motion, the court by which a subpoena was issued, or regarding a subpoena commanding appearance at a deposition, or production or inspection directed to a non-party, the court in the county where the non-party resides, is employed or regularly transacts business in person, shall quash or modify the subpoena if it:

(i) fails to allow reasonable time for compliance; or

(ii) requires a person who is not a party nor an officer, director or managing agent of a party, nor a general partner of a partnership that is a party, to travel more than 50 miles from the county where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c)(3)(B)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held; or

(iii) requires disclosure of privileged or otherwise protected matter and no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) If a subpoena:

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or

(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or

(iii) requires a person who is not a party nor an officer, director or managing agent of a party, nor a general partner of a partnership that is a party, to incur substantial expense to travel from the county where that person resides, is employed or regularly transacts business in person, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) Duties in Responding to Subpoena.

(1)(A) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(B) If a subpoena does not specify the form or forms for producing electronically stored information, a person responding to a subpoena must produce the information in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) A person responding to a subpoena need not produce the same electronically stored information in more than one form.

(D) A person responding to a subpoena need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or to quash, the person from whom discovery is sought must show that the information sought is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(6)(B). The court may specify conditions for the discovery.

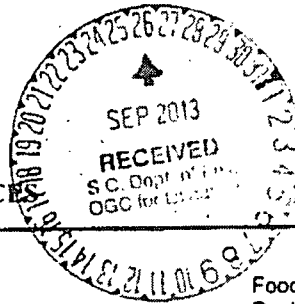
(2)(A) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

(B) If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has and may not use or disclose the information until the claim is resolved. A receiving party may promptly present the information to the court under seal for a determination of the claim. If the receiving party disclosed the information before being notified, the receiving party must take reasonable steps to retrieve the information. The person who produced the information must preserve the information until the claim is resolved.

EXHIBIT "B"



DEPARTMENT OF HEALTH AND HUMAN SERVICES



Food and Drug Administration
Rockville MD 20857

SEP 20 2013

Adam N. Marinelli, Esq.
Counsel for Litigation
South Carolina Department of Revenue
300A Outlet Pointe Blvd.
P.O. Box 12265
Columbia, SC 29211

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

Dear Mr. Marinelli:

This letter is in response to your email request dated June 20, 2013 to the United States Food and Drug Administration (FDA) for the testimony from an FDA employee in the above-referenced litigation. You requested an FDA declaration on the issue of whether a hospital, pharmacy, or medical practitioner may buy a medical device without patient-specific prescriptions for such device, for purposes of keeping the device in inventory for future use.

As you know, requests for the testimony of Department of Health and Human Services (DHHS) employees that pertain to any function of FDA are governed by Title 21, Code of Federal Regulations, Section 20.1. This regulation prohibits DHHS employees from testifying with respect to any information acquired in the discharge of their official duties at FDA except with the express authorization of the Commissioner of Food and Drugs or an employee designated by her to act on her behalf. As Acting Director of the Office of Enforcement and Import Operations, I have been delegated the authority by the Commissioner to review requests made under 21 C. F. R. § 20.1.

Section 20.1 provides that a request for testimony may be granted upon a determination that the testimony requested is both in the public health interest and furthers the objectives of the Federal Food, Drug, and Cosmetic Act (FDCA) and the agency. Because of limited resources and the vast number of requests the agency receives for personnel to testify in litigation to which FDA is not a party, FDA may, in its discretion,

Adam N. Marinelli, Esq.
Page 2

deny a request for testimony even when these prerequisites have been met. FDA must deny requests that are duplicative, unlikely to elicit relevant testimony, unduly burdensome, or otherwise inappropriate. Accordingly, the agency must carefully assess requests for testimony made pursuant to section 20.1.

After considering the merits of your request, FDA has determined that your request for testimony is in the public's interest and promotes the objectives of the FDCA and the agency, and hereby authorizes Steven Silverman to provide testimony on the question of whether a hospital may buy devices to stock in inventory as needed, without a particular patient in mind.

This authorization does not apply to information that FDA is prohibited from disclosing by law, e.g., trade secrets [18 U.S.C. § 1905; § 301(j) of the FDCA (codified at 21 U.S.C. § 331(j))]. Further, FDA retains the right to assert any applicable privilege that an attorney representing the agency determines to be appropriate.

FDA witnesses are specifically prohibited from testifying with respect to trade secrets or confidential commercial or financial information held by third-party companies, individuals, or entities. The above-referenced categories of information are excluded on the basis that government employees are either prohibited by law from disclosing such information, or testimony disclosing such information would not satisfy the standards set forth in Section 20.1.

FDA's Office of Chief Counsel has assigned an attorney, Marci Norton (301-796-8580) to assist with the preparation as needed.

Sincerely,

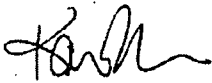

Armando Zamora
Acting Director
Office of Enforcement and Import Operations
Office of Regulatory Affairs
U.S. Food and Drug Administration

EXHIBIT “C”

Adam Marinelli

From: Norton, Marci <Marci.Norton@fda.hhs.gov>
Sent: Monday, September 23, 2013 3:55 PM
To: Adam Marinelli
Cc: DiPaola, Lauren
Subject: RE: FDA affidavit
Attachments: Steven Silverman Affidavit.pdf

Hi Adam,

I have attached a .pdf of the signed affidavit for you. Hopefully, it won't be a problem that the original is printed double-sided. The notary stamp is on the backside of the second page (on page 4).

We are putting it in UPS today for delivery tomorrow. That way, you should have it well in advance of your Thursday deadline. My assistant, Matt Dundon, will email you the tracking information.

Please let me know if there's anything else you need from us.

Thanks,
Marci

EXHIBIT "D"

Adam Marinelli

From: Norton, Marci <Marci.Norton@fda.hhs.gov>
Sent: Thursday, September 26, 2013 5:21 PM
To: Adam Marinelli
Subject: Affidavit of Steven Silverman

Adam,

During our call earlier today, you mentioned that opposing counsel in the CareAlliance Health Services d/b/a Roper/St. Francis Medical Healthcare, Inc., v. South Carolina Department of Revenue case raised the issue of deposing Steven Silverman, Director, Office of Compliance, in FDA's Center for Devices and Radiological Health.

As you know, FDA provided you Mr. Silverman's affidavit after you made a request for such testimony under FDA's regulation, 21 CFR 20.1. Pursuant to 21 C.F.R. 20.1(c), "[a] person who desires testimony from any [FDA] employee may make written request therefor, verified by oath, directed to the Commissioner [of Food and Drugs] setting forth his interest in the matter sought to be disclosed and designating the use to which such testimony will be put in the event of compliance with such request." This housekeeping regulation was designed to promote the public health by ensuring efficient allocation of FDA's limited resources and to protect FDA's impartiality, and provides FDA the sole discretion to decide whether to grant a request for employee testimony. Thus, even if a requester has demonstrated, as required by the regulation, that granting employee testimony (1) would be in the public interest, (2) would promote the objectives of the Federal Food, Drug, and Cosmetic Act, and (3) would advance FDA's mission, FDA may still deny such a request. See 21 CFR 20.1 (stating that if the requirements are met, "the request may be granted.").

Your specific request was for declaration/affidavit testimony, and the Commissioner of Food and Drugs' designee authorized Mr. Silverman to provide declaration/affidavit testimony in this matter. Should any party in your litigation wish to depose Mr. Silverman, it would have to submit a new request under 21 CFR 20.1 specifically requesting deposition testimony. Mr. Silverman could not be deposed unless and until the Commissioner or her designee authorized deposition testimony. Thank you.

Marci

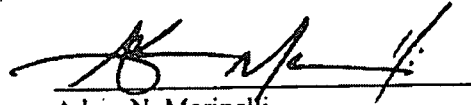
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Please consider the environment before printing this e-mail.

PROOF OF SERVICE

I, Adam N. Marinelli, do hereby certify that I have caused to be electronically transmitted, a copy of the Respondent's Response to Petitioner's Motion to Exclude Steven Silverman's Affidavit in re: Roper/St. Frances Medical Healthcare, Inc., v. South Carolina Department of Revenue, Docket No. 12-ALJ-17-0405-CC to The Honorable Shirley G. Robinson, Raymond Carpenter, Esquire, John C. von Lehe, Jr., Esquire, and Bryson M. Gcer, this 30th day of September 2013. The Original will be hand filed on the day of the hearing.



Adam N. Marinelli

STATE OF SOUTH CAROLINA

ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a Roper	)	Civil Action No. 12-ALJ-17-0405-CC
St. Francis Healthcare,	)	
	)	
Petitioner,	)	
	)	<u>MOTION FOR RECONSIDERATION</u>
vs.	)	<u>UNDER ALC RULE 29(D) AND/OR TO</u>
	)	<u>ALTER OR AMEND UNDER SCRPC</u>
South Carolina Department of Revenue,	)	<u>RULE 59(E)</u>
	)	
Respondent.	)	

Pursuant to Rule 29(D) of the Rules of Procedure for the Administrative Law Court ("ALC") and Rule 59(e) of the South Carolina Rules of Civil Procedure, Petitioner CareAlliance Health Services d/b/a Roper St. Francis Healthcare ("Petitioner" or "Roper") respectfully requests that the ALC reconsider and alter or amend a portion of its Order dated May 20, 2014 (the "Order"), a copy of which is attached hereto as Ex. A, which granted in part and denied in part cross motions for summary judgment filed by Petitioner and the South Carolina Department of Revenue ("Respondent" or "SCDOR") in this matter. This motion is based upon the grounds that the ALC may have overlooked, misinterpreted or failed to apply South Carolina law or may have failed to consider certain evidence and arguments presented, which, when considered, necessitate a finding in favor of Roper on the issues raised below.

A. The ALC Should Have Found that the Cardiac Devices at Issue Replace a Missing Part of the Body.

The ALC should have found that the cardiac devices at issue replace a missing part of the body. However, the ALC concluded that they did not. More specifically, the ALC found that "[e]ssentially, 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." Order at p. 13. The ALC appears to have based its conclusion, at least in part, on its mistaken belief that Dr. Brett M. Baker, an electrophysiologist who provided expert testimony in this matter, "indicated he removes and replaces heart tissue in approximately 1-10% of his patients." See Order at p. 13, n. 13 (citing Baker Dep. at 16-17). The Court then concluded that this amount "is too small to impact this Court's determination that cardiac devices do not replace a missing part of the body." Id.

The facts in the record, including Dr. Baker's deposition testimony and his affidavit (which was submitted as Ex. D to Roper's Amended Motion for Summary Judgment), support the opposite conclusion. First, in the deposition testimony cited in the Order, Dr. Baker was addressing how often he removes an *entire area* of the heart such as the sinus node (1% or less of his cases) and the AV node (5-10% of his cases), not how often he removes or replaces heart tissue generally. See Baker Dep. at 16:18- 17:11. Dr. Baker further explained that while it would be difficult to prove that "completely every single cell from a particular area of the heart's electrical system [such as the sinus node or the AV node] is gone in a patient's electrical system . . . , I think that -- have you lost tissue, the answer is yes." Baker Dep. at 22:23- 23:2. He further stated in his affidavit that the cardiac devices at issue replace missing cardiac tissue that has degenerated over time. Baker Aff at ¶6. This testimony by Dr. Baker was uncontested as SCDOR presented no testimony or evidence that would show that the cardiac devices do not replace missing heart tissue. A device that replaces missing tissue is by definition replacing a missing part of the body. Just as the ALC found that "other tissue"

implants replace a missing part of the body (see Order at p. 13), so it should find that the cardiac devices that replace missing cardiac tissue also replace a missing part of the body.¹

Based on the foregoing, Roper respectfully requests that the ALC (1) reconsider the undisputed facts discussed above and find that the cardiac devices at issue replace a missing part of the body; and (2) alter or amend its Order to so find. In the alternative, if the ALC believes that there is evidence to support the conclusion that the cardiac devices do not replace a missing part of the body, then, based on Dr. Baker's testimony to the contrary, there is at least a disputed issue of fact on this issue. In that event, summary judgment would not be appropriate, Roper would be entitled to a contested case hearing on this issue, and the ALC should alter or amend its Order accordingly.

B. The ALC Should Have Concluded that the Sale of Blood and Products Derived from Blood are Not Taxable Under the Sales and Use Tax Statute Because They are Non-Taxable Services.

The ALC should have concluded that blood and blood products are not taxable under the sales and use tax statute because they are non-taxable services. However, the ALC concluded that such sales were sales of tangible personal property that were subject to sale and use tax. Roper respectfully requests that the ALC reconsider this issue as set forth below.

First, the ALC does not appear to have considered this issue in light of the proper standard. The taxation of the blood proteins at issue is one of imposition of tax or coverage and not of exemption. As such, the imposition statute should be narrowly construed against the imposition of the tax and liberally construed in favor of the taxpayer. Clark v. S.C. Tax

¹ Petitioner would note that Dr. Baker did testify that less than 1% of his patients have defective heart cells versus missing cells, which means that less than 1% of his patients receive cardiac devices that would replace a missing function versus a missing part of the body. See Baker Aff. at ¶7. This de minimus amount should not alter this conclusion.

Comm'n, 259 S.C. 161, 191 S.E.2d 23 (1972) (holding that "[r]evenue laws are generally construed in favor of the taxpayer and against the taxing authority"); Taylor v. Aiken County Assessor, 402 S.C. 559, 741 S.E.2d 31 (Ct. App. 2013) (same). When this standard is applied, it is clear that the blood proteins at issue are not included in the coverage of the sales and use tax statute for all the reasons set forth in Roper's Amended Motion for Summary Judgment.

Additionally, the Court may not have fully considered all of Roper's arguments as to why blood and products derived from blood are sales of services, which are generally not taxed (see S.C. Code Reg. 117-308), versus sales of tangible personal property, which are subject to sales and use tax. One basis for Roper's argument is that such sales are defined as sales of services in the Revised Uniform Anatomical Gift Act ("RUAGA"), also known as the blood shield statute, which is located at S.C. Code Ann. § 44-43-10. Roper's Motion at p. 14. The ALC rejected this argument finding that the blood shield statute "cannot be taken out of context of tort liability and applied to a tax situation." Order at p. 16. While Roper may not agree with the Court's conclusion on this point, Roper made another argument in support of its position, which the ALC may not have fully considered as it is not addressed in the Order.

More specifically, Roper argued that sales of blood and blood products would be considered sales of services under the "true object" test, under which the treatment of professional, personal and other services is evaluated by considering what the "true object" of the service is— obtaining an item of tangible personal property or obtaining a professional service. See S.C. Rev. Ruling 93-4. In the case at hand, sales of blood and products derived from blood are clearly sales of medical services. The "true object" of the purchaser is to obtain the services of a licensed physician and not to obtain the tangible blood or blood product. As a

result, the sale of blood and blood products are sales of medical services (not otherwise identified as taxable as a sale at retail or as an exception to the general rule that services are not taxable) and would not be included in the coverage of the sales and use tax statute.

This conclusion is supported by current SCDOR policies and practices as to all blood and blood products except for blood proteins. SCDOR does not currently tax whole blood, red blood cells, platelets or plasma. See Amended Motion for Summary Judgment at Ex. G, Buddin Dep. at 34:12-25. The reason given by SCDOR for treating blood proteins differently is that it mistakenly believes that blood proteins are "manufactured." As made clear in Roper's Amended Motion for Summary Judgment, Dr. Daud Nawabi's testimony supporting same and Roper's Proposed Order, there is no medical or scientific basis for SCDOR's disparate treatment of these items. See Roper Amended Motion for Summary Judgment at 15-16 and Ex. E attached thereto (Nawabi Aff.) and Roper Proposed Order at 19-20. It is not clear that the ALC considered any of this testimony or evidence, which further supports the correct interpretation of the sale of blood and blood products as being a non-taxable service.

