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THE MEDICAL DEVICES EXCISE TAX (MDET) – A MARKET-SPECIFIC VAT?

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VATs flourish in complex, clearly defined markets. New York discovered this when it converted its single-stage retail sales tax on hotel rooms, the Hotel Room Occupancy Tax (HROT), into a multi-stage European-style Value Added Tax. The statutory change was policy-driven and a direct response to increased market complexity.

New York began to experience HROT problems collecting the full transaction tax when online room remarketers entered the supply chain, placing themselves between the hotel (manufacturing the available rooms) and the (retail) customer¹. While online marketers were embedded in the supply chain their value was not in the tax base.² The impact on revenue was direct³.

The HROT VAT conversion demonstrates that moving to a multi-stage VAT can (a) mitigate or eliminate losses attributable to supply-chain-fragmentation, (b) in a clearly defined market where, (c) a single stage tax is imposed on (d) less than all supply chain stages. In addition, where taxability at one supply chain stage is determined by actions in a distant chain stage, adopting a VAT reduces complexity by making the tax transparent and self-enforcing.

The Medical Devices Excise Tax (MDET) imposes as 2.3% excise tax on manufacturers, producers or importers selling clearly identified medical devices under Internal Revenue Code (IRC) §4191. The MDET, as conceived under proposed regulations like the earlier HROT is a single stage transaction tax levied on one complex

¹ The HROT is very much like a simple manufacturer's tax although the technical taxpayer is the occupant, not the hotel as it would be under a manufacturer's tax. The inventory being produced (manufactured) is vacant hotel rooms. The hotel sells occupancy rights to rooms and collects tax on the transaction. Rooms that remain unoccupied are the bane of this industry. Online room remarketers solve these difficulties by becoming involved in the last minute room rentals that might otherwise remain vacant. Even though they added value to the supply chain with their "demand collection systems" the remarketers value not only escaped tax, but the HROT's structure allowed this value to be removed from what would have been the hotel owner's (manufacturer's) tax base. Redesigning the HROT as a VAT New York closed this tax gap.

² Essentially an online business that has no nexus with the taxing jurisdiction cannot be compelled to collect tax on sales made within the State. See these arguments in: *County of Nassau, NY v. Hotels.com et al.* 594 F. Supp. 2d 251 (E.D.N.Y., 2007) (case dismissed because the county did not exhaust administrative remedies); *County of Nassau, NY v. Hotels.com et al.* 577 F.3d 89 (2nd Cir., 2009) (vacated and remanded for failure to meet requirements for class certification under Fed. R. Civ. P. 23 because it is not clear that all the class members imposed a hotel tax that was similar to the Nassau County hotel tax).

³ For a detailed HROT discussion as a VAT see: Richard T. Ainsworth, *New York Adopts a VAT*, 61 STATE TAX NOTES 223 (July 25, 2011). See also: proposals to modify the retail sales tax in retail gasoline market in Illinois and Michigan to deal with significant fraud issues by following the New York HROT example. Richard T. Ainsworth, *Michigan's Industry-Specific VAT*, 62 STATE TAX NOTES 441 (November 14, 2011).

supply chain stage in a clearly defined market. The major difference between MDET and the former HROT is that MDET is a single-stage *manufacturer* tax while the HROT is a single-stage *retail* tax residing at opposite ends in problematical supply chains.⁴

As a manufacturers excise tax, the MDET attempts to accomplish in the complex medical device market what has been achieved in six other relatively simple commodity markets (sport fishing equipment;⁵ archery equipment;⁶ coal;⁷ tires;⁸ gasoline guzzling automobiles;⁹ and vaccines¹⁰). Difficulties are, however, expected in this market due to the high-value role services and technology play in developing, selling, and distributing these products.

The MDET, like the former HROT, would benefit from being recast as a market-specific VAT. This paper explains why and how this can be achieved.

MDET

MDET has an affirmative and negative part. The affirmative aspect lies in IRC §4191. The negative aspect is the related disconnection between §4191 and Code sections that would have attached to it because the MDET appears in USC subtitle D chapter 32. Both aspects need to be considered to understand the policy options open to the Treasury during implementation.

MDET - *The affirmative aspect under HCERA§1405(a)*

The Health Care and Education Reconciliation Act of 2010 (HCERA)¹¹, in conjunction with the Patient Protection and Affordable Care Act (PPACA)¹², introduced the Medical Devices Excise Tax under HCERA§1405(a). The tax is effective for medical devices sold after December 31, 2012. IRC§4191 states:

§4191 Medical devices

(a) In general

There is hereby imposed on the sale of any taxable medical device by the manufacturer, producer, or importer a tax equal to 2.3 percent of the price for which so sold.

(b) Taxable medical device

For purposes of this section—

(1) In general

⁴ Stated differently, the major HROT problem (coming at the supply chain's end) was how to be sure all the taxable value was included in the base, whereas the major MDET problem (coming as the supply chain begins) is how to tax the full manufactured value with appropriate allowance for refunds based on transactions with final consumers at the other supply chain end.

⁵ IRC §4161 including: fishing rods and fishing poles; fishing tackle boxes; electric outboard boat motors

⁶ IRC §4162 including: bows, quivers, broad heads, points and arrow shafts

⁷ IRC §4121 imposed on coal from mines located in the US sold by the producer

⁸ IRC §§4071-4073 imposed on bias ply or super ply tires, essentially any tire used on highway vehicles

⁹ IRC §4064 applicable to automobiles based on EPA determined fuel economy, model type, and model year

¹⁰ IRC §§4131-4132 (sixteen specific vaccines are listed)

¹¹ Pub. L., No. 111-152, 124 Stat. 1029, 1064-1065 (2010).

¹² Pub. L., No. 111-148, 124 Stat. 119 (2010).

The term “taxable medical device” means any device (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act) intended for humans.

(2) Exemptions

Such term shall not include—

- (A) eyeglasses,
- (B) contact lenses,
- (C) hearing aids, and
- (D) any other medical device determined by the Secretary to be of a type which is generally purchased by the general public at retail for individual use.

The most challenging section within this short provision lies in §4191(b)(2) because each item listed is a **product exemption**. There are three product specific exemptions for eyeglasses, contact lenses and hearing aids with a fourth open-ended exemption at §4191(b)(2)(D). Congress intended the fourth exemption to be **regulatory driven further product exemptions**.

