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## PRIVATE TAXPAYER RULING LR10-002

February 10, 2010

This private taxpayer ruling is in response to your letter dated November 10, 2009, in which you requested a private taxpayer ruling. Your request concerns whether \*\*\* is subject to transaction privilege tax on its sales of two injectable tissue implants or whether these two products qualify for the deduction given prosthetic appliances under Arizona Revised Statutes (A.R.S.) § 42-5061(A)(9). The injectable tissue implants are \*\*\* and \*\*. Pursuant to A.R.S. § 42-2101, the Department may issue private taxpayer rulings to taxpayers and potential taxpayers on request.

### **Statement of Facts:**

Below is a restatement of the facts as provided in your request for a private taxpayer ruling made on behalf of \*\*\*

A. \*\*\*

\*\*\* is a tissue filler implant that is injected by a physician or a nurse under the supervision of a physician. \*\*\* consists of calcium hydroxylapatite (CaHA) particles (25 to 45 microns in diameter), suspended in a water-based gel carrier.

\*\*\* is sold in individually packaged, single dose syringes. \*\*\* packaging carries the following labeling as required by the FDA:

Federal (USA) law restricts this device to sale by or on the order of a physician.

\*\*\* repairs defects in soft tissue of the body by initially replacing lost tissue volume and then stimulating the production of new, long-term natural collagen by the body. Collagen is a fibrous protein that is the chief constituent of the fiber of the connective tissues in soft tissues of the body, including skin.

\*\*\* is used in the treatment of defective, diseased, traumatized, or aging human tissue to correct a number of soft tissue defects, including moderate to severe facial wrinkles and folds (such as nasolabial folds), restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with HIV, vocal fold augmentation to treat speech impediments caused typically by stroke or neurological disorder, acne scars, oral and maxillofacial defects, and nipple reconstruction after mastectomy. The U.S. Food and Drug Administration (FDA) has issued approvals for \*\*\* to be marketed for the following treatments:

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2001	Radiographic tissue marking
2002	Vocal fold augmentation to treat speech impediments caused typically by stroke or neurological disorder
2003	Oral and maxillofacial defects
2006 (Dec)	Facial lipoatrophy
2006 (Dec)	Nasolabial folds and marionette lines

\*\*\* is currently most commonly used by doctors in the U.S. for the treatment of moderate to severe facial wrinkles and folds (such as nasolabial folds). \*\*\* is working with the FDA on clinical studies covering the use of \*\*\* for additional soft tissue treatments as well as using \*\*\* combined with lidocaine, a prescription anesthetic.

### B. \*\*\*

\*\*\* is an injectable implant used as a peri-urethral bulking agent to treat women who have stress urinary incontinence due to poorly functioning urethral sphincter muscles. \*\*\* consists of calcium hydroxylapatite (CaHA) (75 to 125 microns in diameter) suspended in a gel carrier. The \*\*\* implant is injected into the space around the urethra near the bladder. After injection, the \*\*\* implant bulks the tissue near the urethral sphincter and stimulates the production of new, long-term natural collagen by the body, enabling the sphincter to function more effectively.

The FDA has issued an approval for \*\*\* to be marketed for the following treatment:

2005	Peri-urethral bulking agent to treat women who have stress urinary incontinence due to poorly functioning urethral sphincter muscles.
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\*\*\* is sold in individually packaged, single dose syringes. \*\*\* packaging carries the following labeling as required by the FDA:

Federal (USA) law restricts this device to sale by or on the order of a physician.

### **Issues:**

Whether the following injectable implants are subject to Arizona transaction privilege tax, or qualify for the deduction given prosthetic appliances under A.R.S. § 42-5061(A)(9).

- A. \*\*\*, when used to treat moderate to severe facial wrinkles and folds (such as nasolabial folds).
- B. \*\*\*, when used to restore and/or correct signs of facial fat loss (lipoatrophy) in people with HIV.

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- C. \*\*\*, when used for vocal fold augmentation to treat speech impediments caused typically by stroke or neurological disorder.
- D. \*\*\*, when used to treat acne scars.
- E. \*\*\*, when used to treat oral and maxillofacial defects.
- F. \*\*\*, when used for nipple reconstruction after mastectomy
- G. \*\*\*, when used as a peri-urethral bulking agent to treat women who have stress urinary incontinence due to poorly functioning urethral sphincter muscles.

### **Your Position:**

The following is a restatement of your position as provided in your ruling request.

Arizona imposes a transaction privilege tax on the business of selling tangible personal property. The tax base is the gross proceeds of sales or gross income derived from the business. All sales of tangible personal property are subject to tax unless specifically exempt by statute.