Further, the ALC appears to mistakenly believe that SCDOR has "adopted the unofficial policy that blood and its derivatives are tangible personal property" since 1992 or has "consistently taxed blood derivatives in practice, even if it does not have an official policy governing the taxation of blood derivatives." Order at p. 15. The ALC then gives deference to SCDOR's interpretation of sales of blood and blood products as being sales of tangible personal property versus services based on this finding. Id. However, this finding is not supported by the evidence in the record, which showed that SCDOR had no such policy and was not consistently taxing blood derivatives at least as late as 2002. See Ex. H to Roper's

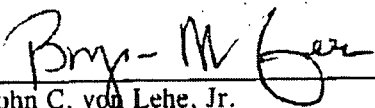
Amended MSJ, Email Correspondence 000048-000050. Thus, no deference should have been accorded to SCDOR's interpretation.

Based on the above, Roper respectfully requests that the ALC (1) reconsider the above discussed evidence, arguments and law; and (2) alter or amend its Order to find that Roper established that the blood proteins at issue are not taxable.

CONCLUSION

Based on the foregoing, Roper respectfully requests that the ALC reconsider its rulings and alter or amend its Order to find in favor of Roper on the above issues.

NELSON MULLINS RILEY & SCARBOROUGH LLP

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Attorneys for CareAlliance Health Services d/b/a Roper St.
Francis Healthcare

Charleston, South Carolina
May 30, 2014

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:

**MOTION FOR RECONSIDERATION UNDER ALC RULE
29(D) AND/OR TO ALTER OR AMEND UNDER SCRCF
RULE 59(E)**

Counsel Served:

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Lydia Spry
Administrative Assistant

May 30, 2014



FILED

MAY 20 2014

**STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT**

SC ADMIN. LAW COURT

CareAlliance Health Services d/b/a, Roper)
St. Francis Medical Healthcare, Inc.,)

Docket No.: 12-AIJ-17-0405-CC

Petitioner,)

v.)

ORDER

South Carolina Department of Revenue,)

Respondent.)

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, Burninate, 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

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)).

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

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 Daconess 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**.

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.

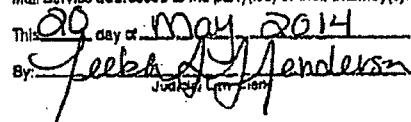
¹⁷ Because the devices are not exempt from the sales tax, they are also subject to the use tax. See S.C. Code Ann. § 12-36-1310.

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 Emergency
Mail Service addressed to the party(ies) or their attorney(s).

This 20 day of May, 2014
By: 
Jeeba A. Henderson
Judicial Law Clerk

**9STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT**

CareAlliance Health Services,	)	Docket No. 12-ALJ-17-0405-CC
d/b/a Roper/St. Francis Medical	)	
Healthcare, Inc.,	)	
	)	
Petitioner,	)	NOTICE OF MOTION
	)	AND MOTION FOR
	)	RECONSIDERATION
	)	PURSUANT TO ALC RULE
vs.	)	29(D), ALC RULE 68, AND
	)	TO ALTER OR AMEND
	)	PURSUANT TO RULE
	)	59(e), SCRCP
South Carolina Department of Revenue,	)	
	)	
Respondent.	)	

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 South Carolina Department of Revenue (Department), pursuant to ALC Rule 29(D), ALC Rule 68, and Rule 59(e), SCRCP, respectfully move this Court to reconsider its Order on Motions for Summary Judgment (Order), dated May 20, 2014, in the above-referenced action and to uphold the Department's Final Agency Determination which denied refund requests on sales taxes paid by the Petitioner on its purchases of certain items, to wit: orthopedic and cardiovascular prosthetic devices, and certain blood derivatives being Gamunex, Plasbumin, Albumin, Albutein, Buminate, Flexbumin, Octagam, Alburx and Albuminar. Written notice of the entry of the Order was received by the Department on May 20, 2014. The grounds for such requested relief are as follows:

- I. This Court properly adopted the three-part test pursuant to Home Medical Systems, Inc. v. South Carolina Dep't of Revenue, 382 S.C. 556, 677 S.E.2d 582 (2009) and S.C. Rev. Rul. # 03-02 (2003) and # 11-3 (2011), but erred in failing to address or apply the first prong that the "sale must require a prescription."

In Home Medical, our Supreme Court clarified the exemption found in S.C. Code Ann. § 12-36-2120(28)(a) (2014) by adopting the rationale contained in the Department's Rev. Rul. # 03-2. Specifically, the Court stated 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 and the device must replace a missing part of the body." Home Medical Systems, Inc. v. South Carolina Dep't of Revenue, 382 S.C. 556, 564, 677 S.E.2d 582, 587 (2009) (citing S.C. Rev. Rul. # 03-02 (2003) (emphasis added)). It logically follows, therefore, that the exemption only applies to sales transactions involving a purchaser that is required to use a prescription in order to obtain the device.¹ This Court properly recognizes the three elements of the test in its Order,² but failed to apply the first prong to the transaction at issue here – a sale between a hospital and a manufacturer.

¹Quoting S.C. Rev. Rul. # 03-2, the Home Medical Court examined this same language – "the sale must require a prescription" – in the context of the companion exemption for "medicines sold by prescription." The Court held that "in order for this 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" Home Medical, 382 S.C. at 564 (emphasis added). The issue in that case was whether or not over-the-counter medicines could qualify for the exemption such that the Court focused on the prong "the medicine must be of a type that requires a prescription." Significantly, this means that the second prong "the sale must require a prescription" focuses not on the type of item purchased, but instead whether a prescription must be produced in order to effectuate the sale. There are no "over-the-counter" surgically implantable prosthetics, and thus this case should turn upon whether or not a hospital must produce a prescription before making the purchases at issue.

²See Order of the Honorable Shirley C. Robinson, dated May 20, 2014 at p. 5.

From the outset of this controversy, the cornerstone of the Department's entire case has been that hospitals and medical providers are not required to have a prescription to purchase prescription items. From morphine to X-ray machines to prosthetic devices, a medical provider has the legal ability to purchase items the general public cannot in order to practice medicine. This argument was supported by relevant statutes, jurisprudence (including Home Medical), administrative guidance, the long standing practice of the Department, and most importantly by the Affidavit of Stephen Silverman, the acting Director of Compliance of the Center for Devices and Radiological Health at the U.S. Food and Drug Administration. This Court erred in failing to rule on the issue regarding the actual transaction between the manufacturer and hospital requiring a prescription and did not address the first prong of the Home Medical test in its Order.

It appears from the Order that this prong was overlooked because the parties stipulated that the devices at issue are FDA regulated Class II and III prescription devices;³ however, that stipulation only addresses the type of device at issue and does not mean a prescription is always required for the sale of the devices. Interestingly enough, in analyzing the second prong of whether or not the prosthetics were "actually sold by prescription," this Court actually arrives at the proper legal conclusion regarding the first prong of the Home Medical test, but fails to apply it. This Court acknowledges in its Order that "a sale to a hospital is not *de facto* a 'sale by prescription,' . . . [b]ecause

³See Order at 5 ("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.'").

federal law does not require a strict 'sale by prescription.'"⁴ The Order goes on to confirm the Home Medical holding, which "implies prescription devices can be sold without a prescription under some circumstances"⁵ A reading of those sentences should unequivocally result in the conclusion that transactions to purchase prosthetic devices do not always require a prescription. Furthermore, by correctly rejecting the Petitioner's contention that 21 C.F.R. § 801.109(a)(2) somehow restricts all sales of the devices at issue to a transaction requiring prescriptions, this Court's Order inherently acknowledges that these transactions do not necessarily "require" a prescription and thus do not squarely fit within the exemption found in § 12-36-2120(28). The Department presented copious amounts of evidence indicating that there exists no legal requirement of a hospital to furnish a prescription in order to make the purchases at issue; consequently, this Court erred in failing to rule that the Petitioner's purchases did not require a prescription and thus, did not meet the first prong of the Home Medical test.

This logic is further supported by this Court's own analysis regarding the trauma devices that are purchased by the hospital without prescriptions. The ability of the hospital to purchase prescription devices in bulk begs the question as to whether a hospital would ever be required to have a patient-specific prescription before it could make a purchase of these devices. This Court correctly agreed with the public policy concerns expressed by the FDA's Director of Compliance, Stephen Silverman, who underscored the absurdity of requiring hospitals and doctors to have prescriptions to

⁴Id. at 6 (emphasis added).

⁵Id. at 7.

purchase prescription items⁶ by declaring that it would undermine the needs of emergency care providers to deny hospitals the ability to purchase restricted items as they see fit. Although Director Silverman's clear rationale is noted in its Order, the Court failed to apply his reasoning to the first prong of the Home Medical test.

The choice the Petitioner has made in buying some prosthetics in bulk and some on a per-patient basis⁷ does not alter its legal ability to buy any prosthetic it needs in bulk and without patient-specific prescriptions. This point was validated by Melanie Hutcherson, a national sales manager for Zimmer, Inc. (one of the manufacturers often used by the Petitioner), who explained that hospitals could keep an inventory of the reconstructive prosthetic devices if they so choose, but because the sales representatives are so accommodating many hospitals do not. Hutcherson Dep. 15:18-23. The distinction made by this Court between "a sale related to a particular individual and a bulk sale to a medical provider" inherently confirms the Department's position that the sale of devices to a hospital does not necessarily require a prescription. The prescription items purchased in bulk for trauma patients are governed by the exact same laws as the reconstructive prosthetics. Nothing under those laws requires the hospital to purchase reconstructive prosthetics with prescriptions while lifting that requirement for trauma

⁶It is important to further clarify that while the parties stipulated that all of the prosthetics at issue are "prescription items," that label is specifically aimed at protections for the sale of these items to the general public – the mission of the FDA.

⁷When asked what documentation the Petitioner sends to the manufacturers Scott Ferguson, the Director of Material Services for the Hospital stated that the Petitioner only 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.

prosthetics. There is absolutely no appreciable legal difference between a heart valve and a knee replacement as it relates to the ability of a hospital to purchase them, and the Petitioner failed to provide one statute, regulation, or case that would suggest otherwise.

In addition, because our sales tax is considered a "transactional tax," this Court erred in holding that it "does not find it determinative that the hospital, and not the patient, pays the bill for the prescription prosthetic."⁸ It is inappropriate to conflate the transaction between the hospital and manufacturer – which is statutorily defined as a retail sale – and the separate transaction between the patient and hospital – which is an untaxable exchange for medical services. It should be absolutely determinative who the seller and purchaser are in a transactional tax, and because the purchaser in this case is a hospital and does not require a prescription to purchase these devices. As such, the sales tax exemption simply does not apply.

Finally, it is also statutorily established in South Carolina that the transaction between the hospital and the device manufacturers does not require a prescription. Pursuant to S.C. Code Ann. § 40-43-60(H) (2011) a licensed practitioner has unfettered access 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.

⁸Order at 11.

By virtue of a medical license, 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 clear that a prescription is not required for a physician to purchase any prosthetic devices, and this Court erred in failing to rule that the prosthetics purchased by the Petitioner are not exempt from sales tax since the sales transactions at issue do not require a prescription and fail the first prong of the Home Medical test.

- II. This Court erred in adopting its own broad definition of “prescription” as it disregards the clear limitations dictated by Home Medical related to written orders by physicians, and does not comport with the applicable South Carolina and Federal Law.**

This Court’s decision to seek guidance from other jurisdictions to determine the definition of “prescription” was inappropriate, as the adoption of the broad result, “a written order prescribing a certain medicine or prosthetic for a particular patient” does not comply with the Supreme Court’s limitation of the term in Home Medical. Our Supreme Court specifically held that a Certificate of Medical Need⁹ was not a “prescription” despite the fact that it was a written memorialization of a doctor’s intended treatment for a patient, ostensibly because it was nothing more than a document used to secure federal subsidy as payment. In this case, the requisition sheet created after the surgical implant of the prosthetics at issue is also nothing more than a document used for

⁹In Home Medical the Petitioner sold the items to its customers in transactions where the customer had a Certificate of Medical Necessity (CMN) signed by a physician setting forth the customer's diagnosis and medical necessity for the item. A CMN is a standard form document used by Medicare and Medicaid and contains a narrative description of all items, accessories and options ordered by a physician for a patient, as well as an attestation by the physician as to the medical necessity of such items, accessories and options.

payment purposes, and should not qualify as a prescription under the exemption.

Indeed, this Court's decision to overlook the South Carolina Pharmacy Practice Act should be reconsidered, as the definitions promulgated by the Board of Pharmacy, the agency charged with administering the law related to prescriptions, should have been determinative. Brown v. S.C. Dep't of Health & Env'tl. 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). This Court's recognition that the Supreme Court chose to disregard the Pharmacy Practice Act in Home Medical is accurate; however, this Court did not follow that holding to its logical end. In Home Medical, the definition of "medicine" was made a part of Title 12, promulgated under S.C. Code Ann. Regs. § 117-332 (Supp. 2008). Under the rules of statutory construction, that tax regulation would control in matters of taxation. In this case, however, there exists no legal definition of "prescription" under Title 12 or its accompanying regulations. To that extent, the Home Medical decision does not stand for the proposition that this Court cannot look to other titles for instructive definitional analysis. Furthermore, despite the fact that the Department's Rev. Rul. # 11-3 (superseding # 03-2) was issued *after* the Home Medical decision and incorporated its reasoning, this Court's decision to decline to follow its rationale as "conclusory and without support"¹⁰ ignores the jurisprudential basis for the conclusions therein.

¹⁰Order at 8.

This Court further erred in failing to rule upon the Department's argument concerning the legal distinction between a "prescription" and a "chart order," which are two separate legal terms under South Carolina law and also under the applicable Federal Regulations.¹¹ In this case, the conduct of the Petitioner's operating physician is more appropriately deemed a "chart order," and a mere requisition sheet completed well after the surgery takes place does not constitute a proper memorialization of a "prescription" pursuant to Home Medical.

Regardless of whether or not this Court adopts the Pharmacy Practice Act's definitions or not, the reliance on extraterritorial cases to determine its definition of a "sale by prescription" was in error. In Northern Virginia Doctors Hospital Corp. v. Department of Taxation, 193 S.E.2d 684 (Va. 1973), the Court was asked to determine whether or not a sales tax exemption for "[m]edicines, drugs . . . prosthetic devices and orthopedic appliances dispensed or sold on prescriptions or work orders of licensed physicians." Id. at 687 (emphasis added.). First, it should be noted that the Northern Virginia court did look to other code sections, specifically the Virginia "Drug Control Act" to arrive at its definition of "prescription." However, in that court's analysis, it declined to determine explicitly whether the process indicated by the taxpayer was a prescription, rather it simply held that "the procedure outlined constitutes a sale on prescription or a work order of a physician." Id. at 688 (emphasis added). This conclusion was due to the fact that the Virginia statute was far more expansive than South Carolina's, as all "work orders" would also qualify for the exemption. Conversely, South Carolina does not exempt prosthetics sold by "work orders," and thus.

¹¹See Respondent's Mot. For Summ. J. at 14-16.

reliance on that case by this Court was misplaced.