In other words, Congressional intent was that the Treasury would compose a *list* of other qualified medical device **products** that met the standard set out in the statute. These were to be products “of a type ... generally purchased by the general public at retail for individual use”¹³.

MDET – The first negative aspect under HCERA §1405(b)(1)

This HCERA section makes four of the six traditional **entity/use** exemptions that are generally available to manufacturer taxes under the IRC inapplicable to the MDET¹⁴ by expressly stating:

Section 4221(a) of the Internal Revenue Code of 1986 is amended by adding at the end the following new sentence:

“In the case of the tax imposed by section 4191, paragraphs (3), (4), (5), and (6) shall not apply.”

The removed exemptions are for supplies purchased for use on vessels and aircraft¹⁵, items State or Local governments purchase for their exclusive use¹⁶, items that

¹³ The Joint Committee on Taxation is very clear that a **product exemptions** list is envisioned. The same language can be found in two different JCT documents:

It is anticipated that the Secretary will publish a list of medical device classifications [a footnote specifies that classifications like those found in Title 21 of the Code of Federal Regulations, Parts 862-892 are to be emulated] that are of a type generally purchased by the general public at retail for individual use.

Joint Committee on Taxation, *General Explanation of Tax Legislation Enacted in the 111th Congress* (JCS-2-11), March 2011, at 366 & n. 986. See also Joint Committee on Taxation, *Technical Explanation of the “Revenue Provisions of the Revenue Reconciliation Act of 2010,” as amended, in combination with the “Patient Protection and Affordable Care Act,”* JCX-18-10 (March 2010) at 138 & n. 296.

¹⁴ The remaining two traditional **entity / use exemptions** applicable to the MDET are the: (1) exemption for a purchaser who will use a medical device for further manufacture, or resold to a second purchaser for further manufacture under §4221(a)(1), and (2) exemption for export, or sale to a second purchaser for export under §4221(a)(2).

non-profit educational organizations purchase for their exclusive use¹⁷, and items purchased by qualified blood collector organizations for use in collecting, storing or transporting blood¹⁸.

Entity exemptions are relatively easy to work *if* there is a direct relationship between the exempt entity and the manufacturer. They are more complicated when a *use* requirement is linked to the entity's status. Each §4221(a) exemption is a combined **entity/use exemption**.

The more remote an exempt party is from the party paying the tax, the more difficult it is to make entity exemptions work in excise taxes. Regulations issued under IRC §4221(a) make it clear that this principle is well understood. Three standard excise tax exemptions (sales to State and local governments, sales for nonprofit educational purposes, and sales to vessels and aircraft) require a direct relationship between the exempt party and the manufacturer for the exemption to be honored. These exemptions are not allowed to pass through a distributor¹⁹ and both the exempt party and manufacturer must register with the IRS²⁰.

Manufactures taxes are averse to passing an exemption certificate through multiple parties in a commercial chain. Other than a limited exception for export sales where three parties are allowed in the exemption chain²¹, all exemptions are direct. Enforcement involves denying an exemption if the manufacturer has “reason to believe that the article sold was not actually intended for the exempt purpose indicated by the purchaser”²².

¹⁵ §4221(a)(3)

¹⁶ §4221(a)(4)

¹⁷ §4221(a)(5)

¹⁸ §4221(a)(6)

¹⁹ *See for example*, Treasury Regulation §48.4221-5(a) indicating that the State and local government exemption under §4221(a)(4) is only available where the manufacturer makes the sale directly to the State or local government for its exclusive use. “No sale may be made tax free to a dealer for resale to a State or local government for its exclusive use, even if it is known at the time of sale by the manufacturer that the article will be resold.” The exact same language can be found in Treasury Regulation §48.4221-6(a) requiring the manufacturer to sell directly to nonprofit educational organizations to qualify for the exemption under §4221(a)(5). The same is true under Treasury Regulation §48.4221-4(a) tax-free article sales for purchaser use as supplies for vessels or aircraft.

²⁰ *See for example*, when making sales to vessels or aircraft both the manufacturer and the purchaser are required to be registered with the IRS. [Treasury Regulation §48.4221-4(d)(1)(i)]. In cases, however, where one or both parties are not registered such as foreign owned vessels or aircraft the manufacturer must possess “prior to or at the time of sale” a properly executed exemption certificate as prescribed under Treasury Regulation §48.4221-4(d)(2)(iii). In cases involving occasional sales, a separate exemption certificate must be obtained for each order. In the case involving frequent orders, a single exemption certificate will suffice and be valid for up to three years. [Treasury Regulation §48.4221-4(d)(2)(ii)]

²¹ *See* Treasury Regulation §48.4221-3(a)(1) indicating that the chain cannot include a “third purchaser for export.” In cases where the second purchaser will export, “the manufacturer must have in his possession a statement from the vendee to whom the manufacturer sold the article stating that the article was in fact exported in due course by the vendee, or was sold to another person who in due course exported the article. The statement must state what evidence is available to establish that the article was in fact exported in due course prior to use or further manufacture, and prior to resale in the United States other than for export.”

²² Treasury Regulation §48.4221-1(b)(3).

Entity/use exemptions are simply not workable under the MDET if Congress intends that the *entity* qualifying for the exemption is a retail consumer *and if* “individual use” is required. The exemption chain would be too long. It would be too difficult to pass a certificate from the consumer all the way back to the manufacturer. On the other hand, **product exemptions** do not have these problems. This is most likely the reason that the three MDET statutory exemptions are **product exemptions**.

MDET – *The second negative aspect under HCERA §1405(b)(2)*

Single stage transaction taxes that allow entity/use exemptions create overpayment situations so refund procedures are needed. This is common in exports, which makes administering the tax cumbersome. For example, if a manufacturer collects tax on a vaccine sold under §4131 but the purchaser or the next buyer exports the article in a manner qualifying for exemption under §4221(a)(2), then the tax the manufacturer already paid is overpaid. A refund is available under §6416(b)(2)(A) if the Treas. Reg. §48.6416(b)(2)-2 requirements are met.

Thus, when MDET was adopted without the four traditional **entity/use exceptions**, four companion provisions dealing with overpayments were disassociated from the MDET²³ by stating:

Section 6416(b)(2) of such Code is amended by adding at the end the following:

“In the case of the tax imposed by section 4191, subparagraphs (B), (C), (D), and (E) shall not apply.”