Arizona provides a deduction from the tax base of the retail classification of the transaction privilege tax for prosthetic appliances that are prescribed or recommended by a licensed health professional. Prosthetic appliances are defined as artificial devices necessary to support or take the place of a part of the body or to increase the acuity of a sense organ.

According to a private letter ruling released in August of 2002, medical supplies are generally subject to transaction privilege tax because they do not meet the requirements for prosthetic appliances or durable medical equipment. However, if an item meets one of the requirements for a prosthetic appliance it will be deemed exempt from transaction privilege tax.

\*\*\*'s injectable tissue implants are available for sale mainly to licensed doctors and medical clinics for use in their professional services. Furthermore, federal law limits the sale of \*\*\*'s injectable tissue implants to sale by or on the order of a physician.

\*\*\*'s injectable tissue implants are intended to treat defective, diseased, traumatized, or aging human tissue by initially replacing lost tissue and then stimulating the body to grow new collagen in the treated areas. \*\*\*'s products directly affect the structure of the tissue system in its patients by stimulating new collagen growth which provides long-term benefits to the patients. \*\*\* is currently most commonly used by doctors in the U.S. for the treatment of moderate to severe facial wrinkles and folds (such as nasolabial folds). \*\*\* is also used for the restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with HIV, vocal fold augmentation to treat speech impediments caused typically by stroke or neurological disorder, acne scars, treatment of oral and maxillofacial defects, and nipple reconstruction after mastectomy. \*\*\* specifically does not have any affect on the patient's

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appearance. It is used to bulk the tissue around the urethra to treat stress urinary incontinence due to poorly functioning sphincter muscles.

\*\*\* believes that \*\*\* should be exempt from transaction privilege tax as a prosthetic appliance. \*\*\* is a Class III medical device intended to support a part of the body by treating defective, diseased, traumatized, or aging human tissue by initially replacing lost tissue and then stimulating the body to grow new collagen in the treated areas. In addition, \*\*\* has a variety of medical uses. For instance, \*\*\* supports a part of the body by augmenting voice function in those who have suffered stroke or experience neurological disorder. In addition, \*\*\* can be used to replace a part of the body by restoring facial fat loss in HIV patients. Therefore, \*\*\* should be deemed a prosthetic appliance. Furthermore, \*\*\* is sold only on prescription and sold directly to physicians, hospitals and medical clinics for their use with their patients.

\*\*\* also believes that \*\*\*, approved by the U.S. Food and Drug Administration as a device, should be exempt from transaction privilege tax as a prosthetic appliance since it is intended to treat stress urinary incontinence by bulking the tissue around the urethra and stimulating the production of new collagen. This enables the sphincter to function more effectively. Thus, \*\*\* is designed to treat a medical condition and to support a part of the body; there are no aesthetic benefits associated with the \*\*\* treatments. \*\*\* is sold only on prescription and sold directly to physicians, hospitals, and medical clinics for their use with their patients.

### **Applicable Law:**

Arizona Revised Statutes (A.R.S.) § 23-501 defines “prosthetic appliance” as “an artificial device necessary to support or take the place of a part of the body, or to increase the acuity of a sense organ.”

A.R.S. § 42-5023 states that it is “presumed that all gross proceeds of sales and gross income derived by a person from business activity classified under a taxable business classification comprise the tax base for the business until the contrary can be established.”

A.R.S. § 42-5061(A) states that “[t]he retail classification is comprised of the business of selling tangible personal property at retail. The tax base for the retail classification is the gross proceeds of sales or gross income derived from the business.”

A.R.S. § 42-5061(A)(9) deducts from the retail classification “[p]rosthetic appliances as defined in § 23-501 prescribed or recommended by a health professional licensed pursuant to title 32, chapter 7, 8, 11, 13, 14, 15, 16, 17, or 29.” These chapters refer to podiatrists, doctors of chiropractic, dentists, physicians and surgeons, naturopathic physicians, nurses, osteopathic physicians and surgeons, and homeopathic physicians.

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A.R.S. § 42-5159(A)(17) exempts from use tax “[p]rosthentic appliances, as defined in section 23-501, prescribed or recommended by a person who is licensed, registered or otherwise professionally credentialed as a physician, dentist, podiatrist, chiropractor, naturopath, homeopath, nurse or optometrist.”

Arizona Administrative Code (A.A.C.) R15-5-156(A)(12) defines “prosthetic appliance” as “an artificial device which fully or partially replaces a part or function of the human body or increases the acuity of a sense organ.”

Arizona Transaction Privilege Tax Ruling (TPR) 99-3, which describes what items used by dentists constitute “prosthetic appliances.”