This Court also relied upon Syncor Intern. Corp. v. Palmer, 542 S.E.2d 479 (W.V. 2001) to arrive at its conclusion. Once again, this case should be considered unpersuasive authority, as the West Virginia exemption at issue applied to radiopharmaceuticals "dispensed upon prescription." First, radiopharmaceuticals are regulated under entirely different laws than prosthetic devices throughout the country, including South Carolina, and those laws absolutely require patient-specific prescriptions before the drug can leave the compounding pharmacy.¹² Second, and more importantly for our purposes, South Carolina's exemption only applies to the "sale" of the prosthetics and not the actual dispensing or use of the item. Because there is a clear sale of the prosthetic to the hospital at issue here, which is separate and distinct from the transaction between the hospital and patient for the services provided by dispensing the prosthetic, the Syncor holding is wholly inapplicable.

Finally, this Court relies upon Deaconess Medical Center v. Department of Revenue, 795 P.2d 146 (Wash. Ct. App. 1990), which is also completely distinguishable. The exemption at issue in that case broadly applied to "sales of drugs for human use dispensed or to be dispensed to patients, pursuant to a prescription." Wash. Rev. Code Ann. § 82.08.0281(1) (emphasis added). The phrase "to be dispensed" adds an open ended expansion which would encompass purchases made by medical providers without specific patients in mind or a need for prescriptions. As such, this Court's use of that decision as guidance is inappropriate.

¹²See S.C. Code Ann. § 40-43-86 (2014).

The distinguishable nature of Virginia, West Virginia, and Washington's statutes related to the sales exemptions at issue are readily apparent, and this Court's use of those cases to craft its own definition of "sale by prescription" was improper. To that extent, the relevant South Carolina law, specifically the Pharmacy Practice Act, should have been considered, at a minimum, as persuasive authority in order to arrive at the proper definition of "prescription." Furthermore, the finding that the requisition sheet is satisfactory as a memorialization of a prescription does not comport with the limitations related to CMN's found in Home Medical. Finally, this Court's decision to overlook the Department's "chart order" argument was in error.

III. This Court erred in ruling that the "other bone, muscle and tissue implants" replace a missing part of the body, as no evidence was presented to support such a conclusion.

It is well settled law 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."). More importantly, our case law dictates that the burden is on claimants to prove their rights to an exemption by bringing themselves clearly within the conditions imposed by the statute. TNS Mills, Inc. v. S. Carolina Dep't of Revenue, 331 S.C. 611, 618, 503 S.E.2d 471, 475 (1998) (citing York County Fair Assoc. v. South Carolina Tax Comm'n, 249 S.C. 337, 341, 154 S.E.2d 361, 363 (1967)); see also Asmer v. Livingston, 225 S.C. 341, 82 S.E.2d 465, 466 (1954) (a refund of taxes is solely a matter of governmental grace, and taxpayers seeking such relief must bring themselves clearly within the terms of the statute authorizing a refund).

The Petitioner in this case presented no evidence – no statutes, no cases, no documentary proof, no affidavits and not a single deposition question answered – to establish that any of the other devices fell within the definitional parameters of the sales tax exemption. In fact, even now, the Department is without sufficient facts to articulate what these broad “catch all” categories of devices would include. This Court recognized that the Department took issue with these “other” devices in its Conclusions of Fact, but took no notice of the complete dearth of evidence presented to describe them.¹³ It is invariably unclear whether these devices replace a part or simply aid in failing body functions, and, therefore, such devices cannot be said to fit squarely into the exemption at issue. In a *sua sponte* conclusory sentence, this Court holds that the “other bone, muscle, and tissue implants replace missing parts of the body.”¹⁴ This conclusion is erroneous as not one fact was presented by the Petitioner to support it. The Petitioner failed to meet its burden as to these “catch all” categories of devices, and as such the Court erred in finding them exempt from sales tax.

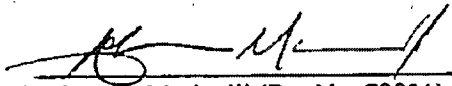
Conclusion

On these grounds, the Respondent respectfully requests that this Court rule upon the issues raised but not ruled upon in its Order and to reconsider the conclusions referenced above pursuant to ALC Rule 29(D), ALC Rule 68, and Rule 59(e), SCRCP.

¹³Order at 2.

¹⁴Order at 13.

Respectfully submitted,

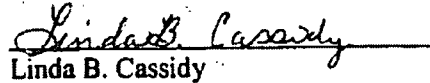


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PROOF OF SERVICE

I, Linda B. Cassidy, do hereby certify that I have caused to be mailed postage pre-paid, a copy of the Respondent's Notice of Motion and Motion for Reconsideration Pursuant to ALC Rule 29(D), ALC Rule 68 and to Alter or Amend Pursuant to Rule 59(e), SCRCF in re: CareAlliance Health Services, d/b/a Roper/St. Frances Medical Healthcare, Inc. v. South Carolina Department of Revenue, Docket No. 12-ALJ-17-0405-CC to Raymond Carpenter, Esquire, 625 Colonial Park Drive, Suite 201, Roswell, GA 30075, John Von Lehe, Esquire and Bryson M. Geer, Esquire, Nelson Mullins Riley & Scarborough LLP, 151 Meeting Street, Sixth Floor, Charleston, SC 29401-2239 this 30th day of May 2014.


Linda B. Cassidy

STATE OF SOUTH CAROLINA

ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a Roper	)	Civil Action No. 12-ALJ-17-0405-CC
St. Francis Healthcare,	)	
	)	
Petitioner,	)	
	)	
vs.	)	<u>PETITIONER'S RESPONSE TO</u>
	)	<u>RESPONDENT'S MOTION FOR</u>
South Carolina Department of Revenue,	)	<u>RECONSIDERATION AND TO</u>
	)	<u>ALTER OR AMEND</u>
Respondent.	)	
	)	

Pursuant to Rule 29(D) of the South Carolina Rules of Procedure for the Administrative Law Court ("ALC") and Rule 59(e) of the South Carolina Rules of Civil Procedure, Petitioner CareAlliance Health Services d/b/a Roper St. Francis Healthcare ("Petitioner" or "Roper") hereby responds to the Notice of Motion and Motion for Reconsideration Pursuant to ALC Rule 29(D), ALC Rule 68, and to Alter or Amend Pursuant to Rule 59(e) ("Motion for Reconsideration") filed by the South Carolina Department of Revenue ("Respondent" or "SCDOR") in this matter regarding the ALC's Order dated May 20, 2014 (the "Order"), which granted in part and denied in part cross motions for summary judgment filed by Petitioner and Respondent.

I. The ALC Correctly Held that the Sales of the Orthopedic and Cardiac Devices at Issue Required a Prescription.

In its Motion for Reconsideration, SCDOR argues that the ALC properly adopted the three-part test set forth in Revenue Ruling #03-2 (as well as #11-3) for determining whether a device qualifies as a "sale by prescription," but that it erred in failing to address or apply the

prong that "the sale must require a prescription."¹ See SCDOR's Motion for Reconsideration at 2. To the contrary, the ALC properly analyzed this issue and reached the correct conclusion that the sales of orthopedic and cardiac devices at issue required a prescription.

As even SCDOR's Food and Drug Administration ("FDA") expert agrees, the relevant FDA regulations exempt prescription prosthetic devices from labeling requirements when the device is:

- 1) 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; and
- 2) Is to be sold only to or on the prescription or order of such practitioner for use in the course of his professional practice.

See 21 C.F.R. § 801.109(a); see also Steven D. Silverman Aff. at ¶ 6.

In the case at hand, each sales transaction at issue takes place in a Roper hospital operating room. John McCrosson, M.D. Dep. dated 6/13/13 ("McCrosson Dep.") at 13:2-17 and 44:1- 45:10; Bret M. Baker, M.D. Dep. dated 7/2/13 ("Baker Dep.") at 15:20- 17:12. When the manufacturer's representative brings the device to the operating room, it is owned by and in the possession of the manufacturer's representative (see Charles Prescott Ferguson Dep. dated 3/29/13 ("Ferguson Dep.") at 11:18- 12:5; Baker Dep. at 15:20- 17:12), who is "in the business of the manufacturing, transportation, storage, or wholesale or retail distribution of such devices." The manufacturer's representative then hands the device over for sale to the hospital upon the oral order or prescription of a physician. McCrosson Dep. at 13:2-17 and 44:1- 45:10; and Baker Dep. at 15:20- 17:12. The regulation very clearly requires this order or prescription of the physician for a sale to take place under these circumstances. See 21

¹ The entire 3-part test is as follows: (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. See S.C. Rev. Ruling #11-3.

C.F.R. § 801.109(a). It is inconceivable that the law, regulations, or the practice of the FDA would allow the particular sales in question to take place without the order of a physician. If the physician was not present in the operating room to select and order the prosthetic device at the time of its sale to the hospital, it is clear that these sales would not and could not take place.² Thus, Petitioner meets the element that a prescription is required for this sale.

SCDOR points to Steven D. Silverman's affidavit as support for its suggestion that no prescription is required. As an initial matter, at the start of the hearing, the ALC denied Petitioner's Motion to Exclude Mr. Silverman's affidavit³ at least in so far as SCDOR was submitting it in response to Petitioner's Amended Motion for Summary Judgment (see 10/1/13 Hearing Tr. at 6-7). However, the ALC later expressed concern about SCDOR's heavy reliance on the affidavit and the fact that Petitioner had not been able to cross-examine him. In response to these concerns, SCDOR stated that the ALC could "remove his affidavit from the record," that it was "immaterial," and that the Court need only consider the law. Id. at 84-85. Petitioner agrees that the Silverman affidavit should be removed from the record and is immaterial and that this Court should only consider the law.

More specifically as to why it is immaterial and irrelevant, the Silverman affidavit does not address or relate to the facts of this case. First, the affidavit appears to only address bulk

² For example, if no physician was in the operating room and a nurse told the manufacturer's representative to go ahead and hand it over, the representative would be in clear violation of the federal regulations to give it to the nurse with no order from a physician to do so.

³ The basis for Petitioner's Motion to Exclude was that SCDOR had not named Mr. Silverman as a witness in the case, did not file his affidavit with its motion for summary judgment, did not file it at all until one week before the hearing and had acknowledged that Mr. Silverman was most likely unavailable for cross examination even if the case went to trial. As a result, Petitioner argued that the admission of this affidavit would be highly prejudicial to Roper and would violate its due process rights. See Motion to Exclude Silverman.

sales to hospitals where the hospital is purchasing and storing prescription devices for later use.⁴ In this case, the orthopedic and cardiac devices at issue are in the possession of the manufacturer and then sold individually to the hospital for immediate use upon the order or prescription of the physician. The devices are not purchased in bulk on the order of a physician and then stored by the hospital for later use by a physician upon his order.⁵ Thus, these purchases clearly require a physician's order under 21 C.F.R. § 801.109(a). To view the regulation or Mr. Silverman's affidavit as allowing manufacturers to sell a prescription device willy nilly to anyone in a hospital who asked for one would completely eviscerate the protections put in place by the FDA regulations, which place the physician in the role of "gatekeeper" of prescription devices to protect the public from harm.

Additionally, the affidavit does not even state that it applies to the items that are at issue in the case, namely *Class II* and *Class III* prescription *prosthetic* devices. Instead, it only states that it relates to "prescription devices". See Silverman Aff. at ¶¶6-7. While the pharmacy of a properly licensed health care facility, through its pharmacist, can order prescription devices that may only be dispensed upon prescription, no such items are at issue here. Thus, Mr. Silverman's affidavit is simply not applicable to the facts of this case.

SCDOR also points to the ALC's statement that the holding in Home Medical Systems, Inc. v. South Carolina Dept. of Rev., 382 S.C. 556, 677 S.E.2d 582 (2009) "implies

⁴ See Silverman Aff. at ¶6-7 (stating that under 21 C.F.R. § 801.109(a), hospitals "may purchase and store prescription devices, provided that they are ultimately to be used on or distributed to patients by a physician or pursuant to a prescription or order of a physician" and stating that nothing in the Act or its regulations prohibits device manufacturers from selling prescription devices in bulk to hospitals for later use by a physician on a patient pursuant to a prescription or order).

⁵ Petitioner argued that the bulk sales also required a prescription, which Petitioner still believes is correct under the relevant law as set forth in its Am. Motion for Summary Judgment at 9-12, but the ALC disagreed. Order at 12.

prescription devices can be sold without a prescription under some circumstances" and argues that this should "unequivocally result in the conclusion that transactions to purchase prosthetic devices do not always require a prescription." SCDOR's Motion at 4. However, if SCDOR agrees that Home Medical implies that devices can be sold without a prescription under some circumstances, then it must also agree that it implies the converse, i.e. certain sales to hospitals do require a prescription. SCDOR fails to address or explain this at all and is asking the ALC to assume that no sales of prescription devices to hospitals ever require a prescription. There is no support for this conclusion under Home Medical or other South Carolina law and certainly not under federal law.

SCDOR then argues that the ALC erred by conflating the transaction between the hospital and the manufacturer with the transaction between the patient and the hospital. The ALC made no such error, and as explained in depth in prior briefing, SCDOR's implied suggestion by this argument that sales to hospitals can never be exempt is simply not true. See S.C. Rev. Ruling #98-9 (stating that once it is established that a sale to a hospital is a retail sale, then one must determine whether the items in question come within an exemption); Petitioner's Memorandum in Opposition to Respondent's Motion for Summary Judgment ("Petitioner's Opposition to Respondent's MSJ") at 3 (for full discussion of this issue) and 12-14 (for discussion of Judge Timmerman's conclusions of law in Boykin v. South Carolina Tax Comm'n, Case no. 1989-CP-0200590, Aiken Co. Court of Common Pleas (an unappealed decision), in which he can find "no credible construction of the statute which restricts, in any manner, the person who are intended to benefit from this exemption" and finding that the work authorizations at issue were prescriptions for purposes of the sales tax exemption statute.

Finally, SCDOR asserts that S.C. Code §40-43-60(H)⁶ establishes that a transaction between a hospital and a manufacturer does not require a prescription. As set forth in detail in prior briefing, this argument is without merit as this code section addresses only *possession* and *administration* by *physicians* not the *purchase* of devices by *hospitals*, and the SCDOR's mis-reading of the statute is contrary to federal law and to the testimony of Petitioner's expert on FDA regulations. See Petitioner's Amended Motion for Summary Judgment ("Petitioner's Am. MSJ") at 9-11 and Petitioner's Opposition to Respondent's MSJ at 4-6.

In sum, the ALC correctly concluded that under the facts of this case, prescriptions are required for the individual sales of the prescription orthopedic and cardiac devices by the manufacturer's representative to the hospital that take place in the operating room upon the physicians' orders, and the ALC should deny SCDOR's Motion for Reconsideration on this issue.

II. The Court Correctly Found that the Oral Orders of the Physicians for the Orthopedic and Cardiac Devices, which were Subsequently Memorialized, Constituted Prescriptions.

SCDOR argues that the ALC adopted an inappropriate definition of prescription, which the ALC defined as "a written order prescribing a certain medication or prosthetic for a particular patient." See SCDOR Motion for Reconsideration at 7-8; Order at 11.⁷ SCDOR first argues that this definition does not comply with the Home Medical decision. SCDOR Motion for Reconsideration at

⁶ The provision reads in full as follows: "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." S.C. Code Ann. §40-43-60(H).

⁷ Petitioner would note that its position continues to be that no written order is necessary and that an oral order is sufficient for all the reasons set forth in its prior briefing. See Petitioner's Am. MSJ at 11-12; Petitioner's Opposition to Respondent's MSJ at 8-11; Petitioner's Reply to Respondent's Response to its Am. MSJ at 2-3.