REGULATORY COMPROMISE

The IRS published Notice 2010-89²⁴ on December 27, 2010 requesting comments on the MDET’s implementation and administration. Shortly thereafter, proposed regulations were issued²⁵ and a public hearing was held on May 16, 2012.

The Proposed Regulations represent a significant compromise in what Treasury perceived to be the major MTEC issue²⁶, how should the retail exemption be drafted? There are at least four other major issues that need to be resolved before regulations are finalized but on this point there is a compromise. The question is *Should the regulations present a comprehensive **product exemptions** list or should the retail exemptions be drafted in an **entity/use** manner?*

What happened was a mixture between both. The medical device industry persuaded the Treasury that a comprehensive **product** exemptions list was not

²³ §1405(b)(2)

²⁴ 2010-52 IRB 908

²⁵ Proposed Treasury Regulation §§48.4919-1 and 48.4919-2; Fed. Reg. Vol. 77, No. 25, at 6028 (February 7, 2012).

²⁶ There are numerous additional issues. The four most important are considered *infra* and Treasury will need to address in the final regulations.

workable²⁷ nor based on past practice was an **entity/use** exemption workable. To institute an **entity/use** exemption Treasury would need to define a (generalized) final consumer *and* also define a (generalized) consumer's personal use²⁸. This approach is also unworkable²⁹.

²⁷ Industry groups, law firms, and accounting firms, opposed a **product exceptions** list in the regulations. The IRS was persuaded. See for example Donald T. Rocen & Marc J. Gerson (Miller & Chevalier), *Letter: Comments to Notice 2010-89, 2010 I.R.B. 908* (March 28, 2011) at 4-5 indicating that the **product exemption** approach would be "difficult (if not impossible)" to carry out:

Although the JCT General Explanation anticipates that the IRS will publish a list of Food and Drug Administration ("FDA") medical device classifications that qualify for the retail exemption, it is respectfully suggested that as a practical matter such a list will be difficult (if not impossible) for the IRS to develop, update and administer, particularly in light of the substantial number and differentiation of medical devices and the frequency of product innovation in the medical device industry. Furthermore, such a list may not sufficiently identify which taxable medical devices properly qualify for the exemption, since a single medical device classification may encompass a large number and type of distinct medical devices some of which are "generally purchased by the general public at retail for individual use" and some of which are generally purchased by health care institutions such as hospitals.

This observation was reinforced by Christopher J. Ohmes & Michael Udell (Ernst & Young), *Making Sense of the New Excise Tax on Medical Devices*, 133 TAX NOTES 1015, 1016-17 (November 21, 2011). Ohmes and Udell present specific data on the difficulties the IRS would face with a **product exemption** regulatory approach:

Although Congress envisioned that this retail sale exclusion would be implemented through an item list that may be impractical. There are more than 5,630 FDA product codes for medical devices. Eyeglasses, contact lenses, and hearing aids, which are tax exempt by statute, constitute 25 of them. Thus, Treasury and the IRS would need to address more than 5,600 device types to promulgate a list. We estimate that of those, roughly 266 may be eligible for the retail sales exclusion depending on how the limits of the exclusion are defined. No matter how the definitional questions are resolved, to derive a list, Treasury and the IRS will need a great deal of information that is not publicly available for all those device types. Moreover, even if the data were available, it would take a significant amount of effort to characterize the data by the "general public," "individual use," and "retail" filters and then apply whatever definition of the phrase "generally sold" is to be used.

All through this process the medical device industry was making similar comments. See for example AdvaMed (the Advanced Medical Technology Association) opposition per Stephen J. Ubl, *Letter responding to Notice 2011-89's request for comments specifically on §4191(b)(2)(D)*, March 22, 2011, at 5 – 10, followed up by an additional *Letter: HIGHLIGHTS: AdvaMed Comments on the Medical Device Tax* (March 3, 2012) at 2, and finally *Letter: AdvaMed Comments on Implementation of Medical Devices Excise Tax Provisions of the Affordable Care Act* (May 3, 2012) at 1, which thanks the IRS for rejecting the **product exemption** approach in the proposed regulations:

At the outset, AdvaMed appreciates the consideration given by Treasury to the complexity of the medical device industry. ... [and] for determining whether a device is exempt by reason of the retail exclusion [for taking] ... a thoughtful approach that took into account the comments received in response to IRS Notice 2010-89, in particular that **a "list" not be the mechanism to define those devices exempt** under the retail exemption in the dynamic and diverse medical device market. (emphasis added)

²⁸ A. Paige Keener (Novo Nordisk), *Letter: Comments on REG-113770-10, Taxable Medical Devices*, (May 7, 2012) at 3, available at TAX ANALYSTS, Doc 2012-9994 or 2012 TNT 93-98 (agreeing with the IRS that a market data approach if applied overall to the retail exemption would not be workable, however, suggesting that when market data is available then it could be used effectively).

²⁹ This approach would entail regular retail medical device marketplace national surveys. See: Stephen J. Ubl, *Letter: AdvaMed Comments on Implementation of Medical Device Excise Tax Provisions of the*

Product exemptions are set out in a regulatory “safe harbor”³⁰ list that responded favorably to many public comments the Treasury received. The safe harbor list is:

1. Devices included in the FDA’s online IVD Home Use Lab Tests (Over-the-Counter Tests) database,³¹
2. Devices that are described as “OTC” or “over the counter” devices in the relevant FDA classification regulation heading.
3. Devices that are described as “OTC” or “over the counter” devices in the FDA’s product code name, the FDA’s device classification name, or the “classification name” field in the FDA’s device registration and listing database,³²
4. Devices that qualify as durable medical equipment, prosthetics, orthotics, and supplies, as described in Subpart C of 42 CFR Part 414 (Parenteral and Enteral Nutrition) and Subpart D of 42 CFR Part 414 (Durable Medical Equipment and Prosthetic and Orthotic Devices), for which payment is available on a purchase basis under Medicare Part B payment rules, and are:
 - (a) “Prosthetic and orthotic devices,” as defined in 42 CFR 414.202, that do not require implantation or insertion by a medical professional;
 - (b) “Parenteral and enteral nutrients, equipment, and supplies” as defined in 42 CFR 411.351 and described in 42 CFR 414.102(b);
 - (c) “Customized items” as described in 25 CFR 414.224;
 - (d) “Therapeutic shoes,” as described in 42 CFR 414.228(c); or
 - (e) Supplies necessary for the effective use of DME, as described in section 110.3 of chapter 15 of the Medicare Benefit Policy Manual (Centers for Medicare and Medicaid Studies Publication 100-02).