### **Case Law:**

*Renal West v. Arizona Department of Revenue*, 189 Ariz. 409, 943 P.2d 769 (Ct. App. 1997), addressed whether kidney dialysis machines, solutions, testing equipment and supplies constitute an exempt prosthetic appliance.

### **Discussion:**

Arizona's transaction privilege tax is a tax on the privilege of conducting business in the State of Arizona. It is a tax on the *seller*, not on the purchaser. The seller may pass the burden of the tax on to the purchaser; however, the seller is ultimately liable to Arizona for the tax. The Arizona transaction privilege tax is imposed under 16 separate business classifications, including *retail* sales of tangible personal property. In addition, county excise taxes “piggyback” the imposition of the state's transaction privilege tax. All sales that are subject to the transaction privilege tax are also subject to applicable county excise taxes.

A.R.S. § 42-5061 imposes the transaction privilege tax under the retail classification. The retail classification is comprised of the business of selling tangible personal property at retail. The tax base for the retail classification is the gross proceeds of sales or gross income derived from the business. All sales of tangible personal property are subject to the transaction privilege tax under the retail classification unless specifically deducted or excluded by statute.

Unlike the retail deduction for *drugs* on the prescription of a licensed member of the medical, dental or veterinarian profession, there is no general deduction from the tax base of the retail classification for *medical devices* on prescription.

Furthermore, sales of tangible personal property to medical professionals or facilities do not qualify as sales for resale. A.A.C. R15-5-156 provides:

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E. Purchases by a final consumer of nonprescription products and those medical supplies or appliances not provided for under subsection (B) are subject to tax.

F. Purchases of nonprescription products or other medical supplies or appliances by doctors, dentists, or veterinarians are subject to tax unless the purchase qualifies as a purchase for resale and the doctor, dentist, or veterinarian is a retailer in the business of reselling the property.

A.A.C. R15-5-104(A) provides that “[g]ross receipts from the sales of tangible personal property to a person engaged in a professional or personal service occupation or business are taxable if the tangible personal property is used or consumed in the performance of the service or is sold only as an inconsequential element of the nontaxable service provided.”

A.R.S. § 42-5061(A)(9) specifically deducts from the tax base gross proceeds of sales of “[p]rosthetic appliances as defined in § 23-501 prescribed or recommended by a health professional licensed pursuant to title 32, chapter 7, 8, 11, 13, 14, 15, 16, 17, or 29.” These chapters refer to podiatrists, doctors of chiropractic, dentists, physicians and surgeons, naturopathic physicians, nurses, osteopathic physicians and surgeons, and homeopathic physicians.

A.R.S. § 23-501(7) defines “prosthetic appliance” as “an artificial device necessary to support or take the place of a part of the body, or to increase the acuity of a sense organ.” In addition, A.A.C. R15-5-156(A)(12) defines “prosthetic appliance” as “an artificial device which fully or partially replaces a part or function of the human body or increases the acuity of a sense organ.”

In the ruling request the position taken is that \*\*\*’s injectable tissue implants are intended to treat defective, diseased, traumatized, or aging human tissue by initially replacing lost tissue and then stimulating the body to grow new collagen in the treated areas. The products directly affect the structure of the tissue system in its patients by stimulating new collagen growth which provides long-term benefits to the patients.

For instance, “\*\*\* supports a part of the body by augmenting voice function in those who have suffered stroke or experience neurological disorder. In addition, \*\*\* can be used to replace a part of the body by restoring facial fat loss in HIV patients. Therefore, \*\*\* should be deemed a prosthetic appliance.” Referring to \*\*\*, “should be exempt from transaction privilege tax as a prosthetic appliance since it is intended to treat stress urinary incontinence by bulking the tissue around the urethra and stimulating the production of new collagen. This enables the sphincter to function more effectively. Thus, \*\*\* is designed to treat a medical condition and to support a part of the body . . . .”

This view of the deduction fails to qualify under the statute because the injectable tissue implant is not replacing a functioning body part, but rather serving as an augmentation or an addition to a functioning body part. Injectable tissue implants, or bulking agents, in effect, augment soft tissue volume and stimulate the production of natural collagen but are

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not devices that support or take the place of a part of the body nor do they increase the acuity of a sense organ. The statutory definitions of “prosthetic appliances” for purposes of the deduction under A.R.S. § 42-5061(A)(9) and A.R.S. § 42-5159(A)(17), along with A.R.S. § 23-501(7), indicate a prerequisite absence of a body part or a body function.