7-8. Petitioner addressed this argument in depth in prior briefing, but suffice it to say that Home Medical, which was addressing whether Certificates of Medical Necessity ("CMNs") for certain durable medical equipment (which are neither prescription nor prosthetic devices) were equivalent to prescriptions, does not apply to the facts of this case in which neither CMNs or durable medical equipment are at issue. Obviously, the laws and regulations governing wheelchairs are and would be expected to be far different than those controlling the sale of implantable prosthetic devices. See Petitioner's Opposition to Respondent's MSJ at 11.

Next, SCDOR complains that the ALC did not adopt the definition of prescription in the South Carolina Pharmacy Act. SCDOR Motion for Reconsideration at p. 8. First and foremost, as the ALC correctly noted, Pharmacy Code definitions do not apply to the tax code. Home Medical Systems, Inc. v. South Carolina Dept. of Rev., 382 S.C. 556, 677 S.E.2d 582 (2009); S.C. Code Ann. §40-43-30 ("definitions contained herein are "[f]or purposes of this chapter"); Order at 6-7; Petitioner's Response to Respondent's MSJ at 8.

Even if the Pharmacy Code definitions did apply to the tax code, there are numerous other reasons why SCDOR's arguments are not persuasive, which are all discussed in detail in prior briefing. See Petitioner's Opposition to Respondent's MSJ at p. 8-11. Petitioner will briefly summarize the primary reasons below:

- Federal law preempts state law as to whether a prescription is required under the facts of this case in order for a hospital to purchase a prescription prosthetic device. As South Carolina has not obtained an exemption from these requirements, it therefore cannot now argue that the prescription devices at issue can be ordered in a manner not in keeping with those requirements. Petitioner's Opposition to Respondent's MSJ at 8-9 and McCormack Dep. at 93-94 (wherein SCDOR's Senior Administrator for Policy within the Office of General Counsel, Tax and Regulatory Services agrees that SCDOR does not set the requirements for devices to be sold by prescription and that that is done by other agencies).

- Although SCDOR is asking the ALC to adopt the definitions of the Pharmacy Code, the Pharmacy Code does not even define "sold by prescription" or a "prescription." Instead, the closest term defined by the Pharmacy Code, which governs permitting and regulations related to *pharmacies*, is a "prescription drug order", which is defined as simply "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. . . ." See S.C. Code Ann. §40-43-30(7); Petitioner's Opposition to Respondent's MSJ at 9-10.
- No prescription could be written for a prosthetic device that would meet the requirements of S.C. Code Ann. §40-43-86(E), which is clearly directed towards prescription drugs, as many of the requirements are simply inapplicable to devices (for example, number of re-fills, strength, dosage, etc.). To impose these rules on prosthetic devices would mean that they could never be exempt, which cannot be in accordance with legislative intent and would be inconsistent with SCDOR's own Revenue Ruling 11-3.⁸ Petitioner's Opposition to Respondent's MSJ at 10-11.

In sum, SCDOR's arguments that the ALC erred in not adopting the definition for "prescription" from the Pharmacy Code, particularly when that term is not even defined in the Pharmacy Code, has no merit, and the ALC should deny SCDOR's Motion for Reconsideration on this issue.

III. The Court Correctly Found that the "Other Bone, Muscle and Tissue Implants" Replace a Missing Part of the Body.

SCDOR's Motion for Reconsideration asserts that the ALC erred in finding that the other bone, muscle and tissue implants replace a missing part of the body because Petitioner did not present evidence to establish that these implants replace a missing part of the body. This argument is without merit as the ALC may make such a basic and logical conclusion under the facts of this case. There is no conceivable argument that a physician would implant bone, muscle or tissue into a patient if the patient was not missing some bone, muscle or tissue. Thus, the Court properly concluded that these implants replace a missing part of the body.

⁸ In SCDOR's Revenue Ruling #11-3, the example of an exempt sale is "*the sale of prescription lenses that replace a missing part of the eye . . . , as for example eyeglasses prescribed for a person whose natural lenses have been surgically removed.*" Eyeglasses would not require, *inter alia*, a number of refills, dosage form or instructions for use and yet the Department agrees their sale would be exempt.

CONCLUSION

For the foregoing reasons, the ALC should deny SCDOR's Motion for Reconsideration.

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Charleston, South Carolina
June 13, 2014

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:

**PETITIONER'S RESPONSE TO RESPONDENT'S MOTION
FOR RECONSIDERATION AND TO ALTER OR AMEND**

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Lydia Spry
Administrative Assistant

June 13, 2014

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a Roper	)	Civil Action No. 12-ALJ-17-0405-CC
St. Francis Healthcare,	)	
	)	
Petitioner,	)	<u>PETITIONER'S MEMORANDUM IN</u>
	)	<u>SUPPORT OF THE ALC</u>
vs.	)	<u>PROCEEDING WITH A HEARING</u>
	)	<u>ON THE ISSUES NOT APPEALED BY</u>
South Carolina Department of Revenue,	)	<u>RESPONDENT</u>
	)	
Respondent.	)	
	)	

In follow-up to the status conference on Friday, July 11, 2014, Roper CareAlliance Health Services d/b/a Roper St. Francis Healthcare ("Petitioner" or "Roper") submits this brief on the issue of whether the Administrative Law Court ("ALC") may move forward with matters not affected by the appeal filed by the South Carolina Department of Revenue ("Respondent" or "SCDOR"). For the reasons set forth below, Roper respectfully submits that the ALC may proceed with a hearing on the remaining issues in the case.

FACTUAL BACKGROUND

This is a sales and use tax matter involving the following issues: (1) whether the sale to Roper upon the lawful orders of physicians of prescription prosthetic devices (including orthopedic and cardiac devices implanted into the human body) are exempted from sales and use tax because they (a) qualify as having been "sold by prescription" under S.C. Code Ann. §12-36-2120 (28), and (b) replace a missing part of the body per S.C. Code Reg. § 117-332; and (2) whether the sale of blood derivatives is a sale of medical services versus a sale of tangible personal property and therefore not subject to the imposition of sales and use tax.

Both parties filed cross motions for summary judgment on all issues in this case. On May 20, 2014, the ALC issued an order (1) granting Roper's motion for summary as to the orthopedic prosthetic devices; (2) granting SCDOR's motion for summary judgment as to the cardiac prosthetic devices on the basis that they did not replace a missing part of the body; and (3) granting SCDOR's motion for summary judgment as to the blood derivatives (the "Summary Judgment Order"). Both parties then filed Rule 59 (e) motions for reconsideration and/or to alter or amend. On June 27, 2014, the ALC issued an order on these motions reaffirming its grant of summary judgment in favor of Roper on the orthopedic devices and granting Roper's motion to reconsider as to the cardiac devices and the blood derivatives (the "Reconsideration Order"). On these latter two issues, the ALC ruled that it would conduct a hearing on whether the cardiac devices replace a missing part of the body and whether the blood derivatives were not subject to sales tax. Reconsideration Order at 2. The practical effect of this order is to deny the parties' motions for summary judgment on these issues leaving them as remaining issues to be decided by the ALC following a hearing. The ALC subsequently sent correspondence indicating that it would like to schedule a hearing during the first week of September.

On July 3, 2014, SCDOR served a notice of appeal and attached both the Summary Judgment Order and the Reconsideration Order. The ALC then sent correspondence to the parties indicating that it was uncertain as what issues SCDOR was appealing and whether any remaining issues could go forward. During a subsequent status conference call with the ALC on July 11, 2014, counsel for SCDOR stated that it intended to appeal the ALC's ruling on the orthopedic devices but did not intend to appeal the blood derivatives issue. He stated that the Department had not yet made a decision as to whether it would be appealing the findings by

the ALC that the cardiac prosthetic devices qualify as "sold by prescription." During the call, Roper requested, and the ALC graciously granted, the opportunity to brief the issue of whether the remaining issues in the case may go forward in spite of the appeal of some issues in the case.

LEGAL ARGUMENT

A. The Lower Court May Proceed as to Matters Not Affected by the Appeal.

The law is clear that a partial appeal does *not* divest the trial court of jurisdiction over matters not affected by the appeal, and the automatic stay does *not* prevent the trial court from proceeding with those other matters. *See* Rule 205, SCACR ("Nothing in these Rules shall prohibit the lower court . . . from proceeding with matters not affected by the appeal."); Rule 241(a), SCACR ("The lower court . . . retains jurisdiction over matters not affected by the appeal"); *Bickerstaff v. Prevost*, 398 S.C. 231, 236, 727 S.E.2d 769, 772 (Ct. App. 2012) ("Pursuant to Rule 205, SCACR, '[u]pon the service of the notice of appeal, the appellate court shall have exclusive jurisdiction over the appeal,' but nothing shall prohibit the lower court from proceeding with matters not affected by the appeal. . . ."); *Tillman v. Oakes*, 398 S.C. 245, S.E.2d 45 (Ct. App. 2012) (same); *Jackson v. Speed*, 326 S.C. 289, 311, 486 S.E.2d 750, 761 (1997) (same).

In *Tillman v. Oakes*, the South Carolina Court of Appeals noted that "[t]he question of when a lower court may proceed with a case after one of its orders has been appealed can be a difficult one to answer." *Tillman*, 398 S.C. at 254, 728 S.E.2d at 50. The Court then explained that the lower court was mistaken in determining that an appeal of its order making a permanent change in custody and establishing permanent visitation rights stayed all matters between the parties. The Court of Appeals ruled that the lower court should have considered

whether the issue raised in a petition requesting a temporary suspension of one of the party's visitation rights based on events occurring after the appealed order was entered was "a matter affected by the appeal." *Tillman*, 398 S.C. at 256, 728 S.E.2d at 51. The Court held that it was not and that the lower court should have ruled on the petition. Similarly in *Jackson v. Speed*, the South Carolina Supreme Court held that the lower court could proceed to determine an attorney's fee award where the plaintiff had requested them prior to appeal by the defendants of the jury's verdict and the defendants had not appealed the propriety of an attorney's fee award. *Jackson*, 326 S.C. at 311, 486 S.E.2d at 761.

In this case, at the July 11th status conference, counsel for SCDOR stated that the Department intended to appeal the ALC's granting of summary judgment in favor of Roper on the orthopedic prosthetic devices and did not intend to appeal the blood derivatives issue. SCDOR had not yet decided whether to appeal the ALC's findings regarding the cardiac prosthetic devices, but one thing is clear-- SCDOR cannot appeal a finding regarding whether the cardiac devices replace a missing part of the body because the ALC has not yet made any such findings. Instead, the ALC ruled in the Order on the Motions for Reconsideration that it would grant a hearing on both that issue and the blood derivatives issue. Reconsideration Order at 2. The issue on appeal will be whether the orthopedic prosthetic devices at issue were sold by prescription and possibly, if SCDOR decides to pursue an appeal on an issue that has not been fully and finally decided, an appeal as to whether the cardiac prosthetic devices were sold by prescription. Neither of these issues affects in any way the lower court proceeding to make a determination on whether the cardiac devices replace a missing part of the body or whether the blood derivatives are not subject to sales tax.

B. The ALC Should Not Grant a Stay as to the Remaining Issues.

Because there is no stay of other issues or divestiture of jurisdiction, the only basis on which further proceedings on other issues before the ALC could be stayed is by SCDOR requesting and the ALC granting a motion for a complete stay—a motion that rests entirely in the discretion of the lower court and is not often granted. *City of Spartanburg v. Belk's Dept. Store of Clinton*, 199 S.C. 458, 20 S.E.2d 157, 167 (1942) (noting that in the absence of an automatic stay, the stay of a proceeding pending appeal “rests entirely within the discretion of the trial Judge”). Courts generally look at whether the issues are distinct and may also look at considerations of efficiency and judicial economy. For example, in *Hiott v. Contracting Services*, the South Carolina Supreme Court held that a trial court erred by staying a wife’s loss of consortium suit pending the resolution of her husband’s appeal of his personal injury action, the Court found that the two causes of action were entirely different and the outcome in one was not dependent on or dispositive of the other. *Hiott v. Contracting Services*, 276 S.C. 632, 281 S.E.2d 224 (1981), overruled in part on other grounds by *Edwards v. SunCom*, 369 S.C. 91, 631 S.E.2d 529 (2006). The substance of both suits in *Hiott* obviously arose from the same set of facts (the injury of Mr. Hiott), and while not dispositive of each other, the two causes of action have some of the same elements. For example, in both cases, a court would need to determine whether the defendant negligently caused the injury of Mr. Hiott; nevertheless, the Court determined that the loss of consortium claim could proceed.

Courts also examine whether the interests of efficiency are best served by continuing with proceedings on related cases or remaining issues in a case. *See, e.g., Briggins v. Elwood Tri, Inc.*, 2013 U.S. Dist. LEXIS 13457, *7-8 (N.D. Ala. Feb. 1, 2013) (finding “that judicial efficiency weighs against staying the district court proceedings” pending the appeal by certain

other defendants of their dismissal from the case); *Foster v. CEVA Freight, LLC*, 2012 U.S. Dist. LEXIS 108770, *12 (W.D.N.C. Aug. 3, 2012) (“[B]ecause the Court and parties have been preparing for and are scheduled to begin trial on August 20, 2012, the Court concludes that proceeding to trial as scheduled would be more efficient than staying this case pending interlocutory appeal. THEREFORE, the Court sua sponte denies a stay pending appeal.”); *Yost v. Stout*, 2007 U.S. Dist. Lexis 65988 (D. Kan. Sept. 5, 2007) (denying a motion to stay proceedings pending an interlocutory appeal of related issues, concluding that judicial economy was better served by the case proceeding); *Motorola Credit Corp. v. Uzan*, 282 F. Supp. 2d 133, 137-38 (S.D.N.Y. 2003) (“Given, as the Second Circuit has noted, that the purpose of any divestiture rule involving interlocutory appeals is to advance efficiency and judicial economy, not impede them, [] the situation presented thus required the Court to deny any stay and move forward with the litigation.”); *German Am. Capital Co. v. Brampton Plantation, LLC*, 2011 Bankr. Lexis 5331 (S.D. Ga. Bankr. Dec. 6, 2011) (finding it to be “in the interest of judicial economy to conduct the hearing” and denying a motion to stay pending appeal); *In re US Airways, Inc.*, 54 Bankr. Ct. Dec. 227, *8 (E.D. Va. Bankr. June 8, 2011) (“With respect to [judicial economy], the court, by separate order, has denied Ms. Holcombe’s request to stay all proceedings on the objection to her claim until the District Court rules on her interlocutory appeals.”).

In this case, the interests of judicial efficiency and economy are best served by moving forward with a hearing on the remaining issues in the case. Because all of the evidence to be considered on both issues is already in the record and all parties and the ALC are currently very familiar with the facts, issues and law in this matter, the hearing will take little time and effort for the parties to prepare and present the arguments on these issues and for the Court to

hear and rule upon these matters.¹ Roper estimates that the hearing could be completed in a few hours at most. Assuming the hearing could go forward the first week of September and the Court ruled shortly thereafter, all matters involved in this case could go up on appeal at approximately the same time and could be consolidated for appeal and heard together. Given that many if not most appeals take several years, this is highly preferable to having a piecemeal appeal where only the orthopedic devices issue is heard and then several years later, the lower court must hold a hearing on the blood derivatives and the cardiac devices (on the latter issue, assuming that SCDOR's appeal is denied). With the voluminous record in this case, such a delayed hearing would cause the parties and the Court to spend substantial time and expense to reacquaint themselves with the facts, issues and law in the case.