The **entity/use exemption** formulation in the Proposed Regulation is unusual. The reason for odd draftsmanship here is that the normal approach for having the exempt entity (retail consumer) issue an exemption certificate that the taxable party (manufacturer) will use to remove the tax is nearly impossible to design.

Rather than clearly identifying an *entity* and a clearly specifying a *use* the regulation relies on a speculative “facts and circumstances” test. The manufacturer applies this two-pronged “test” as it examines the specific device’s nature. The two-part test has affirmative and negative aspects. The first (inclusive) test identifies factors that determine if an item is “regularly available for purchase and use by individual consumers” while the second (exclusionary) test determines if a device is “primarily for use in a medical institution or office or by a medical professional.”

Affordable Care Act, May 3, 2012) at 17 (discussing applying Revenue Ruling 80-273, 1980-2 C.B. 315 to the medical device area and indicating that the 75% rule should be applied generally for determining the constructive price unless it can be shown on an industry-wide basis that a lower percentage should apply). It would be similar to the way that Michigan and Illinois determine values for imposing the sales tax on retail gasoline. [See: Richard T. Ainsworth, *Michigan’s Industry-Specific VAT*, 62 STATE TAX NOTES 441 (November 14, 2011)].

³⁰ Proposed Treasury Regulation §§48.4919-2(b)(2)(iii).

³¹ Available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfIVD/Search.cfm>

³² Available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/rl.cfm>

The device qualifies for the retail exemption if it passes the first test but is not picked up under the second test. There are no exemption certificates, no tracing actual purchase/use,³³ and no provision for overpayments based on a specific consumer's transaction.³⁴

UNANSWERED QUESTIONS

There are several unanswered questions in the proposed regulations that were aired at the May 16th public hearing. While easy answers do not appear likely given the way the regulations are currently drafted, some answer will be needed before the tax goes into effect on January 1, 2013. The four most troubling questions relate to:

Double taxation - Do the “further manufacturing” operating rules and the pervasive kits, dual-purpose devices, and combined products in the medical device market create a situation where double taxation is likely?

Related party pricing - Will the traditional constructive price rules apply in the medical devices area, most notably the 75% valuation safe harbor rule under Revenue Ruling 80-273³⁵? Given the related party transactions typical in the medical device market and the probability that transactions may be structured among related parties to reduce exposure to the MDET, this issue could impact the revenue raised under this tax.

Title passage - How should the Chapter 32 title passage rules be incorporated into the MDET? While Treasury Regulation §48.0-2(a)(5) specifies that title must pass for a sale to be taxable, critical value added services and software may not be included if this is the dominant rule in place for the MDET.

Objective valuation - Can the MDET depart from the objective valuation standard utilized in the Chapter 32 manufacturers excise taxes, or can subjective valuation be used instead? This change would align the MDET more closely with normative accounting standards, ease compliance costs, and make the tax fairer when medical devices charitable contributions are considered.

Unanswered Question (1) – Double Taxation

³³ See: AdvaMed (the Advanced Medical Technology Association) Stephen J. Ubl, *Letter responding to Notice 2011-89's request for comments specifically on §4191(b)(2)(D)*, March 22, 2011, at 18 available at TAX ANALYSTS, Doc 2011-6160 or 2011 TNT 58-12 (asking for a credit mechanism in MDET, but one that does not require device-by-device tracing taxes paid in the manufacturing chain).

³⁴ An overpayment might be made though the manufacturer's misjudgment in applying the facts and circumstances tests. This could be handled in a traditional audit. Overpayments are anticipated in circumstances where a primary manufacturer collects tax when it sells to a secondary manufacturer such as a kit assembler. A credit or a refund claim can be made under §6416(b)(3), and Treasury Regulation §48.4221-2(b).

³⁵ 1980-2 C.B. 315

Manufacturing taxes are premised on a single tax assessment, with the time and place for assessment taking place when the manufacturing phase ends³⁶. As a result, no tax is due when there is *further manufacture* within the supply chain. Thus, IRC §4221(a) sets out a *further manufacture* exception for enterprises that *are* manufacturers yet are not the *last* manufacturer in the supply chain. Congress intends these rules to apply to the MDET³⁷.

Under regulations prescribed by the Secretary, no tax shall be imposed under this chapter ... on the sale by the manufacturer ... of an article –

(1) for use by the purchaser for *further manufacture*, or resale by the purchaser to a second purchaser for use by such second purchaser in *further manufacture*, (emphasis added)

The term “manufacturer” has a regulatory definition in part 48 relating to all excise taxes imposed under IRC chapters 31 and 32. The definition is broadly drafted, and “unless otherwise expressly indicated”³⁸ applies to the MDET. It states:

The term “manufacturer” includes any person who produces a taxable article from scrap, salvage, or junk material, or from new or raw material, by reprocessing, manipulating, or changing the form of an article or *by combining or assembling two or more articles*. The term also includes a “producer” and an “importer.”³⁹

The operative principle underlying manufacturers’ taxes is that by applying this definition link-by-link throughout a supply chain, each party can determine if they are the person on whom the tax is imposed. One simply asks am I: (1) a manufacturer and (2) the last manufacturer.

If the supply chain is a simple one, then all a manufacturer needs to do is to assess how one’s customers intend to use the provided supply⁴⁰. The most problematical part in

³⁶ Jill Witter (Novation), *Letter: Comments to REG-113770-10* (May 7, 2012) at 4, available at TAX ANALYSTS, Doc 2012-10986 or 2012 TNT 100-17, *Company Suggests Changes to Proposed Regulations on Medical Device Excise Tax* (“Generally, the manufacturer is determined by looking at each party is a particular supply chain and the last party to perform significant transformative activities on a particular product that rises to the level of manufacturing is the one on whom the tax is imposed.”)

³⁷ Joint Committee on Taxation, *General Explanation of Tax Legislation Enacted in the 111th Congress*, JCS-2-11 (March 2011) at 367. (“The present law manufacturers excise tax exemptions for further manufacture ... apply to tax imposed under this provision ...” See also: Joint Committee on Taxation, *Technical Explanation of the “Revenue Provisions of the Revenue Reconciliation Act of 2010,” as amended, in combination with the “Patient Protection and Affordable Care Act,”* JCX-18-10 (March 2010) at 138.

