REFERENCE NO: FASC12048

VIA ELECTRONIC DELIVERY (www.regulations.gov)

May 7, 2012

Steven T. Miller
Deputy Commissioner for Services and Enforcement
Internal Revenue Service
CC:PA:LPD:PR (REG-113770-10)
Room 5203
PO Box 7604
Ben Franklin Station
Washington, DC 20044

Re: REG-113770-10 (Proposed Rulemaking on Taxable Medical Devices)

Dear Deputy Commissioner Miller:

The Plasma Protein Therapeutics Association (PPTA) appreciates the opportunity to comment on Internal Revenue Service (IRS) notice of proposed rulemaking on the medical device tax (77 Fed. Reg. 6028 (Feb. 7, 2012) (Proposed Rule)).

PPTA is the association that represents human plasma collection centers and the manufacturers of lifesaving medicinal therapies, including albumin, alpha$_1$-proteinase inhibitor, antithrombin III, blood clotting factors, C1 esterase inhibitor, immune globulin, hyperimmune immune globulin, and protein C concentrate, from this human plasma.[1] Some of our members also use recombinant DNA technology to produce blood clotting factors. Collectively, these therapies – both plasma-derived and recombinant – are known as "plasma protein therapies." The manufacturer membership of PPTA in the United States currently includes Baxter, Biotest, Cangene, CSL Behring, Grifols and Kedrion. The majority of plasma protein therapies are solely approved for marketing in the U.S. by the Food and Drug Administration (FDA) for the treatment of one or more rare disease, disorder, and condition. In the U.S., a "rare disease or condition" is generally defined as a disease or condition that affects less than 200,000 people.[2]

PPTA is pleased to offer comments in response to the Proposed Rule issued by the IRS related to the excise tax imposed on the sales of certain medical devices under

[1] Human plasma is the clear liquid portion of blood that remains after the red cells, leukocytes, and platelets are removed. Due to its human origin, complexity, and richness in therapeutically useful proteins, human plasma is a unique biological material. *See* Thierry Burnouf, *Plasma Proteins: Unique Biopharmaceuticals – Unique Economics*, *in* 7 PHARMACEUTICALS POLICY AND LAW, BLOOD, PLASMA AND PLASMA PROTEINS: A UNIQUE CONTRIBUTION TO MODERN HEALTHCARE 209.
[2] *See* 21 U.S.C. § 360bb(a)(2) (2006).

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section 4191 of the Internal Revenue Code (IRC). Plasma protein therapies are unique non-interchangeable biologics approved by the FDA under the Public Health Service Act and are subject to the annual fee imposed on branded pharmaceutical manufacturers under 26 U.S.C. § 4001 (unless excluded because of orphan drug designation). While these therapies are often packaged with medical devices, we do not believe the sales of plasma protein therapies should also be subject to the tax on medical devices. The Proposed Rule lacks clarity on how such situations are addressed, and PPTA seeks confirmation that the sales of plasma protein therapies will not be subject to the medical device tax. Such confirmation is consistent with the proposed definition of "taxable medical devices" and is needed to avoid double taxation of plasma protein therapies.

In addition, due to the unique nature of plasma protein therapies, there are a number of devices that may be used in the development or testing necessary to produce these therapies that we ask the IRS to confirm are not subject to the medical device tax.

I. Plasma Protein Therapies Are Not Taxable Medical Devices

Plasma protein therapies are approved by the FDA as biologic products under the Public Health Service Act and through this designation are subject to the annual fee imposed on branded pharmaceutical manufacturers under 26 U.S.C. § 4001 (unless excluded due to orphan drug designation). Many plasma protein therapies are packaged with ancillary supplies or sold in prefilled syringes used to administer the therapies. PPTA is concerned that these ancillary supplies could be listed as a "taxable medical device" under section 510(j) of the Federal Food, Drug, and Cosmetic Act (FFDCA), which would lead to a double taxation of plasma protein therapies under the Proposed Rule.