SCDOR's position appears to be that it is more efficient to have the issue of whether the orthopedic prosthetic devices are "sold by prescription" decided first and then if the Court of Appeals decides that the ALC's decision is wrong on this point, then the question of whether the cardiac devices are sold by prescription will also be decided against Roper and the issue of whether the cardiac devices replace a missing part of the body would be moot. But this assumes that the ALC order is wrong. If instead the Court of Appeals upholds the ALC on that issue, then not only can there be no argument that efficiencies are created by staying

¹ Roper would note that counsel for SCDOR advised during the July 11th status conference that it may seek to re-open discovery in order to name a new witness on the issue of whether the prosthetic devices replace a missing part of the body. Roper would be glad to fully brief this issue if SCDOR makes this request; however, suffice it to say that such a request would be untimely and should not be granted. The reason given by SCDOR as to why they would be naming a new witness at this late date is that the Department did not think Roper's case was strong but now apparently sees that it has merit. This is an insufficient reason to re-open discovery. The parties filed cross-motions for summary judgment on August 26, 2013, and trial was scheduled to begin the week of September 30, 2013. SCDOR was apparently prepared to go forward with a trial at that point with no witness. Now, almost one year later, SCDOR wants a witness. The Court should deny such a request as untimely and prejudicial to Roper. Additionally, the trial date had already been postponed once before at SCDOR's request in order to conduct additional discovery. See SCDOR's First Motion for Continuance filed June 20, 2013.

the remaining issues, inefficiencies are created by delay in deciding the issue of whether cardiac devices replace a missing part of the body. A decision by the Court of Appeals upholding this Court's order that the orthopedic devices are sold by prescription will end this litigation if the issue of whether the cardiac devices replace a missing part of the body is decided now and this issue is also before the Court of Appeals. And as both sides agree, a decision on whether the blood derivatives are subject to tax will be wholly unaffected by the appeal and only delayed. That issue should also be decided now so that all matters in question can be brought before the Court of Appeals at the same time. There is no question that the blood derivatives issue is completely and utterly unrelated to the issue on appeal, and that a hearing must take place at some point in time no matter what happens on the appeal. To require Roper to wait to obtain a final ruling on that issue for several years would be inefficient and, more importantly, unjust.

CONCLUSION

For the foregoing reasons, Roper respectfully requests that the ALC move forward with a hearing on the two remaining issues in the case, i.e. whether the cardiac devices replace a missing part of the body and whether the sale of blood derivatives is the sale of a medical service, which is not subject to sales tax. In the alternative, should this Court find that the cardiac device issue is affected by the appeal of the orthopedic devices, then Roper would ask that the ALC move forward with the blood derivatives issue, which all parties agree is unaffected by and unrelated to the appeal.

NELSON MULLINS RILEY & SCARBOROUGH LLP

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(770) 998-2722

Attorneys for CareAlliance Health Services d/b/a Roper St.
Francis Healthcare

Charleston, South Carolina
July 18, 2014

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:

**PETITIONER'S MEMORANDUM IN SUPPORT OF THE
ALC PROCEEDING WITH A HEARING ON THE ISSUES
NOT APPEALED BY RESPONDENT**

Counsel Served:

Lauren Acquaviva
Counsel for Litigation
Office of General Counsel for Litigation
South Carolina Department of Revenue
301 Gervais Street (29201)
PO Box 12265
Columbia, SC 29211


Donna Horn
Administrative Assistant

July 18, 2014

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 BRETT M. BAKER,
M.D. IN SUPPORT OF MOTION FOR
SUMMARY JUDGMENT

I, Brett M. Baker, M.D., being first duly sworn, state as follows:

1. I am a board certified cardiologist specializing in the field of cardiovascular electrophysiology, and I practice at Roper St. Francis Hospital.

2. I am authorized to implant implantable cardioverter defibrillators ("ICDs") and pace makers (collectively the "Cardiac Devices") into my patients who require them.

3. The Cardiac Devices are prescription devices and may only be sold by prescription.

4. I issue an oral order for the Cardiac Devices that I implant during surgery, which is when I finally determine exactly what device, including the components and leads, the patient needs. I consider this oral order to be a prescription as required by law.

5. This prescription is then memorialized in writing at the conclusion of the surgery via a detailed report that is kept in my office as well as placed in the patient's medical records and sent to other physicians who are involved in the patient's care.

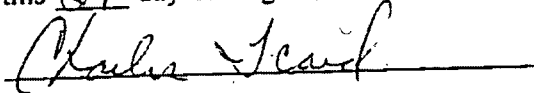
6. Many of my patients are experiencing some type of heart irregularity. The cause is most commonly that some portion of the patient's heart's electrical system has degenerated over time and that portions of the heart tissue or cells responsible for conduction of electrical signals to the heart have died off. The Cardiac Device replaces this missing cardiac tissue and restores the normal heart rhythm.

7. There are situations where a patient is born with a genetic defect of the heart (and thus heart cells are defective versus missing), but this represents less than 1% of my patients.

FURTHER AFFIANT SAYETH NOT.


Bret M. Baker, M.D.

SWORN to and subscribed before me
this 29 day of August, 2013

 (L.S.)

Notary Public for the State of South Carolina
My commission expires 8/12/2014

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:

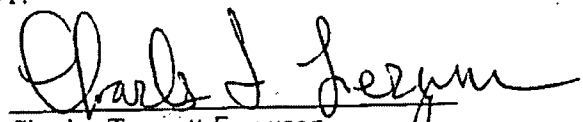
1. I am the Director of Material Services for Roper St. Francis Healthcare, Inc., the Petitioner in the above litigation.
2. In this capacity, I have personal knowledge of Petitioner's business practices regarding the purchase of prescription orthopedic prosthetic devices (such as hip, knee and shoulder 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

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.

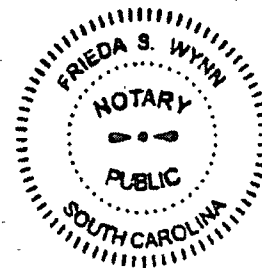
FURTHER AFFIANT SAYETH NOT.


Charles Trescott Ferguson

SWORN to and subscribed before me
this 26th day of August, 2013

 (L.S.)

Notary Public for South Carolina
My commission expires May 19, 2016



STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

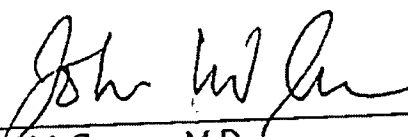
CareAlliance Health Services d/b/a Roper	)	Civil Action No. 12-ALJ-17-0405-CC
St. Francis Healthcare,	)	
	)	
Petitioner,	)	
	)	
vs.	)	<u>AFFIDAVIT OF JOHN McCROSSON,</u>
	)	<u>M.D. IN SUPPORT OF MOTION FOR</u>
South Carolina Department of Revenue,	)	<u>SUMMARY JUDGMENT</u>
	)	
Respondent.	)	

I, John McCrosson, M.D., being first duly sworn, state as follows:

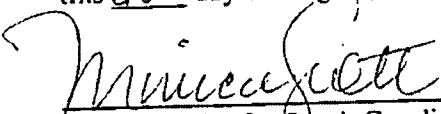
1. I am a board certified orthopedic surgeon specializing in hip and knee joint replacements, and I practice at Roper St. Francis Hospital.
2. I am authorized to implant orthopedic hip and knee joint replacements into my patients who require them.
3. These orthopedic prosthetic devices are prescription devices and may only be sold by prescription.
4. I issue an oral order for the orthopedic prosthetic device I am going to implant into one of my patients during surgery, which is when I determine exactly what size and type of device the patient needs. I consider this oral order to be a prescription as required by law.
5. 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.

6. A patient who requires a joint replacement will always be missing cartilage. Additionally during surgery, I remove more of the patient's joint to accommodate the orthopedic prosthetic device I am implanting. The device replaces the missing cartilage and joint of the patient.

FURTHER AFFIANT SAYETH NOT.


John McCrosson, M.D.

SWORN to and subscribed before me
this 28th day of August, 2013


(L.S.)
Notary Public for South Carolina
My commission expires 1.24.2023

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a Roper) Civil Action No. 12-ALJ-17-0405-CC
St. Francis Healthcare,)

Petitioner,)

vs.)

South Carolina Department of Revenue,)

Respondent.)

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 through 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.

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)

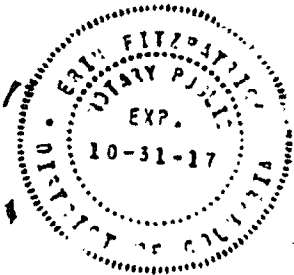
FURTHER AFFIANT SAYETH NOT.

Mary Kendergast
Mary K. Kendergast

SWORN to and subscribed before me
this 23 day of August, 2013

[Signature] (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

SUPPLEMENTAL AFFIDAVIT OF
MARY K. PENDERGAST

I, Mary K. Pendergast, being first duly sworn, state as follows:

1. As set forth in my previous affidavit filed in the above matter, 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 (December 1990- December 1997). 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 (July 1979 - December 1997). Since leaving the FDA I have provided regulatory guidance on FDA matters to companies, universities and other entities.

2. 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.

3. 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 prescription prosthetic devices at issue in this case.

4. I have also reviewed the Affidavit of Steven Silverman that was recently filed with this Court.

5. I do not think that it is correct to say that hospitals are "storage" facilities within the meaning of the phrase "[i]n 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" as used in 21 CFR § 801.109(a)(1)(i) for several reasons which are presented below.

(A) The common understanding of that phrase while I was at the FDA and since then in my professional work is that the phrase refers to the logical steps that take place between the time a medical device is first made and when it is distributed to the user of the device.

(B) There are FDA regulations and guidances that describe in detail the obligations of a device manufacturer to properly store a medical device. See, for example, the FDA's device "Quality System" (QS) regulations that cover the manufacture, storage, distribution, and installation of finished medical devices. Regulations governing a manufacturer's "storage" of a medical device are located at 21 CFR § 820.150 and address matters such as stock rotation, and procedures for avoiding mixups, damage, deterioration, contamination, "or other adverse effects pending use or distribution." Hospitals are not mentioned or otherwise included in these regulations.

(C) To the best of my knowledge, there is no FDA regulation, guidance document, or case law that refers to hospitals as storage facilities for prescription medical devices, including prescription prosthetic devices.

(D) Based on my understanding of FDA practices, if hospitals were medical device storage facilities, there would be a FDA regulation or guidance document that provided specific requirements or instructions to hospitals regarding what they need to do to properly "store" medical devices.

(E) FDA has issued "Warning Letters" to manufacturers telling them that their medical device storage activities are inadequate, but I could find no such letter to any hospital regarding medical device storage requirements. See Warning Letter to KBD, Inc., a device manufacturer, located at <http://www.fda.gov/iceci/enforcementactions/warningletters/2011/ucm284022.htm> (issue 11).

(F) Based on my review, I can find no support for the position that hospitals are storage facilities within the meaning of 21 CFR § 801.109(a)(1)(i).

(G) Because a hospital is not a "storage" facility, then no manufacturer can sell a prescription prosthetic medical device to a hospital without a prescription without violating the misbranding provisions of the Federal Food, Drug, and Cosmetic Act. 21 USC §§ 331(b), (c) (misbranding a device and the sale of a misbranded device are prohibited acts); 21 USC § 352(f)(1) (a device is deemed misbranded if it does not have adequate directions for use unless exempted from that requirement); 21 CFR § 801.109 (exemption for adequate directions for use).

6. If a broad exemption from the prescription requirement for the sale of prescription medical devices were allowed for a sale to an entity that would simply "store" and then later use the device on the order of a physician, then a prescription device manufacturer could sell a prescription device to a beauty parlor or tattoo parlor without there being any

prescription in place before the sale was made. This shows that the "storage" argument has no logical boundaries and is not rooted in the statutory scheme, which is designed to carefully control the sale and use of prescription devices.

7. There is no FDA regulation, guidance, or case law that exempts hospitals from needing to have a prescription before the hospital can purchase a prescription prosthetic device. To the best of my knowledge, no FDA official has ever before taken the position articulated in this case.

8. When the United States Congress wants to create special rules for hospitals, it knows how to do so. For example, in the misbranding section of the Federal Food, Drug, and Cosmetic Act at issue here, 21 USC § 352(f), Congress created a specific exemption from the requirement for paper labeling for prescription devices used in hospitals, but it did not, as is suggested, eliminate the requirement for a prescription. Section 352(f) reads in part as follows:

Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments may be made available solely by electronic means...

9. FDA too knows how to carve out exceptions to its rules, and it has exempted entities other than hospitals from the prescription requirement. For example, no adequate directions for use or prescription are required for sales to entities that process, repack, or manufacture the devices, activities not relevant to this case. 21 CFR § 801.122. Nor are adequate directions for use or a prescription required if a prescription device is sold to:

persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or engaged in law enforcement, or in research not involving clinical use, or in chemical analysis, or physical testing, and is to be used only for such instruction, law enforcement, research analysis, or testing.

21 CFR § 801.125. This exemption does not apply to hospitals because the care of patients is considered "clinical use." These examples demonstrate that FDA could have, but did not, exempt hospitals from needing a prescription to purchase a prescription prosthetic device from a manufacturer.

10. It is the manufacturer of a device, not a purchaser such as a hospital, that is responsible for the labeling of the prosthetic devices at issue in this case. The obligations of the manufacturer regarding the medical devices' labeling are set out in 21 CFR §§ 820.120 and Part 801.

11. If a device manufacturer sells a prescription prosthetic device to a hospital without proper labeling, the manufacturer is liable for misbranding the device. See paragraph 1(F) above.

12. Permitting hospitals to stock up on prescription devices is good public policy, since it assures patients will have access to the devices needed for their treatment. However, it does not follow that no prescription is required before a prosthetic device manufacturer can sell a prescription prosthetic device to a hospital. A prescription is still required, and a lawful order of a physician is a prescription for purposes of federal device laws and regulations.

13. In conclusion, to be consistent with the requirements of the Federal Food, Drug, and Cosmetic Act, a hospital must make a purchase of a prescription prosthetic device

through the use of a prescription. Without a prescription from the hospital, the medical device manufacturer would be selling a misbranded prosthetic device.

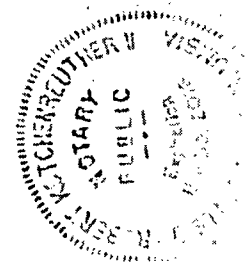
FURTHER AFFIANT SAYETH NOT.

Mary K. Pendergast
Mary K. Pendergast

SWORN to and subscribed before me
this 30 day of September, 2013

[Signature] (L.S.)

Notary Public for the District of Columbia
My commission expires 11-30-2014



FILED

SEP 24 2013

SC ADMIN. LAW COURT

AFFIDAVIT OF STEVEN D. SILVERMAN, J.D.

Steven D. Silverman, J.D., being first duly sworn, deposes and says:

1. I am the Director, Office of Compliance, Center for Devices and Radiological Health ("CDRH"), United States Food and Drug Administration ("FDA"). My office is located at 10903 New Hampshire Avenue, Silver Spring, Maryland. I have been in this position for approximately three years. As Director of the Office of Compliance, I oversee a staff of regulatory personnel who ensure that medical devices regulated by FDA comply with the relevant provisions in the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations. Among other things, my position requires that I personally review, interpret, and apply the Act and its regulations as they pertain to medical devices and to parties involved in investigating, developing, manufacturing, producing, and distributing medical devices. This affidavit is based on my personal knowledge and information obtained by me in my official capacity.