³⁸ Treasury Regulation §48.0-2(a)

³⁹ Treasury Regulation §48.0-2(a)(4)(i) (emphasis added), referenced by Prop. Treasury Regulation §48.4191-1(c)

⁴⁰ In a relatively linear supply chain this is not a difficult task. Revenue Ruling 79-192, 1979-1 CB 340 (modifying an automobile truck chassis – shortening the wheel base – to permit use in street sweeping chassis is subsequent manufacture; but using the chassis without modification is not); Revenue Ruling 67-374, 1967-2 CB 376 (combining a conventional fishing reel with a power unit constitutes further manufacture because an electric fishing reel is created); Priv. Ltr. Rul. 84-030-36 (Oct. 18, 1983) (purchasing individual components from various distributors and then gluing them together to make a finished arrow is subsequent manufacture).

applying this definition has always been the final disjunctive phrase “*or by combining or assembling two or more articles.*” The question raised is whether this provision requires that something more needs to be done (than mere packaging or repackaging) to be a manufacturer⁴¹?

Considerable authority indicates that *combining or assembling* must result in a transformation, either in form or function, so that a *new taxable article* is created. Cases dealing with packaging mascara⁴², replacement parts for automobiles⁴³, and rulings dealing with packaging rear view truck mirrors are all consistent in this regard⁴⁴.

This authority however, does not fit well with the MDET. IRC §4191(b)(1) takes away the flexibility previously enjoyed when applying these rules by defining a “taxable medical device” as a “device” under Federal Food, Drug, and Cosmetic Act §201(h). As a result, we are not applying a flexible legal test but rather a rigid statutory test that relies on an externally produced list of qualifying items. The most immediate problem this creates involves medical kits⁴⁵.

Under §201(h), the FDA lists medical kits as a *new or different* “medical device”, separate and distinct from the scalpel (for example) included in the kit. The tax consequence under §201(h) are that the scalpel manufacturer is *not* subject to MDET for scalpels sold to kit-makers if these scalpels are *combined or assembled* into medical kits. The kit-maker, on the other hand, is a *subsequent manufacturer* subject to tax on the full kit price rather than the price for the individual medical devices contained within the kit.

This kit-maker, however, would *not* be a *subsequent manufacturer* if it re-sold the scalpel absent the kit. In this case, it is the scalpel manufacturer who is the *last manufacturer* and subject to tax.

To make this application very clear, the proposed regulations expressly adds kit assembly to the *further manufacturing* regulations at §48.4221-2(b)(3)⁴⁶. At this point, the Medical Device Manufacturers Association (MDMA) objects, because:

This unnecessarily over-inclusive approach will result in imposition of the excise tax on items that Congress never intended to be taxable and will effectively result in double taxation of certain kits and combination devices ... many kits consist not only of devices but also pharmaceuticals

⁴¹ There have been several Service rulings indicating that mere packaging is not manufacturing. Revenue Ruling 72-561 (“the mere association of two or more articles in a single container [does not] result in the packager becoming a manufacturer”); G.C.M. 34332 (Aug. 7, 1970) (“mere packaging together of automobile parts, general purpose items, or automobile parts and general purpose items in a kit which is intended to be sold primarily for use in the repair of automobiles does not, without more, constitute the manufacture of a new taxable article).

⁴² *Williams v. Harrison*, 110 F.2d 989, 994 (7th Cir. 1940).

⁴³ *Sealed Power Corp. v. Kavanaugh*, 81 F. Supp. 459 (E.D. Mich. 1948).

⁴⁴ Revenue Ruling 72-561, 1972-2 C.B. 548

⁴⁵ In general, a kit is two or more different medical devices, or a combination of medical devices and other items, that are packaged together. When a kit is listed as a device with the FDA pursuant to FDA requirements, the proposed regulation would impose tax on the entire price of the kit.

⁴⁶ Treasury Regulation §48.4221-2

and other goods not subject to the tax that add substantially to the cost of the kits.⁴⁷

The MDMA explained at the May 16th hearings that the *further manufacturing* exception does not work in the MDET due primarily to the market itself and the medical device manufacturing process:

[T]he proposed regulations fail to take into account the unique nature and use of many medical device technologies. Until now, excise taxes were only imposed on commodity products. This is likely due to the fact that such products are easily identifiable and, the affected industries are involved in manufacturing of less complex products designed for a readily apparent use. In contrast, the medical devices which would be taxed under the proposed regulations are virtually all scientifically complex, and may be designed for a disparate range of uses⁴⁸.

Although theoretically assuring a single tax (only the *further manufacturer* is actually liable for tax), commentators contend that logistical issues will make double taxation a near certainty. According to BayCare Health System,

- Under the MDET device manufacturers will be inclined to tax all sales to kit makers, because following up with all customers to determine whether or not there is intent for further manufacturing would be too difficult⁴⁹.
- Kit-making customers that purchased medical devices (some for use in kits and some for direct re-sale) might not know in advance the number of kit that would be made. To get the tax right will require an internal tracking system and retrospective reporting⁵⁰.

Standard hospital operations present precisely this problem because hospitals purchase kits from third parties along with internally assembling kits⁵¹. The Federation of American Hospitals believes that at a minimum a hospital's kit assembly should be a safe harbor exception because "... kit assembly and sterilization [of included devices] do

⁴⁷ Medical Device Manufacturers Association, *Letter* (May 7, 2012) at 2, available at TAX ANALYSTS, Doc 2012-9990 or 2012 TNT 93-94 *Manufacturers Group Suggests Narrowing Scope of Proposed Regulations on Medical Device Excise Tax*.

⁴⁸ Comments of Thomas Novelli at Public Hearing on Proposed Regulations 26 CFR Part 48 "Taxable Medical Devices" [REG-113770-10] (May 16, 2012) *unofficial transcript available at TAX ANALYSTS*, Doc 2012-2232 or 2012 TNT 24-20.