According to the Proposed Rule, a "taxable medical device" is a product that is listed as a device with the FDA under section 510(j) of the FFDCA. While it is possible that some plasma protein therapies are packaged with ancillary supplies or sold in prefilled syringes that may be listed as devices under the FFDCA, the plasma protein therapy itself is not listed as a device. Examples of the ancillary supplies that facilitate the delivery of a plasma protein therapy include infusion sets, intravenous sets, filter needle component packs, transfer devices, mix vials, tubing and alcohol swabs. PPTA believes that the inclusion of these items should not subject plasma protein therapies to the medical device tax in addition to the annual pharmaceutical fee.

Should the IRS take a contrary position, the therapy would be subject to both the medical device tax and the annual pharmaceutical fee. There is no evidence to suggest that Congressional intent in enacting the annual pharmaceutical fee and the medical device tax was to subject manufacturers to both taxes based on supplies included with their products.

PPTA is concerned that double taxation in these situations would prove unduly burdensome and operationally difficult for manufacturers to implement. In a plasma protein therapy package that includes ancillary supplies, a manufacturer or other entity would have to determine what portion of the total sale price to attribute to (1) the "device" (for the device tax) and (2) the "medication" (for the pharmaceutical annual fee). As the pharmaceutical annual fee relies on updated, complete information from government agencies, we believe it would prove difficult for the IRS to accurately separate ancillary device costs from drug costs.

PPTA is also concerned that imposing a medical device tax on the ancillary supplies used to administer the plasma protein therapy would discourage manufacturers from including such items with their products. These ancillary items are included for the convenience or other benefit of patients. It would be detrimental to patients who rely on regular administration of plasma protein therapies if they were required to obtain these ancillary items elsewhere.

Accordingly, PPTA asks the IRS to clarify in the Final Rule that the ancillary supplies used to administer plasma protein therapies are not subject to the medical device tax.

II. Other Issues

The development and manufacturing of plasma protein therapies is a complex process that involves highly specialized equipment. This equipment is used to develop and test plasma protein therapies, assure quality and product integrity and hold/transfer product. Although they may be listed as devices by the FDA, PPTA does not believe that such devices fit within the statutory definition of "taxable medical device". Section 4191(b) of the IRC indicates that a "taxable medical device" must be intended for humans. The devices used to develop and manufacture a finished biological product (that can be sold for use by humans) are not intended for humans.

A. Devices Used for Collecting and Testing Plasma Protein Therapies

Many plasma protein therapies use human plasma as the starting material and require extensive testing throughout the manufacturing process. This includes testing at the time of plasma collection, after collection and before a finished plasma protein therapy is distributed to patients. This testing may be performed using medical devices that may be listed as devices by the FDA. PPTA believes that it would be inappropriate to subject the sales of these testing devices to the device tax.

The same would hold true with regard to apheresis machines, which are a tool used to collect plasma from donors throughout the country. Moreover, the plasma donor is not the beneficiary of any medical treatment by means of an apheresis machine.

B. Software

Manufacturers of plasma protein therapies use software programs to manage and track plasma donations, to ensure quality of the finished product. These software programs may be listed as a device by the FDA. Just as with the testing devices discussed above, the software program is not intended for humans and thus, by statute, cannot be subject to the device tax. PPTA asks the IRS to confirm that software programs used in the manufacture of plasma protein therapies are not subject to the device tax.

C. Product Containers

Containers used merely to hold or transport products, such as plastic tubing, pooling bottles, and plastic vials may be listed as a device by the FDA. Again, they are not intended for human use. Accordingly, they do not fit within the statutory definition of "taxable medical device." PPTA asks the IRS to confirm that these products are not subject to the medical device tax.

III. Conclusion

In summary, PPTA seeks clarification from the IRS regarding the Proposed Rule on Taxable Medical Devices. First and foremost, the IRS should state clearly that sales of plasma protein therapies, which include ancillary supplies or prefilled syringes, are not taxable medical devices and therefore are not subject to the medical device tax. Finally, PPTA also asks the IRS to confirm that devices used in the development or manufacturing of plasma protein therapies are not subject to the medical device tax, as they are not intended for human use.

If you have any questions concerning this letter, please do not hesitate to contact Kym Kilbourne, Director, Federal Affairs at kkilbourne@pptaglobal.org.

Sincerely,

Julie A. Birkofer
Senior Vice President, North America