2. The statements in this affidavit are made in response to a request from the State of South Carolina, Department of Revenue, Office of General Counsel for Litigation, in connection with the *CareAlliance Health Services d/b/a Roper/St. Francis Medical Healthcare, Inc. v. SC Dept. of Revenue*, 12-ALJ-17-0405-CC (S.C. Admin. Ct.) case.

3. I have been authorized by the Commissioner of Food and Drugs' designee to give testimony in this matter.

4. Under FDA's regulations, a "prescription device" is 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." 21 C.F.R. § 801.109.

5. FDA can require by regulation that a device be a prescription device. See 21 U.S.C. § 360j(e)(1)(A) ("The Secretary may by regulation require that a device be restricted to sale, distribution or use only upon the written or oral authorization of a practitioner licensed by law to administer or use such device"). FDA can also require that a device be a prescription device in its order approving an application for premarket approval ("PMA") for a specific device under 21 U.S.C. § 360e(d)(1)(B)(ii) ("An order approving [a PMA] for a device may require as a condition to such approval that the sale and distribution of the device be restricted" as provided for in 21 U.S.C. § 360j(e)). A third way a device could become a prescription device is through FDA's clearance of a premarket notification under 21 U.S.C. § 360(k) for a device indicated for prescription use.

6. The Act deems a device to be misbranded unless its labeling bears adequate directions for its use. 21 U.S.C. § 352(f)(1). FDA's regulations exempt prescription devices from such labeling requirement when, among other things, the device is "[i]n 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,*" and the device "*[i]s to be sold only to or on the prescription or order of such practitioner for use in the course of his*

professional practice." 21 C.F.R. § 801.109(a) (emphases added). 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 or pursuant to a prescription or order of a physician.

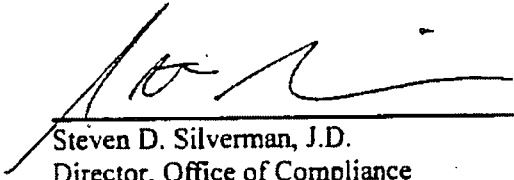
7. There is nothing in the Act or its regulations that prohibits device manufacturers from selling prescription devices to properly-licensed healthcare facilities that do not have patient-specific physician orders for such devices at the time of purchase by the healthcare facility, to be stored in inventory by the facility for ultimate distribution to or use on a patient by a licensed practitioner or pursuant to a prescription or other order from a licensed practitioner. To prohibit 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 (e.g., infusion pumps, ventilators, cardiac pace makers, and dialysis equipment) in their inventory for immediate access to render care to their patients.

Executed this 23rd day of September, 2013.

FILED

SEP 24 2013

SC ADMIN. LAW COURT

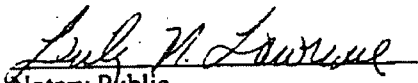


Steven D. Silverman, J.D.
Director, Office of Compliance
Center for Devices and Radiological Health
United States Food and Drug Administration

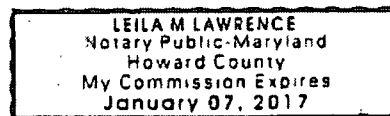
State of Maryland)
County of Montgomery) ss:

I, Leila M. Lawrence, a Notary Public for said County and
State, do hereby certify that Steven D. Silverman, J.D., personally appeared before me this day
and acknowledged the due execution of the foregoing instrument.

Witness my hand and official seal, this the 23rd day of September,
2013.


Notary Public

My commission expires January 07, 2017



State of South Carolina
Department of Revenue
Office of General Counsel, Tax & Regulatory Services
300A Outlet Point Blvd., (29210); P.O. Box 12265, Columbia, South Carolina 29211
Telephone (803) 898-5130 Telecopier (803) 898-5147

September 25, 2013

The Honorable Shirley G. Robinson
Administrative Law Court
Edgar A. Brown Bldg.
1205 Pendleton St., Ste. 224
Columbia, SC 29201

Re: CareAlliance Health Services d/b/a Roper St. Francis Healthcare v.
South Carolina Department of Revenue
Docket No.: 12-ALJ-17-0405-CC

Dear Judge Robinson:

The Department is in receipt of the Petitioner's Reply to Respondent's Response to Petitioner's Amended Motion for Summary Judgment, and the letter concerning the possible objections to the Department's filing of Steven Silverman's sworn Affidavit. This letter shall address both in kind.

The Department objects to the inclusion of Petitioner's Reply to the record of this case, as it is untimely – both under ALC Rule 19(A) and the scheduling order that was in place for this case. Rule 19(A), in pertinent part, states that “[a]ny party may file a written reply within five (5) days of the filing of a response, unless otherwise ordered by the administrative law judge.” Here, the Department's Response to Petitioner's Amended Motion for Summary Judgment was filed on September 6, 2013. A reply, pursuant to the rule, would have been due no later than September 13, 2013. This reply was untimely filed by the Petitioner approximately ten days past that date. Moreover, the email sent by your law clerk on June 26, 2013 clearly stated that “Judge Robinson is asking that all pretrial motions be made no later than Monday, August 26, 2013 and that the written responses to the pretrial motion(s) be filed no later than Friday, September 6, 2013.” The Department respectfully posits that this most recent Reply is therefore untimely and should be disregarded by this Court.

As to the letter regarding the Department's filing of Steven Silverman's affidavit, the noted objections presented by the Petitioner are without merit. Rule 56(c) SCRPC unequivocally states that “The adverse party may serve opposing affidavits not later than two days before the hearing.” See also Jernigan v. King, 312 S.C. 331, 440 S.E.2d 379 (Ct. App. 1993). This affidavit was filed a week prior to the scheduled hearing, and was therefore timely.

Furthermore, the Petitioner has had notice of pending written testimony from the U.S. Food and Drug Administration (“FDA”) since the beginning of the discovery process in this case. In fact, the procurement of such testimony was one of the stated grounds for the Department's request for continuance on June 20, 2013.

In addition, it is the policy of the FDA to only provide written testimony in declaratory format unless under exigent circumstances, and thus the Department had no option to name a possible FDA witness in discovery. Finally, the South Carolina Rules of Civil Procedure do not impose a duty upon an adverse party to allow opposing counsel an opportunity to depose declarants in affidavits prepared for a motion for summary judgment. As such, the Petitioner's objections should be disregarded and the affidavit should remain filed and part of the record.

Should this Court require anything further regarding these matters, do not hesitate to contact me at your convenience at MarineA@sctax.org or (803) 898-5153.

With kind regards,

OFFICE OF GENERAL COUNSEL FOR LITIGATION



Adam N. Marinelli
Counsel for Litigation

ANM:jmo

Enclosures

c: John C. von Lehe, Jr., Esquire
Bryson M. Geer, Esquire
Raymond Carpenter, Esquire

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

JOINT STIPULATIONS OF FACT

Petitioner CareAlliance Health Services d/b/a Roper St. Francis Healthcare ("Roper") and Respondent South Carolina Department of Revenue ("SCDOR") hereby stipulate to the following facts in the above matter:

1. There are three basic categories of items at issue in this matter: (a) prescription reconstructive musculoskeletal and prescription trauma musculoskeletal prosthetic devices ("Prosthetics A"); (b) prescription cardiac prosthetic devices ("Prosthetics B"); and (c) blood derivatives.

2. The Prosthetics A category includes the following items:

a. **Reconstructive Musculoskeletal Devices**

1. Hips
2. Knees
3. Shoulders
4. Mastectomy reconstruction implants
5. Other skeletal
6. Other bone, muscle and tissue implants

- b. Trauma Musculoskeletal Devices
 1. Pins
 2. Screws
 3. Nails
 4. Plates
 5. Other trauma implants
3. The Prosthetics B category includes the following items:
 - a. Cardiovascular
 1. Pacemakers
 2. Implantable cardioverter-defibrillators ("ICDs")
4. The amount of the refund requested in this matter is as follows:

Refund Requests	
Prosthetics A	\$1,502,408.29
Prosthetics B	\$1,553,408.41
Blood Derivatives	\$ 435,368.74
Total Amount at Issue	\$3,491,185.44

5. Because the auditor denied the refund amounts related to prescription devices and blood derivatives on legal grounds, the amount in controversy identified in no. 4 above is based upon estimates, and the invoices provided by the taxpayer were not thoroughly reviewed. The invoices used to substantiate the refund claims may contain ancillary products purchased by the hospital that are not exempt from sales tax and were never intended by the taxpayer to be included as part of the claim. As such, should this Court rule in favor of the taxpayer on the legal questions presented, the case should be remanded to the Department to fully audit the actual invoices at issue. That further review will be limited solely to the removal of non-exempt items from the refund claim and to properly ascertain the actual

amount due to the taxpayer by determining the amount of prosthetics and blood derivatives in those invoices. Any such review will be completed within a reasonable period of time.

6. All devices in question are FDA regulated Type II and Type III prescription prosthetic devices.

7. The Prosthetic A devices listed in no. 2(a)(1), (2), (3) and (4) replace a missing part of the body.¹

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

¹ Petitioner asserts that the Prosthetic A Devices listed in no. 2(a)(5)-(6), 2(b)(1)-(5) and the Prosthetic B devices listed in 3(a)(1)-(2) also replace a missing part of the body, but Respondents have not agreed to a stipulation to that effect on those devices.

WE SO STIPULATE AND AGREE:

NELSON MULLINS RILEY & SCARBOROUGH LLP

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Attorneys for CareAlliance Health Services d/b/a Roper St.
Francis Healthcare

Charleston, South Carolina
September 26, 2013

SOUTH CAROLINA DEPARTMENT OF REVENUE

By: Adam N. Marinelli w/ permission by Brea
Adam N. Marinelli
Lauren Acquaviva
Counsel for Litigation
Office of General Counsel for Litigation
South Carolina Department of Revenue
Box 12265
Columbia, SC 29211

Columbia, South Carolina
September 27, 2013

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

CareAlliance Health Services d/b/a Roper	)	Civil Action No. 12-ALJ-17-0405-CC
St. Francis Healthcare,	)	
	)	
Petitioner,	)	
	)	
vs.	)	<u>ORDER ON CROSS MOTIONS FOR</u>
	)	<u>SUMMARY JUDGMENT</u>
	)	
South Carolina Department of Revenue,	)	
	)	
Respondent.	)	

APPEARANCES: For the Petitioner: Raymond P. Carpenter, Esquire
John C. von Lehe, Jr., Esquire
Bryson M. Geer, Esquire

For the Respondent: Adam N. Marinelli, Esquire
Lauren Acquaviva, Esquire.

STATEMENT OF THE CASE

This matter comes before the Administrative Law Court ("ALC") pursuant to cross motions for summary judgment filed by Petitioner CareAlliance Health Services d/b/a Roper St. Francis Healthcare ("Roper" or "Petitioner") and Respondent South Carolina Department of Revenue ("SCDOR" or "Respondent"). Petitioner contests Respondent's Final Determination finding that it is not entitled to a tax refund. Petitioner contends that purchases of certain prescription prosthetic devices should have been exempted from sales tax and that certain purchases of blood products should have been excluded from sales and use tax. An Administrative Hearing was held on these motions before me on October 1, 2013. Any issues raised in the motions or the proceedings but not addressed in this Order are deemed denied.

LEGAL ISSUES RAISED

The following legal issues have been presented to the ALC:

- I. Whether the sale of prescription prosthetic devices implanted into the human body (consisting here of prescription reconstructive musculoskeletal, prescription trauma musculoskeletal and prescription cardiovascular prosthetic devices), which were sold to Roper upon the lawful order of a physician, qualify as being "sold by prescription" as that term is used in the sales tax exemption statute at S.C. Code Ann. §12-36-2120 (28) and whether these prescription prosthetic devices replace a missing part of the body as required by S.C. Code Reg. § 117-332 such that they 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 Uniform Anatomical Gift Act as adopted in South Carolina and therefore is excluded from the imposition of sales and use tax.

UNDISPUTED FACTS

Having reviewed the written submissions of both parties and considered the arguments presented at the hearing, I find that there is no genuine issue of material fact as to the facts set forth below.

I. Facts Related to the Prescription Prosthetic Devices at Issue

A. Purchasing Practices regarding all Prescription Prosthetic Devices at Issue

The prescription prosthetic devices at issue in this case include (1) orthopedic reconstructive implants (such as artificial hips, knees, shoulders, mastectomy reconstruction implants), other skeletal implants and other bone, muscle and tissue implants (the "Orthopedic Devices"); (2) orthopedic trauma implants such as plates, pins, nails and screws (the "Trauma Devices"); (3) cardiovascular implants such as implantable cardioverter defibrillators ("ICDs") and pacemakers (the "Cardiac Devices"). See Joint Stipulations of Fact at ¶1. Both parties agree that all of the prosthetic devices at issue are Federal Food and Drug Administration ("FDA") regulated Type II and Type III prescription prosthetic devices. Joint Stipulations of Fact at ¶6.

Thus, collectively, these devices will be referred to herein as the "Prescription Prosthetic Devices."

Petitioner purchases all of the Prescription Prosthetic Devices only upon the prescription or order of physicians who are board certified and authorized to prescribe such devices in their practices. See Affidavit of Charles Trescott Ferguson ("Ferguson Aff."), attached as Ex. B to Roper's Amended Motion for Summary Judgment, at ¶3(b); Affidavit of John McCrosson, M.D. ("McCrosson Aff."), attached as Ex. C to Roper's Amended Motion for Summary Judgment, at ¶4 (stating that he issues an oral order to the manufacturer's representative for the orthopedic prosthetic devices he implants during surgery); Affidavit of Brett M. Baker, M.D. ("Baker Aff."), attached as Ex. D to Roper's Amended Motion for Summary Judgment, at ¶4 (stating same as to cardiac devices).¹ As the physicians in the case testified, these orders constitute the prescriptions of the physicians. See McCrosson Aff. at ¶4; Baker Aff. at ¶4.

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. Ferguson Aff. at ¶3(a) and (d). See also McCrosson Aff. at ¶5 (stating that he memorializes his orders for orthopedic devices); Baker Aff. at ¶5 (same as to cardiac devices). 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. Ferguson Aff. at ¶3(e). The hospital has not been held in violation of laws or regulations of the state or federal government or the hospital

¹ 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. Ferguson Aff. at ¶3(c). Even these Trauma Devices kept in inventory, however, are ordered only upon the order or prescription of a physician. Id.

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).

Mary Pendergast, former Deputy Commissioner and Senior Advisor to the Commissioner of the FDA, also provided testimony regarding the relevant FDA statutes and regulations. She stated that the FDA is the only governmental agency, federal or state, with legal authority to regulate the labeling, distribution, and restrictions regarding the use of prosthetic devices implanted in human beings. Affidavit of Mary K. Pendergast ("Pendergast Aff."), attached as Ex. A to Roper's Amended Motion for Summary Judgment, at ¶6(a). She further stated that the State of South Carolina has no authority to modify, limit or expand restrictions placed on these prosthetic devices without specific authority from the FDA. Id. at ¶6(b). FDA regulations provide an appeal process for states to request exemptions from such restrictions, but South Carolina has not requested such an exemption. Id. at ¶6(d). 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. Id. at ¶6(e). Hospitals can only purchase such restricted prosthetic devices upon the lawful "prescription or other order" of a physician licensed to use such devices in his medical practice. Id. 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. Id. at ¶6(g).