⁴⁹ Federation of American Hospitals (and others), *Letter: Notice of Proposed Rulemaking and Notice of Public Hearing on Taxable Medical Devices* (77 Fed. Reg. 6.028 [Feb. 7, 2012]) at 4 indicating that "as purchasers of medical devices, hospitals and group purchasing organizations are concerned that medical device companies will eventually pass through this entire tax to their customers")

⁵⁰ Judith P. Lipscomb (BayCare Health System) *Letter: Comments on Proposed Rulemaking on Taxable Medical Devices* (REG-113770-10) at 2, available at TAX ANALYSTS, Doc 2012-9987 or 2012 TNT 93-91, *Health System Raises Concerns About Double Taxation Under Proposed Regulations on Medical Device Excise Tax*

⁵¹ Federation of American Hospitals (and others), *Letter: Notice of Proposed Rulemaking and Notice of Public Hearing on Taxable Medical Devices* (77 Fed. Reg. 6.028 [Feb. 7, 2012]) at 9.

not cause a hospital to be a ‘manufacturer’ (or ‘importer’) subject to the medical device tax”⁵².

The Academy of Dentistry has similar concerns. The *further manufacture* rule would “increase the cost of care by taxing certain devices twice and taxing items that are not medical devices.”⁵³ Cardinal Health, an enterprise that assembles four million kits per day for delivery to over 60,000 locations, suggests that the correct answer is to exempt all kits in the safe harbor provision⁵⁴.

Conclusion – Unanswered Question (1)

It is not clear how the IRS will respond because there are several revenue and policy implications in the answer to the double taxation issue:

Revenue: The further down the commercial chain the MDET goes before it reaches a final manufacturer, the more revenue it will produce. Double taxation is very likely if the rules are difficult to interpret and there is no prohibition on passing through the tax⁵⁵. Businesses will resolve these ambiguities by taxing transfers and passing the burden on, even though a subsequent party may tax the same transfer again.

Policy: Determining who is a manufacturer based primarily on the FDA’s medical devices listing under §201(h) is inconsistent with the traditional thrust of manufactures excise taxes which is to apply conceptual legal tests.

Unanswered Question (2) – Related Party Pricing

The MDET is imposed at 2.3% on the price for which a taxable medical device is sold with the *price* defined in IRC §4216 and Treasury Regulations §§48.4216(a)-1 through 48.4216(e)-3⁵⁶.

The proposed regulations indicate that there should be a “... basic sales price [that] assume[s] that the manufacturer sells the taxable article in an arm’s length transaction (that is, in a transaction between two unrelated parties) to a wholesale distributor that then sells the taxable article to a retailer that resells to consumers.”⁵⁷ The basic sales price presumes a traditional manufacturer-wholesaler-retailer-consumer marketplace. In cases where the basic sales price is not available, a constructive price will be determined, as an exception.

⁵² *Id.*, at 8

⁵³ Academy of General Dentistry (and others), *Letter: Internal Revenue Service Notice of Proposed Rulemaking, Taxable Medical Devices* REG-113770-10 (May 7, 2012) at 4, available at TAX ANALYSTS, Doc 2012-9985 or 2012 TNT 93-89, *Dentistry Groups Comment on Proposed Regs on Medical Device Excise Tax*

⁵⁴ Lloyd Fort (Cardinal Health), *Letter: Proposed Taxable Medical Device Excise Tax Regulations* (May 7, 2012) at 3, available at TAX ANALYSTS, Doc 2012-9988 or 2012 TNT 93-92, *Medical Products Maker Suggests Changes to Proposed Regulations on Medical Device Excise Tax*.

⁵⁵ See: David Hawkins, *HR 3509*, HARVARD BUSINESS SCHOOL CASE STUDY, N9-111-056 (Rev. December 1, 2010) a business school note prepared as the basis for class discussion concerning accounting issues that would allow or prevent the pass-through of the MDET to customers.

⁵⁶ Proposed Treasury Regulation § 48.4191-1(b)

⁵⁷ Proposed Treasury Regulation § 48.4191 (preamble)

The reality is, in the MDET, the exception will be the rule. The way the medical device market is structured, the price upon which the MDET is based will almost always be determined under the Treasury Regulation §48.4216(b)-1 constructive price rules. America's Blood Centers observes:

[V]irtually all of the medical device tax is likely to be determined based on constructive prices because very few medical devices are sold by manufacturers to wholesalers that sell to retailers that sell to end users.⁵⁸

Rocen and Gerson agree. The standard distribution network in this market segment will compel most manufacturers to determine the tax base through constructed prices because almost all manufacturer sales will be made to related parties.

It is our understanding that members of the medical device industry frequently utilize a network of affiliated corporations within their respective U.S. consolidated groups to manufacture, import and distribute taxable medical devices both domestically and internationally. Although the structure of these networks may vary, it is our understanding these networks typically involve a number of intercompany transactions before the medical devices are sold or leased to the ultimate customer, whether it be a hospital or an individual.⁵⁹

The medical device industry is exceedingly top-heavy. Although the Medical Device Manufacturers Association (MDMA) observes that 80% to 98% of the medical device manufacturers swept up in the MDET will be small businesses⁶⁰, 86% of the \$20 billion the MDET is expected to generate over ten years will come from the ten largest firms⁶¹. Thus, even though the MDET will be a considerable administrative burden for numerous companies, the government's revenue will come primarily from the largest publicly traded multi-entity groups⁶².

⁵⁸ Jim L. MacPherson (American's Blood Centers) Letter: REG-113770-10 – Notice of Proposed Rulemaking on Taxable Medical Devices (May 7, 2012) at 3, *available at* TAX ANALYSTS, Doc 2012-9984 or 2012 TNT 93-88, *Blood Center Comments on Proposed Regulations on Medical Device Excise Tax*.

⁵⁹ Donald T. Rocen & Marc J. Gerson (Miller & Chevalier), *Letter: Comments to Notice 2010-89, 2010 I.R.B. 908* (March 28, 2011) at 7, *available at* TAX ANALYSTS, Doc 2011-6537 or 2011 TNT 61-28.

⁶⁰ Comments of Mark B. Leahey (Medical Device Manufacturers Association), *Letter on Proposed Regulations* (REG-113770-10) at 2 (May 7, 2012) *available at* TAX ANALYSTS, Doc 2012-9990 or 2012 TNT 93-94 *Manufacturers Group Suggests Narrowing Scope of Proposed Regulations on Medical Device Excise Tax*

[t]he medical technology industry is comprised primarily of small businesses. Approximately 80% of medical technology companies have fewer than 50 employees, and 98% have fewer than 500 employees.

