

## REQUEST LETTER

08-001

October 24, 2007

From:  
NAME  
COMPANY  
ADDRESS  
PHONE  
FAX

Dear Sir or Madam:

The COMPANY is a professional corporation composed of seven physicians and one nurse practitioner who provide medical care to women.

In DATE, an auditor from the Utah State Tax Commission told us that we had to pay use tax on intrauterine contraceptives devices. At that time, the auditor classified the intrauterine devices as “prosthetics.” Since then, we have been paying their tax on Paragard and Mirena contraceptives.

However, after reviewing Publication 53, “Sales Tax Information for Health Care Providers,” I believe that the Mirena and Paragard should be classified as drugs, not as prosthetics, and therefore should be exempt for use tax.

More than two decades ago, the intrauterine contraceptive devices were composed of a plastic inert substance. However those devices are no longer on the market and haven't been used in the U.S. since the 1970's. The two currently prescribed intrauterine contraceptives each meet the criteria as a “drug”, as defined by Publication 53. the Mirena slowly releases levonorgestrel and the Paragard releases copper ions into the uterine cavity to prevent pregnancy.

Publication 53 states that amounts paid for a drug are exempt from sales tax if:

1. the item is intended for human use; and
2. a prescription was issued for the item or the item was purchased by a hospital or other medical facility.

Another contraceptive, the implanon subdermal implant, has recently been approved for use. It slowly releases a medication, etonogestel to prevent pregnancy. We have been paying sales tax on the Implanon as well, but according to Publication 53, it should also be tax exempt.

Just as clinics order injectable vaccines in advance of use which are then administered when the patient is seen, the same is true for these drugs. They can only be prescribed by a physician, ordered directly from the manufacturer, and then they are inserted under the skin (Implanon) or placed in the uterus (Mirena and Paragard).

The guidance provided by Publication 53 states that a drug is defined as a compound, substance or preparation that is recognized in the official United States Pharmacopoeia and is intended to affect any function of the body. The intrauterine contraceptives and subdermal implants clearly meet this definition. These can only be inserted by physicians or other licensed practitioners and are ordered by our office just as we order vaccines in advance, anticipating their administration when the patient is seen.

Based on this information, I believe that the Mirena, Paragard, and Implanon should be exempt from use tax per the criteria set forth in Publication 53. I have attached the FDA information for you on these three drugs.

I would be happy to meet with you to discuss this further and would be available to answer any questions you have about alternative drug delivery systems which are now available.

I would appreciate an official opinion as soon as possible regarding this issue.

Sincerely,

NAME  
COMPANY

cc: SECOND NAME  
THIRD NAME

## **RESPONSE LETTER**

NAME  
COMPANY  
ADDRESS

Re: Private Letter Ruling 08-001

Dear NAME,

This letter is in response to your request for tax guidance. This letter ruling is not intended as a statement of broad Tax Commission policy. It is an interpretation and application of the tax law as it relates to the facts presented in your request letter and the assumptions stated in the Analysis portion of this ruling letter. If the facts or assumptions

are not correctly described in this letter ruling, please let me know so we can assure a more accurate response to your circumstances.

### **Facts**

The Commission understands that the COMPANY is a professional corporation composed of seven physicians and one nurse practitioner who provide medical care to women, including the sale and implantation of contraceptive devices. Among the contraceptive devices the clinic offers are three devices sold under the names of Paragard, Mirena, and Implanon. The clinic indicates that all of these devices require a prescription. The Clinic has inquired whether sales of these devices are subject to sales tax.

Paragard and Mirena are intrauterine contraceptive devices. Unlike intrauterine contraceptive devices in the past, which were made of inert plastic and prevented pregnancy by their presence in the uterus, Paragard and Mirena function by releasing chemical agents into the body in which they are inserted. Paragard releases copper ions into the patient's body. According to the clinical listings for Paragard, the release of copper provides contraceptive effect. The clinical listings for Mirena indicate that it releases a compound called Levonorgestrel, causing contraceptive effects.

While the effectiveness of Paragard and Mirena may be enhanced by being a foreign body placed in the patient's uterus, they primarily work by releasing chemical agents. That these devices are meant to gain their effectiveness by chemical means is supported by the limited life span of the devices. The manufacturer of Mirena recommends removal after five years, while Paragard's manufacturer recommends removal at ten years.

The Implanon device is not placed in the uterus of the user, but under the skin of the user. There, the Implanon releases a hormone called etonogestrel to prevent pregnancy. Implanon functions through the release of etonogestrel. The Implanon should be removed after three years.

### **Relevant Authority**

Utah Code §59-12-103(1)(a) imposes sales tax on amounts paid or charged for "retail sales of tangible personal property made within the state;"

Utah Code § 59-12-104(10) provides exemption from sales tax for a drug, if the drug meets two requirements. First, the drug must be "intended for human use." Second, it must either be purchased by a hospital or medical facility or issued under a prescription.

Utah Code § 59-12-102(29) defines "drug" as follows:

- (a) "Drug" means a compound, substance, or preparation, or a component of a compound, substance, or preparation that is:
  - (i) recognized in:
    - (A) the official United States Pharmacopoeia;
    - (B) the official Homeopathic Pharmacopoeia of the United States;
    - (C) the official National Formulary; or
    - (D) a supplement to a publication listed in Subsections (29) (a)(i)(A) through (C);
  - (ii) intended for use in the:
    - (A) diagnosis of disease;
    - (B) cure of disease;
    - (C) mitigation of disease;
    - (D) treatment of disease; or
    - (E) prevention of disease; or
  - (iii) intended to affect:
    - (A) the structure of the body; or
    - (B) any function of the body.
- (b) "Drug" does not include:
  - (i) food and food ingredients;
  - (ii) a dietary supplement;
  - (iii) an alcoholic beverage; or
  - (iv) a prosthetic device.

### **Analysis and Ruling**

The Commission has indicated in a previous Private Letter Ruling (PLR 06-021), that certain birth control devices were subject to sales tax. However, the devices as described in PLR 06-021 did not release a drug into the body.

The devices as described by the Clinic, on the other hand, do release drugs into the body of the patient. The primary, if not sole, clinical effect of these devices is through those drugs. Each of the agents released by the Paragard, Mirena, and Implanon devices is a “compound, substance, or preparation, or a component of a compound, substance, or preparation . . . intended to affect . . . any function of the body” and is thus a “drug” as defined in Utah Code § 59-12-102(29). The drugs released by these devices also meet the requirements for exemption in Utah Code § 59-12-104(10). The drugs require a prescription and are “intended for human use.”

Although the agents released by the Paragard, Mirena, and Implanon devices are drugs not subject to sales tax, the Commission considers whether the devices may be subject to taxation. While these devices release drugs, they are not themselves drugs and could be subject to taxation if the essence of the transaction is for a device rather than for drugs. However these devices, as described, have little or no clinical value other than as a vehicle to deliver drugs. Thus, the essence of the transaction for sale of these devices is

a sale of drugs. The Commission considers the purpose and value of these devices incidental to the sale of the drugs and therefore finds that sales of these devices are not subject to sales or use tax.

### **Conclusion**

Under Utah law, sales of the devices Paragard, Mirens, and Implanon are transactions for the delivery of tax-exempt drugs under a doctor's prescription. They have little or no use other than as drug-delivery vehicles. Therefore, sales of these devices by a medical facility under a prescription are thus not subject to Utah sales or use tax.

For the Commission,

Marc B. Johnson  
Commissioner

MBJ/CDJ  
08-001