SCDOR presented the affidavit of Steven Silverman with the FDA in opposition to Ms. Pendergast's affidavit and to Roper's Amended Motion for Summary Judgment. However, the affidavit does not appear to provide testimony that directly relates to any factual issues in dispute in this matter. Mr. Silverman states that a hospital "may purchase and store *prescription devices*, provided that they are ultimately to be used on or distributed to patients by a physician or

pursuant to a prescription or order of a physician." Affidavit of Steven Silverman ("Silverman Aff.") at ¶6 (citing 21 C.F.R. § 801.109(a)) (emphasis added). However, Mr. Silverman does not define the term "prescription devices" and he does not specify that it includes only prescription prosthetic devices that are implanted into the body and not prescription devices that are not implanted into the body. For example, a review of 21 C.F.R. §801.109(b)(1) reveals that the term "prescription devices" includes surgical instruments, which obviously are not implanted into the body, and for which the regulation provides different requirements. Therefore, Mr. Silverman's affidavit is overbroad, and it is unclear whether he is addressing the devices at issue in this case, which are **Type II** and **Type III** prescription **prosthetic** devices, which are implanted into the body.² The other fact set forth in Mr. Silverman's affidavit is that there is nothing in the law that "prohibits device manufacturers from selling prescription devices to properly-licensed health care facilities that do not have patient specific orders. Silverman Aff. at ¶7. Although patient specific orders were issued for all of the Orthopedic and Cardiac Devices in this case, Roper agrees that the lawful order of a physician does not need to contain patient specific information at the time of purchase as long as such information is memorialized after implantation into a patient. Thus, whether patient specific orders are required is not an issue in dispute. Accordingly, this Court finds that Mr. Silverman's affidavit does not directly address any factual issue in dispute in this case.

B. Replacement of a Missing Part of the Body by the Prescription Prosthetic Devices

Both parties agree that the hip, knee and shoulder devices as well as the mastectomy reconstructive implants, which are implanted into the musculoskeletal system, all replace a

² This Court would also note that Mr. Silverman was not available for a deposition in this case and, thus, an in-depth explanation for his testimony is not available to the Court.

missing part of the body. Joint Stipulations of Fact at ¶7. SCDOR did not concede that the implanted cardiac devices, a portion of the Orthopedic Devices (including, other bone, muscle and tissue implants) and the trauma devices (pins, screws, nails, plates and other trauma implants), all of which are either implanted into the cardiovascular system or the musculoskeletal system, replace a missing part of the body. However, the evidence in the record and the practical application of surgically implanting these prosthetic devices into the body indicates that they do.

Regarding the cardiac prosthetic devices, Dr. Brett Baker, a board certified cardiologist who specializes in the field of cardiovascular electrophysiology, 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 Aff. at ¶6. He further stated that the Cardiac Devices replace this missing cardiac tissue and restore the normal heart rhythm. Id.³ This testimony is similar to the testimony provided by Dr. McCrosson, a board certified orthopedic surgeon, who testified that a patient receiving a knee replacement is missing cartilage, and during surgery, more of the patient's joint is removed to accommodate the prosthetic knee replacement such that the Orthopedic Devices replace the missing cartilage and joint. McCrosson Aff. at ¶6. SCDOR presented no evidence or testimony that would support a finding that although an orthopedic device, which replaces missing cartilage and joint, replaces a missing part of the body, a cardiac device, which replaces missing cardiac tissue, does not.

As to the remaining reconstructive musculoskeletal implants and trauma musculoskeletal implants, which SCDOR has not stipulated as replacing a missing part of the body, these devices

³ 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 Aff. at ¶7.

are implanted into the body. See e.g. Joint Stipulations of Fact at ¶2(a) and (b) (referring to the prosthetics as including "other bone, muscle and tissue implants" and "other trauma implants"). Just as a hip, shoulder or knee implant replaces missing cartilage and joint, to the extent these remaining reconstructive prosthetic and trauma prosthetic devices are implanted into the musculoskeletal system of the human body, this Court finds that such items replace a missing part of the body.

II. Facts Related to the Blood Derivatives at Issue

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. Joint Stipulations of Fact at ¶8. 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. See Affidavit of M. Daud Nawabi, M.D. ("Nawabi Aff."), attached as Ex. E to Roper's Amended Motion for Summary Judgment, at ¶10. These blood proteins are extracted from the plasma in whole blood. Id. at ¶5. They are processed in a similar manner to other blood products, including red blood cells, white blood cells, plasma and platelets. Id. at ¶6. As with these other blood products, there is nothing in the processing of the blood proteins that in any way alters, modifies or changes their nature. Id. at ¶8. The blood proteins are not synthetic, artificial, or pharmaceutical and they are not manufactured; rather, they are created by the human body. Id. at ¶9.

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 SCDOR for a period in excess of twenty years. See E-mail Correspondence Bates-stamped 000048-000068, attached as Ex. H to Roper's Amended Motion for Summary Judgment. Although it is not the policy or practice of

SCDOR to tax whole blood and certain blood derivatives, to date, the Department has issued no definitive revenue regulation or policy statement regarding these items. See Deposition of John P. McCormack ("McCormack Dep."), attached as Ex. F to Roper's Amended Motion for Summary Judgment, 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. See Deposition of Christine Buddin ("Buddin Dep."), attached as Ex. G to Roper's Amended Motion for Summary Judgment, at 28:1- 25 and 32:10- 34:25 and 37:19 -40:5. This has resulted in the sales and use tax as to blood being applied in a non-uniform manner with different policies being applied in different field offices of the Department. Some hospitals have been taxed on purchases of certain blood derivatives while others have not.

CONCLUSIONS OF LAW

I. Burden of Proof

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).

II. Petitioner Purchased the Subject Prescription 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 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 sales tax exemption statute does not elaborate further on the term "sold by prescription;" however, Revenue Ruling #11-3 provides that in order to qualify as "sold 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 South Carolina tax code does not define the term "prescription," and SCDOR has issued no regulations, private letter rulings or other guidance to tax payers that would indicate that prescription means anything other than the plain and ordinary meaning that it is the lawful order of a physician. Finally, a tax code regulation defines the term "prosthetic device" to include "an artificial device used to replace a missing part of the body. . . ." S.C. Code Reg. § 117-332. Beyond the four requirements above, no case law, statute or regulation controls the exact facts and issues in this case; therefore, this is a case of first impression for the courts of South Carolina on this issue.⁴ As will be discussed below, Petitioner meets all four requirements 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

⁴ SCDOR has argued that Home Medical Systems, Inc. v. South Carolina Department of Revenue, 382 S. C. 556, 677 S. E. 2d 582 (2009) is applicable to this matter. Home Medical involved sales of various prescription devices (such as ventilator devices) and a non-prescription or over-the-counter medicine (enteral nutritional formula). The Court held that none of the prescription devices at issue were prosthetic devices (i.e. they were not implanted into the body and did not replace a missing part of the body) and so they did not qualify as prescription prosthetic devices sold by prescription. The Court also held that a Certificate of Medical Necessity ("CMN"), which is a standard form used by Medicare and Medicaid for reimbursement of over-the-counter medicines, could not convert a non-prescription item into a prescription item, and thus, the non-prescription formulas did not qualify as medicines sold by prescription. Unlike Home Medical, the devices at issue here are prosthetic devices, which are implanted into and replace a missing part of the body. In addition, neither prescription medicines nor CMNs are at issue here. Therefore, the factual and legal conclusions drawn in Home Medical are not applicable to this case.

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 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 apply 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.

Both parties agree that all of the prosthetic devices at issue are FDA regulated Type II and Type III prescription devices, and therefore, Petitioner has established that the devices are of a type that requires a prescription. Joint Stipulations of Fact at ¶6.

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 Services 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).⁵

⁵ Under S.C. Code Ann. 19-3-150, this Court may take judicial notice of foreign law, which could be interpreted to

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 Pendergast Aff. at ¶6(e).⁶ 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; 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; 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 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 21 U.S.C.

include federal statutes and regulations being applied to a case pending in state court.

⁶ The South Carolina Pharmacy Code even adopts this federal law on at least two occasions: (1) the definition of a device in S.C. Code Ann. § 40-43-30: "Federal law restricts this device for sale by or on the order of a physician" and (2) the restriction on the sale of devices set forth in S.C. Code Ann. § 40-43-86 (EE), which states: "Caution: Federal law restricts devices for sale by or on the order of a physician."

§360(k); 21 C.F.R. §808; see also Pendergast Aff. at ¶6(b). FDA regulations provide an appeal process for states to request exemptions from such restrictions, but South Carolina has neither requested nor received an exemption. 21 CFR §808; 21 C.F.R. §801.109; Pendergast Aff. at ¶6(c)-(d).

In this case, the Prescription Prosthetic Devices are all devices regulated by the FDA, which mandates that they be "sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice." See 21 CFR § 801.109(a)(2); Pendergast Aff. at ¶6(f). This is consistent with the legal doctrine known as the "learned intermediary rule," which provides that manufacturers of prescription drugs and devices discharge their duty of care to patients by providing warnings to the prescribing physicians. See Madison v. American Home Products, 358 S.C. 449, 595 S.E.2d 493 (1995); Talley v. Danek Med., Inc., 179 F.3d 154, 163 (4th Cir. 1999). In the context of prescription prosthetic devices, the policy considerations behind both rules is the same and the two rules serve a similar purpose: consumers cannot purchase such devices directly from manufacturers or pharmacies; physicians are in the best position to know what prescription prosthetic devices are needed by their patients and to adequately advise and warn their patients of any benefits and risks associated with such devices; and, thus, the law seeks to ensure that such devices are only ordered upon the prescribing physician's order upon whom the law places this legal burden to adequately advise and warn. Moreover, if Roper 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; Pendergast Aff. at ¶6(g). Thus, under the relevant federal law, the sales transactions at issue all require a prescription.

Prescriptions may be written or oral under federal law. 21 U.S.C. § 360j (e)(1)(providing that devices may be restricted to sale, distribution or use "only upon the written or oral authorization of a practitioner licensed by law to administer or use such device"). See also Pendergast Dep. ("Pendergast Dep."), attached as Ex. B to Petitioner's Memorandum in Opposition to Respondent's Motion for Summary Judgment, at 49:7-14. Common knowledge and general usage also support the fact that physicians often "call in" or otherwise electronically notify pharmacies to prescribe medications. The Court finds no requirement in the law that a prescription must be in writing.⁷

SCDOR has asserted numerous arguments for restricting hospitals from qualifying for the prosthetic devices exemption, including that hospitals can never qualify, that the prescription must contain certain details, that the prescription must be sent to the manufacturer, that the prescription must be written to the person who is claiming the exemption, etc. The Court sees no merit in any of these arguments. The Court finds that SCDOR's narrow interpretation of what constitutes a "prescription" for purposes of qualifying a prosthetic device is not consistent with SCDOR's revenue rulings, policies and procedures, which clearly provide that a hospital can qualify. S.C. Rev. Ruling #98-9 (stating that once it is established that a sale to a hospital is a retail sale, then one must determine whether the items in question come within an exemption); S.C. Rev. Ruling #96-4 (stating that radioactive isotopes sold to hospitals can qualify as medicines "sold by prescription" such that they are exempt from sales and use tax); McCormack Dep. at 90:25- 92:4 (testimony of Senior Administrator for Policy in the Office of General

⁷ As Dr. McCrosson explained, patients cannot go purchase the devices at issue directly, and thus it would make no sense for physicians to write a prescription to a pharmacy for the devices at issue. See also McCrosson Dep. ("McCrosson Dep."), attached as Ex. C to Petitioner's Memorandum in Opposition to Respondent's Motion for Summary Judgment, at 51:8- 52:4. In fact, even the South Carolina Pharmacy Code allows oral prescriptions. S.C. Code Ann. §40-43-86(F)(6) (allowing prescribing practitioner to "... authorize his agent to transmit a prescription drug order orally or electronically to the pharmacy ...").

Counsel, Tax and Regulatory Services at SCDOR agreeing that 96-4 allows diagnostic radioactive isotopes to qualify if sold by prescription). Additionally, by way of example, no prescription could ever be written for a prosthetic device that would meet the requirements of S.C. Code Ann. §40-43-86(E), including the one example of a qualifying device given in SCDOR's own revenue ruling.⁸ This section of the Pharmacy Code is clearly directed towards prescription drugs, as many of the requirements are simply inapplicable to devices (for example, number of re-fills, strength, dosage, etc.). Interpreting the exemption to require compliance with the Pharmacy Code's definition of what is required for a prescription drug to be dispensed by a pharmacist would be counter to the legislative intent of the statute and would contravene SCDOR's own revenue rulings, policies and procedures.

SCDOR also presses the Court to adopt its construction of the statute due to the long standing nature of its interpretation and to the consideration that a court is required to give to the interpretation of a statute by the agency charged with its enforcement.⁹ In support of this, SCDOR presented, in oral argument, a letter from a former Tax Commissioner to a State Senator stating that the exemption was intended to cover only sales by prescription to individuals. See Boykin v. S.C. Tax Comm'n, Civil Action No. 89-CP-02-590, Court of Common Pleas, Aiken County, (1989), attached as Ex. D to Roper's Memorandum in Opposition to SCDOR's Motion for Summary Judgment and as Ex. C. to Motion for Summary Judgment in Boykin. However, the letter further informs the legislator that the language actually used in the exemption statute

⁸ The example of an exempt device provided in Revenue Ruling #11-3 is "*the sale of prescription lenses that replace a missing part of the eye . . . as for example eyeglasses prescribed for a person whose natural lenses have been surgically removed.*" Eyeglasses would not require, *inter alia*, a number of refills, dosage form or instructions for use and yet the Department agrees their sale would be exempt.

⁹ Commissioners of Public Works v. S.C. Dep't of Health and Environmental Control, 372 S. C. 351, 649 S. E. 2d 763 (Ct. App. 2006) (quoting Brown v. S. C. Dept. of Health and Environmental Control, 348 S. C. 507, 560 S. E. 2d 410 (2002)) (holding that the interpretation 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).

"is much broader in scope and would include all drugs sold to hospitals, doctors, nursing homes, etc." Id. Indeed, the letter urges the Legislature to increase the revenue impact of the exemption in anticipation of claims by hospitals such as Roper. Id. In the Boykin case, Judge Timmerman found that there was no credible construction of the statute that would limit the persons who could benefit from the exemption. Accordingly, SCDOR's construction of the statute to limit the exemption to purchases by individuals is due no weight by this Court, because, by SCDOR's own admission, the statutory language does not exclude Roper from the benefit of the exemption statute.

3. The Devices at Issue Were, In Fact, Sold by Prescription.

The physicians in this case have testified that they issue oral orders 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. McCrosson Aff. at ¶4; Baker Aff. at ¶4. The physicians have further testified that these oral orders constitute their prescriptions. McCrosson Aff. at ¶4; Baker Aff. at ¶4. The physicians then memorialize the orders in writing. McCrosson Aff. at ¶5; Baker Aff. at ¶6. In addition, Petitioner also purchases the Trauma Devices upon the orders of physicians. 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 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 e.g. 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."

Both parties agree that the hip, knee and shoulder devices as well as the mastectomy reconstructive implants, which are implanted into the musculoskeletal system, all replace a missing part of the body. Joint Stipulations of Fact at ¶7. SCDOR did not concede that the implanted cardiac devices, a portion of the Orthopedic Devices (including, other bone, muscle and tissue implants) and the trauma devices (pins, screws, nails, plates and other trauma implants), all of which are either implanted into the cardiovascular system or the musculoskeletal system, replace a missing part of the body. However, the evidence in the record and the practical application of surgically implanting these prosthetic devices into the body indicates that they do.