⁶¹ Staff of Massachusetts Medical Devices Journal, *Medical device tax would mostly hit the biggest firms*, MEDCITY NEWS, March 24, 2010, <http://www.medcitynews.com/2010/03/medical-device-tax-would-mostly-target-the-biggest-companies/>.

⁶² Id., listing the top 10 firms as: Medtronic Inc., Baxter International Inc., Johnson & Johnson, Boston Scientific Corp., Stryker Corp., St Jude Medical Inc., Agilent Technologies, Inc., Beckman Coulter, Inc., C.R. Bard, Inc., and Kinetic Concepts, Inc.

Tax planning will give rise to two common fact patterns. Either (a) a *further manufacturer* will sell the medical device within an affiliated group (involving several intercompany transactions) to an end user at retail, or (b) the medical device will be sold, and re-sold in a series of intra-group transactions with the tax due on a related party internal transfer. The first structure takes advantage of Revenue Ruling 80-273. The second structure's advantage is that valuable software can be added to a device outside the MDET's ambit.

The attractiveness in Revenue Ruling 80-273 is its simple clarity and tax-base reducing attributes⁶³. It applies in cases where a manufacturer makes sales at retail⁶⁴ but the same or similar articles are not sold to wholesale distributors⁶⁵. This is the fact pattern that Rocen and Gerson (and several other commentators⁶⁶) asked the Service to specifically address and to place in examples⁶⁷. Unfortunately, the Treasury did not accept the invitation.

If shown to apply in the medical device area, Revenue Ruling 80-273 would deem the devices' tax price to be 75% of the price the customer was actually charged. The holding is:

The constructive sale price for computing the taxes imposed by IRC §§4061(b)(1), 4161(a), 4161(b) and 4181, where the articles are sold at retail by manufacturers, producers, or importers who do not sell like articles to wholesale distributors, is 75 percent of the actual selling price after taking into account the adjustments provided by §4216(a) unless it can be shown on an industry-wide basis that a lower percentage should

⁶³ This is a fact pattern that fits into IRC § 4216(b)(1)(A) where the tax "shall ... be computed on the price for which such articles are sold, in the ordinary course of trade, by manufacturers or producers thereof, as determined by the Secretary"

⁶⁴ A "retail sale" is the "sale of an article to a purchaser who intends to use or lease the article rather than sell it." [Treasury Regulation §48.4216(b)-1(c)(1)] In the MDET context this would be (for example) the magnetic resonance imaging (MRI) equipment sales to a hospital or doctor's office

⁶⁵ A "wholesale distributor" is defined as "a person engaged in the business of selling articles to persons engaged in the business of reselling such articles." [Treasury Regulation §48.4216(b)-1(c)(3)]

⁶⁶ See: Philip Albert (Medtronic), *Medtronic, Inc. Comments on Implementation of Medical Device Excise Tax Provisions of the Affordable Care Act* – REG-113770-10 (May 4, 2012) at 37, available at TAX ANALYSTS, Doc 2012-9991 or 2012 TNT 93-95 *Medtronic Comments on Proposed Regulations on Medical Device Excise Tax*. Also see: Stephen J. Ubl (AdvaMed), *AdvaMed Comments on Medical Device Excise Tax* (March 22, 2011) 15, available at TAX ANALYSTS, Doc 2011-6160 or 2011 TNT 58-12.

⁶⁷ Donald T. Rocen & Marc J. Gerson (Miller & Chevalier), *Letter: Comments to Notice 2010-89, 2010 I.R.B. 908* (March 28, 2011) at 7-8, available at TAX ANALYSTS, Doc 2011-6537 or 2011 TNT 61-28.

For example, in a representative structure, a taxpayer will utilize a number of affiliated corporations, including (i) a manufacturing/importing corporation ("Manufacturing") that manufactures and imports taxable medical devices, (ii) a services corporation ("Services") that provides shared corporate services, and (iii) a sales/leasing corporation ("Sales") that sells and leases the medical devices to the ultimate customer.

Given the prevalence of these types of distribution networks in the medical device industry, we respectfully suggest that the guidance issued under Section 4191 provide illustrative examples with respect to a variety of transactions, including not only those involving intercompany sales through a series of affiliated corporations as illustrated above

apply. No further adjustments under §4216 are allowable. The manufacturer's cost is not to be a factor in determining the constructive sale price.

Intra-group tax - The Chapter 32 excise tax rules are applied on a separate entity rather than affiliated group basis, even though requests have been made to allow MDET reporting on this basis⁶⁸. Because MDET applies to transactions between affiliated group members⁶⁹, taxpayers have some opportunity to control the tax point.

Rocen and Gerson make this point when they suggest an answer to the hypothetical proposed (*supra* note 67) involving three affiliated group members (“Manufacturing,” “Services,” and “Sales”) transferring a medical device among themselves before selling it to an end user. Rocen and Gerson indicate:

[the] illustrative example [should] confirm that (i) the sale of the medical devices from Manufacturing to Services is subject to the medical device excise tax because this constitutes a sale by the “manufacturer, producer or importer,” and (ii) the subsequent sales of medical devices from Services to Sales and from Sales to the ultimate customers are not subject to the medical device excise tax.⁷⁰

The critical point is that the “Services” value added is not taxed because the value provided by “Services” is not an independently listed medical device under Federal Food, Drug, and Cosmetic Act §201(h)⁷¹. “Services” is not engage in *further manufacturing* nor *combining or assembling* its value added with another taxable medical device.

⁶⁸ David Fisher (Siemens Healthcare) comments at Public Hearing on Proposed Regulations 26 CFR Part 48 “Taxable Medical Devices” [REG-113770-10] (May 16, 2012) *unofficial transcript available at* TAX ANALYSTS, Doc 2012-2232 or 2012 TNT 24-20.

Therefore, we recommend that the regulations provide an option that would permit a U.S. corporate group to designate a common parent to report the device tax on behalf of all of its U.S. affiliates on a single Form 720 and to make a single semi-monthly tax deposit.

Philip Albert (Medtronic), *Letter: Comments on Implementation of Medical Device Excise Tax Provisions of the Affordable Care Act* – REG-113770-10, (May 4, 2012) at 4-5, *available at* TAX ANALYSTS, Doc 2012-9991 or 2012 TNT 93-95 *Medtronic Comments on Proposed Regulations on Medical Device Excise Tax*.