The facts that have been presented for most of the FDA approved treatments do not indicate an absence of any body part, but in some of the FDA approved treatment applications the facts indicate that there is a part of the body that is not functioning properly. The improperly functioning part affects the normal function of the human body. In these instances the tissue implants temporarily replaces or temporarily supports the function of the human body.

In *Renal West L.C. v. Arizona Dept. of Revenue*, 189 Ariz. 409, 943 P.2d 769 (App. 1997), the court decided that the entire process of dialysis complies with the definition of a prosthetic appliance because it substitutes for a function of the human body. In that case, the process of dialysis was held to fall within the definition of prosthetic appliance because it substituted for the use of a body part that could no longer function.

The court’s decision suggests functional, as well as physical, substitutes may qualify under the statutory definition of prosthetic appliances. As provided by A.A.C. R15-5-156(A)(12), “prosthetic appliance” is “an artificial device which fully or partially replaces a part or function of the human body . . .”

Arizona Transaction Privilege Tax Ruling (TPR) 99-3, which describes what items used by dentists constitute “prosthetic appliances,” explains that the *Renal West* process analysis is not applicable to items used for processes that do not replace a bodily process.

Whether a conclusion can be made that \*\*\* or \*\*\* is actually replacing or supporting a function of the human body depends on whether there is a part that is not functioning properly. In *Renal West*, the process of dialysis was replacing, or supporting, the normal function of the kidneys. The organs could no longer function in their normal capacity. The dialysis was necessary to perform the normal, everyday function of the organs (or support it) without physically replacing the organs themselves.

Laryngeal injections of bulking agents to treat vocal cord paralysis and urethral injections of bulking agents to treat stress urinary incontinence are two examples of treatments that support a normal body function where a part of the body is not functioning properly.

### **Ruling:**

Based on the facts presented in your request, the Department rules that the gross proceeds from the sale of the injectable tissue implants \*\*\* and \*\*\* for the FDA approved uses as follows.

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- A. \*\*\*, when used to treat moderate to severe facial wrinkles and folds (such as nasolabial folds).

\*\*\* fails to meet the definition of a prosthetic appliance in this treatment. Sales of \*\*\* to treat moderate to severe facial wrinkles and folds are subject to transaction privilege tax.

- B. \*\*\*, when used to restore and/or correct signs of facial fat loss (lipoatrophy) in people with HIV.

\*\*\* fails to meet the definition of a prosthetic appliance in this treatment. Sales of \*\*\* to restore and/or correct signs of facial fat loss are subject to transaction privilege tax.

- C. \*\*\*, when used for vocal fold augmentation to treat speech impediments caused typically by stroke or neurological disorder.

\*\*\* supports a function of the body meeting the definition of a prosthetic appliance in this treatment. Sales of \*\*\*, which are used for vocal fold augmentation to treat speech impediments caused typically by stroke or neurological disorder, are not subject to transaction privilege tax.

- D. \*\*\*, when used to treat acne scars.

\*\*\* fails to meet the definition of a prosthetic appliance in this treatment. Sales of \*\*\* that is used to treat acne scars are subject to transaction privilege tax.

- E. \*\*\*, when used to treat oral and maxillofacial defects.

\*\*\* fails to meet the definition of a prosthetic appliance in this treatment. Sales of \*\*\* that is used to treat oral and maxillofacial defects are subject to transaction privilege tax.

- F. \*\*\*, when used for nipple reconstruction after mastectomy.

\*\*\* fails to meet the definition of a prosthetic appliance in this treatment. Sales of \*\*\* that is used for nipple reconstruction after mastectomy are subject to transaction privilege tax.

- G. \*\*\*, when used as a peri-urethral bulking agent to treat women who have stress urinary incontinence due to poorly functioning urethral sphincter muscles.

\*\*\* supports a function of the body meeting the definition of a prosthetic appliance in this treatment. Sales of \*\*\*, which is used as a peri-urethral bulking agent to treat women who have stress urinary incontinence due to poorly functioning urethral sphincter muscles, are not subject to transaction privilege tax.



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The conclusions of this private taxpayer ruling do not extend beyond the facts as presented in your letters and attachments dated November 10, 2009.

**This response is a private taxpayer ruling and the determinations herein are based solely on the facts provided in your request. The determinations are subject to change should the facts prove to be different on audit. If it is determined that undisclosed facts were substantial or material to the Department's making of an accurate determination, this taxpayer ruling shall be null and void. Further, the determination is subject to future change depending on changes in statutes, administrative rules, case law or notification of a different Department position.**

**The determinations in this private taxpayer ruling are applicable only to the taxpayer requesting the ruling and may not be relied upon, cited nor introduced into evidence in any proceeding by a taxpayer other than the taxpayer who has received the private taxpayer ruling.**