SCDOR contends that the cardiac devices do not replace a missing part of the body. However, Dr. Baker testified that the ICDs and pacemakers 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. Baker Aff. at ¶6. SCDOR presented no evidence or testimony to refute these facts. This is analogous to Dr. McCrosson's testimony that an artificial knee or hip replaces missing cartilage in the joint(s) of the patient and any portion of the joint removed during surgery. McCrosson Aff. at ¶6. There is no principled basis upon which to make a distinction between these devices on this issue; they both replace a missing part of the body— orthopedic implants replace missing cartilage that has degenerated over time (as well as whatever portion of the joint is removed during the surgery), while cardiac devices replace the missing cardiac tissue that has died off. Thus, this Court finds that the pacemakers and ICDs replace a missing part of the body.

As to the remaining reconstructive musculoskeletal implants and trauma musculoskeletal implants, which the parties have not stipulated as replacing a missing part of the body, these devices are implanted into the body. See e.g. Joint Stipulations of Fact at ¶2(a) and (b) (referring to the prosthetics as including "other bone, muscle and tissue implants" and "other trauma implants"). Just as a hip, shoulder or knee implant replaces missing cartilage and joint, to the extent these remaining reconstructive and trauma prosthetic devices are implanted into the musculoskeletal system of the human body, this Court finds that such items replace a missing part of the body.

III. The Sale of Blood and Products Derived from Blood is a Sale of a Service Excluded from the Sales and Use Tax Statute.

The taxation of the blood proteins in question is one of imposition of tax or coverage and not of exemption. As such the imposition statute should be narrowly construed against the imposition of the tax and liberally construed in favor of the taxpayer. Clark v. S.C. Tax Comm'n, 259 S.C. 161, 191 S.E.2d 23 (1972) (holding that "[r]evenue laws are generally construed in favor of the taxpayer and against the taxing authority"); Taylor v. Aiken County Assessor, 402 S.C. 559, 741 S.E.2d 31 (Ct. App. 2013) (same). When this standard is applied, it is clear that the blood proteins at issue are excluded from coverage of the sales and use tax.

The South Carolina sales and use tax statute imposes a tax on sales of tangible personal property and certain specifically enumerated services, which are collectively defined as sales of "tangible personal property." See S.C. Code Ann. §12-36-910; S.C. Code Ann. §12-36-60. Unless a service is specifically enumerated, then sales of services are 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") 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).¹⁰

Sales of blood and products derived from blood, and other human harvested products are sales of medical services. Even if this Court were to disregard RUAGA, which very clearly defines the sale of blood and blood products as sales of services, the same result would follow under the "true object" test. S.C. Rev. Ruling 93-4. Under this test, sales of blood and blood

¹⁰ 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).

products would be sales of services because the true object of the purchaser/patient is to obtain the treatment of a licensed physician or other health care provider and not the tangible blood, blood product or blood derivative. Thus, the sale of these medical services is not taxable, and the blood proteins at issue are exempt from sales and use tax.

This conclusion is supported not only by the relevant statutes but also by current SCDOR policies and practices as to whole blood and all blood products except for the blood proteins at issue. The Department does not currently tax whole blood, red blood cells, platelets or plasma. See Buddin Dep. at 34:12-25. The blood proteins, which are found in the plasma of the blood,¹¹ appear to be the only product derived from blood upon which SCDOR (at various times including the present) has attempted to impose a sales tax. The reason appears to be that SCDOR believes that the blood proteins are manufactured while the other blood products it currently exempts are not. However, Dr. Daud Nawabi, a board certified oncologist who practices in the areas of oncology and hematology, testified that the blood proteins at issue are not manufactured, but rather they are all created by the human body. Nawabi Aff. at ¶9. As he explained, the blood proteins are separated out from the plasma of the blood. Id. at ¶5. They are then processed in a similar way to red blood cells and platelets (which SCDOR exempts), which can include screening for infectious diseases, re-suspending in a buffer and adding a preservative. Id. at ¶6. Dr. Nawabi testified that nothing in the processing of red blood cells, platelets or blood proteins in any way alters, modifies or changes their nature in any way. Id. at ¶8. He also stated that the blood proteins at issue are not synthetic, artificial or pharmaceutical. Id. at ¶9. SCDOR presented no evidence or testimony that would contradict or refute Dr. Nawabi's testimony. Thus, the only evidence presented in the case establishes that the blood proteins at issue are not manufactured but are created by the human body and are no "less

¹¹ Nawabi Aff. at ¶5.

human" or more processed than the other blood products that SCDOR exempts from sales and use tax. Accordingly, SCDOR's policy of exempting blood products from sales and use tax should be applied to blood proteins:

The Department of Revenue asserts that 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) prevents application of RUAGA in sales tax matters; however, the Court finds that this unpublished decision is not persuasive. In 92-26, the former Tax Commission stated that although it had previously applied RUAGA in sales tax matters, it now found the better approach to be that RUAGA should not apply and further stated that sales of blood and blood products were sales of tangible personal property. First, the facts in this case are distinguishable from those in 92-26. The only items at issue in that decision were blood collection bags and labels used in the storage of blood and products derived from blood. These products are not mentioned in RUAGA and would not be covered thereunder. Because blood proteins and blood products were not at issue in that decision, 92-26 is distinguishable from the facts of this case. Moreover, SCDOR has not adopted this decision in its policies and does not actually follow this decision in practice.¹² Under this decision, whole blood, red blood cells, white blood cells, plasma and platelets would all be taxable tangible personal property. However, by its own admission, SCDOR does not currently tax these items.¹³ Because 92-26 is unpublished, has not

¹² This decision is not mentioned in any SCDOR publication available to the public or to its employees. See Buddin Dep. at 48:9- 49:8.

¹³ The auditor in this matter testified that SCDOR gives the auditors a chart to provide guidance on these items. See Buddin Dep. at 34:12-18- 35:18 (discussing chart provided by SCDOR to auditors that indicates that whole blood, red blood cells, white blood cells, plasma and platelets are not taxable while albumin, globulin and fibrinogen (all blood proteins) are taxable); Chart, attached as Ex. G to Roper's Amended Motion for Summary Judgment. In fact, in this same audit, the Department allowed Roper's requested refunds for Humate (a blood plasma product), human tissue and rib cartilage. See Refund Claim Documents, attached as Ex. H to Roper's Amended Motion for Summary Judgment. The Department cited RUAGA as the basis for these exemptions. Id.

been adopted by the Department in its policies or procedures, is not followed by the Department and is distinguishable from the facts of this case, this decision is not persuasive.

ORDER

Based on the foregoing, I find the following:

- I. The sale of prescription reconstructive musculoskeletal, prescription trauma musculoskeletal and prescription cardiovascular prosthetic devices upon the lawful order of a physician qualify as being "sold by prescription" as that term is used in the sales tax exemption statute at S.C. Code Ann. § 12-36-2120 (28), and these prescription prosthetic devices, which are intended to be surgically implanted into the human body, replace a missing part of the body as required by S.C. Code Reg. § 117-332 such that they are exempted from sales and use tax.
- II. The sale of blood derivatives is a sale of medical services as that term is used in the Revised Uniform Anatomical Gift Act as adopted in South Carolina and therefore is excluded from the imposition of sales and use tax.

IT IS THEREFORE ORDERED that Petitioner's Motion for Summary Judgment is Granted and Respondent's Motion for Summary Judgment is denied.

AND IT IS SO ORDERED.

The Honorable Shirley C. Robinson

_____, 2013
Columbia, South Carolina

STATE OF SOUTH CAROLINA)
COUNTY OF AIKEN)

IN THE COURT OF COMMON PLEAS
Case No. 89-CP-82-590

DR. WILLIAM J. BOYKIN,
PLAINTIFF,

ORDER

-vs-
THE SOUTH CAROLINA TAX COMMISSION,
DEFENDANT

This is an action maintained by the Plaintiff pursuant to S.C. Code Ann. Section 12-47-440 (1976 and Cum. Supp. 1988) to require the South Carolina Tax Commission to refund use taxes paid by the Plaintiff for the years 1985 through 1988. Now before the Court are cross motions for summary judgment. The Court has before it all pleadings in this case, including a stipulation of mutually agreed facts. A hearing on the parties' respective motions was heard on November 15, 1989.

Findings of Fact

Based upon the stipulation of the parties, I find that there is no dispute regarding the existence of the following material facts. Plaintiff is a citizen and resident of the City of Aiken, South Carolina, and is a dentist duly licensed to practice in South Carolina. During the years 1985 through 1988, he purchased from out of state various items which constitute prosthetic devices within the meaning of S.C. Code Ann. Section 12-35-550(31), and upon which he paid South Carolina use taxes on August 25 and October 13, 1988, in the amounts of \$429.77 and \$3,868.93, respectively. The prosthetic devices were sold to Plaintiff pursuant to written work authorizations issued by Plaintiff and were used by Plaintiff in providing dental services to his patients.

Plaintiff timely filed for a refund of the above-mentioned use taxes, which claim was denied. Plaintiff then appealed the denial of his refund claim to the Commission. The Commission upheld the denial, resulting in the Plaintiff's filing of the present lawsuit.

Conclusions of Law

Based upon the foregoing facts, the Court concludes that this case presents only issues of law for decision. The Court further concludes that there being no dispute as to any material fact, the Plaintiff is entitled to judgment as a matter of law. The legal grounds for the Court's conclusion are as follows:

In his complaint before this Court, Plaintiff cited as grounds for refund that such items were exempt from sales and use taxes pursuant to S.C. Code Ann. Section 12-35-550(31), which states in relevant part that "[t]here are exempted from the provisions of this article, and from the computation of the amount of the tax levied, assessed, or payable under this article, the following . . . (31) Gross proceeds from the sale of medicine and prosthetic devices sold by prescription. . . ." Although the above exemption relates only to the sales tax, S.C. Code Ann. Section 12-35-820(2) provides an

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James L. [Signature]
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EXHIBIT D

exemption from use tax to all tangible property exempted from the sales tax. Therefore, the exemption of Section 12-35-550(31) applies to both the sales tax and the use tax.

Plaintiff maintains that the exemption is applicable on its face, since the parties have stipulated all relevant facts and, furthermore, since a "work authorization" is subsumed in the definition of prescription. See United States v. Patterson, 155 F.Supp. 669, 673 (N.D. Ill. 1957), aff'd, 314 F.2d 491 (7th Cir. 1963). Defendant maintains that the "work Authorization" issued is not a "prescription" as required by the exemption statute. To so hold would emasculate the statute and deny its purpose, since Defendant can point to only a single prosthetic device (i.e., eyeglasses for cataract patients) which would be subject to the exemption under its interpretation. This would deny the plain language of the statute and the intent of the Legislature to exempt an entire class of items constituting prosthetic devices. See Etiwan Fertilizer Co. v. South Carolina Tax Comm'n, 217 S.C. 354 80 S.E.2d 682 (1950). (If the terms are clear and unambiguous, they must be taken in their plain, ordinary sense, unless it fairly appears from context that the Legislature intended to use such terms in a technical or peculiar sense.) The Court therefore holds that work authorizations issued by dentists for prosthetic devices are prescriptions for purposes of Section 12-35-550(31) as a matter of law.

Defendant's second argument involves the proposition that to be exempt a prosthetic device must be sold by prescription directly to a patient. The Court can find no basis in the statute to support this view. The language of the tax exemption statute must be given its plain, ordinary meaning and must be strictly construed against the exemption being claimed. John D. Hollingsworth on Wheels, Inc. v. Greenville County Treasurer, S.C. 314, 278 S.E.2d 340 (1981). The Court finds, however, that no credible construction of the statute restricts in any manner the persons who are intended to benefit from the exemption.

Based upon the foregoing, it is hereby

A. ORDERED that Plaintiff's motion for summary judgment be, and the same hereby is, GRANTED.

B. It is ORDERED further that judgment be, and the same hereby is, GRANTED, in favor of Plaintiff for refunds in the amounts of \$429.77 and \$3,868.93, together with pre-judgment and post-judgment interest at the maximum legal rates and court costs as allowed by law.

C. It is ORDERED further that the Clerk is to enter judgment pursuant hereto on the Judgment Roll forthwith.

D. It is ORDERED further that Defendant's Motion for Summary Judgment be, and the same hereby, is DENIED.

Done and Ordered in chambers this 22 day of Nov, 1989, at Lexington, South Carolina.

George Bell
George Bell, Timmerman, Jr., SPECIAL
Presiding Judge
Second Judicial District

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MBT

COMMON PLEAS COURT

CASE NO. 89-CP-02-590

NO. J. R. 78.070

Dr. William J. Boykin

VS

The S. C. Tax Commission.

PLAINTIFF (S)

DEFENDANT (S)

[] Jury verdict This action came before the court for a trial by jury. The issues have been tried and the jury has rendered its verdict.

[x] Decision by court. This action came to trial or hearing before the court. The issues have been tried or heard and a decision has been rendered.

rendered.

[] Action Dismissed [] Rule 40 (c) (3), SCRPC [] Rule 12 (b), SCRPC
[] Settled [] Vol. nonsuit [] Other, Explain _____

IT IS ORDERED AND ADJUDGED: ☒ See attached order
☐ Statement of Judgment by Court

Dated at Aiken, South Carolina, this 27th day of Nov, 1988

James T. Eubank
Deputy Clerk

This judgment/order was ~~entered~~ filed on the 27th day of Nov, 1989, and a copy mailed first class this 27th day of Nov, 1989, to attorneys of record or to parties (when appearing pro se) as follows:

Robert Young, Esquire

P. O. Box 12525

Columbia, S. C. 29211-2525

Attorney (s) for Plaintiff (s)

Ray N. Stevens, Deputy Attorney Gen.

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South Carolina Tax Commission

ROBERT C. WASSON
CHAIRMAN



Columbia

WYATT E. DUNHAM
M. WAYNE JONES, JR.
ROBERT C. WASSON
COMMISSIONERS

June 19, 1974

Senator Rembert C. Dennis
State House
Columbia, S. C.

Re: Part II, Section 5, 1974-75 Appropriation Bill
Exemption Proceeds from Sale of Drugs from the Sales Tax

Dear Senator Dennis:

By letter
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 sales tax. It appears, however, that in preparing the wording of same the exemption is much broader in scope and would include all drugs sold by hospitals, doctors, nursing homes, etc.

The initial estimate given to the House when the amendment was proposed from the floor was a \$2,000,000 loss in revenue. This was based upon the assumption that the exemption would be restricted to individual taxpayers. It appears, however, that because of the broad terms of the Section that there would be a loss of revenue of approximately \$6,000,000. The Section is drawn up to provide for an effective date of February 1, 1975. By doing this, it, of course, would result in a substantial lessening of the loss in revenue of the first fiscal year of its enactment. We estimate that if the Bill goes through as written, there would be a loss in revenue of \$2,000,000.

EXHIBIT C

EXHIBIT E

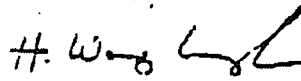
Senator Rember C. Dennis

June 19, 1974

the first fiscal year and \$6,000,000 for every year thereafter.
If the amendment as prepared and attached hereto is substituted,
we estimate that there would be a loss in revenue for the first fiscal
year of \$666,667 and \$2,000,000 for all subsequent fiscal years.

Thanking you, I am

Sincerely,



H. Wayne Unger, Jr.

HWUJr/cs

Enclosure

THE STATE OF SOUTH CAROLINA
In The Court Of Appeals

APPEAL FROM THE ADMINISTRATIVE LAW COURT

HONORABLE SHIRLEY C. ROBINSON, ADMINISTRATIVE LAW JUDGE

CASE NO. 12-ALJ-17-0405-CC

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

v.

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

CERTIFICATE OF COUNSEL

The undersigned certifies that this Record on Appeal contains all material proposed to be included by the above-referenced parties and not any other material in compliance with Rule 210(g), SCACR.



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