In order to reduce this burden [of compliance by multiple entities in a single group], while having no impact on the actual taxes collected by the US Government, Medtronic requests that the Treasury Department update the excise tax payment requirements to allow companies within a controlled group of companies, under §1563, to have one entity make the required excise tax deposits and file the quarterly excise tax return on behalf of all controlled group members, if so elected. ... All data will be captured by the paying entity with details as to each controlled group member's excise tax responsibility.

⁶⁹ IRC §§4216(b)(3) and 4216(b)(4) apply constructive sales price rules to transactions between members of the same affiliated group.

⁷⁰ Donald T. Rocen & Marc J. Gerson (Miller & Chevalier), *Letter: Comments to Notice 2010-89, 2010 I.R.B. 908* (March 28, 2011) at 8, *available at* TAX ANALYSTS, Doc 2011-6537 or 2011 TNT 61-28.

⁷¹ See: David Fisher (Siemens Healthcare) comments at Public Hearing on Proposed Regulations 26 CFR Part 48 “Taxable Medical Devices” [REG-113770-10] (May 16, 2012) *unofficial transcript available at* TAX ANALYSTS, Doc 2012-2232 or 2012 TNT 24-20.

The same analysis underpins the proposed regulations preamble when the Treasury excludes “warranties paid at the purchaser’s option” from the otherwise taxable medical device sales price under IRC §4216(a) and Treasury Regulation §48.4216(a)–1. There is a considerable value that can escape tax by structuring intercompany transactions in this manner. As Dean Zerbo at the Alliantgroup points out:

Medical devices can be subject to extensive servicing and software updates. Proper operation of certain medical devices requires long-term and supplemental technician training. Such future servicing is comparable to a warranty for replacement parts, and manufacturers wishing to provide purchasers with a warranty covering software updates, physical servicing (including calibration), and/or supplemental training would benefit from greater clarity.⁷²

Conclusion – Unanswered Question (2)

It is not clear how the IRS will respond because there are revenue and policy implications in answering the related party pricing issue:

Revenue: If widely applied, Revenue Ruling 80-273 could potentially reduce the MDET tax base by 25% by structuring related party transactions so that valuable services and software are added after the MDET is imposed.

Policy: From a policy perspective, the question is whether the constructive price rules currently in place, and developed more than twenty years ago for commodity pricing (sport fishing equipment, archery equipment, coal, tires, gasoline guzzling automobiles, and vaccines), achieve the right result in the high-technology medical device market? Should federal income tax transfer pricing rules under IRC §482 apply to the MDET as AdvaMed has suggested⁷³?

Unanswered Question (3) – Title Passage

The Chapter 32 manufacturers’ excise taxes are all taxes on goods sold, rather than taxes on services. Taxes on goods sold typically look to the title passage rules adopted for the core definitions on all these taxes. Under these rules, a sale is defined as:

⁷² Dean Zerbo (Alliant group), *Letter: Comments to REG-113770-10, Taxable Medical Devices* (May 7, 2012) at 3, available at: TAX ANALYSTS, Doc 2012-9980 or 2012 TNT 93-84, *Group Suggests Changes to Proposed Regulations on Medical Device Excise Tax*.

⁷³ AdvaMed (the Advanced Medical Technology Association) Stephen J. Ubl, *Letter responding to Notice 2011-89’s request for comments specifically on §4191(b)(2)(D)*, March 22, 2011, at 16 available at TAX ANALYSTS, Doc 2011-6160 or 2011 TNT 58-12, available at TAX ANALYSTS, Doc 2011-6160 or 2011 TNT 58-12.

AdvaMed recommends that the IRS adopt, within the limits of what the statute permits, a constructive pricing regime that recognizes the highly competitive nature of the industry, the high degree of product differentiation, and complexity of the industry’s distribution network. That regime should maintain the objective of the existing constructive price regime, i.e., to identify a constructive price equal to the fair market price that would be paid by an independent wholesale distributor. *That regime should allow the industry to rely on the existing well-developed body of arm’s length pricing principles in the Federal income tax law without the development for purposes of the excise tax of rigid regulatory formulas.* (emphasis added)

“an agreement whereby the seller transfers the property (that is, the *title* or the substantial incidents of ownership) in *goods* to the buyer for a consideration called the price, which may consist of money, services, or other things⁷⁴.

The proposed regulations for MDET make no changes to this sales definition nor do they change any of the other title / goods-centric definitions contained in Chapter 32. The proposed regulations preamble state:

Generally, the manufacturers excise tax attaches when the *title* to the taxable article passes from the manufacturer to a purchaser. When *title passes* is dependent upon the intention of the parties as gathered from the contract of sale and the attendant circumstances.⁷⁵

Changes at this point might have indicated that Treasury understood MDET to be a fundamentally different manufacturer tax than had previously been the case under Chapter 32. Justification for a change could have come through differentiating high-technology manufacturing from traditional commodity manufacturing but the Treasury does not appear to be making that decision⁷⁶.

The consequences in casting the MDET as a traditional manufacturers tax, on goods with title passage determining the tax point, is that issues involving over-reaching and under-reaching arise. The MDET over-reaches when transactions are taxed that do not seem to be the proper object for the excise tax such as charitable donations, samples, demonstration products, products provided for evaluation, loaned instruments, and test / development products. The MDET also under-reaches when very significant services and software products integral to the high-tech medical devices functioning are carved from the tax base such as software that is critical for initial use, continuing software updates, and optional service and warranty agreements.

Over-reaching - The proposed regulations preamble specifically reference Revenue Ruling 72-563⁷⁷ which holds that providing taxable products free of charge for promotional purposes are taxable for Chapter 32 purposes⁷⁸ because title passes and there is consideration in kind.

⁷⁴ Treasury Regulation §48.0-2(a)(5) (emphasis added). *See also*: Treasury Regulation §48.0-2(b)(1) indicating that manufactures excise taxes attach when title to the article sold passes from the manufacturer to a purchaser

⁷⁵ Proposed Treasury Regulation §§48.4919-1 and 48.4919-2 (preamble)

⁷⁶ For example, the proposed regulations do not alter the installment sales and lease definitions. An installment sale remains a contract with “*title reserved* in the seller, or under a conditional sale contract, chattel mortgage arrangement or other arrangement creating a security interest [in the seller] ...” [Treasury Regulation §48.4216(c)-1 (emphasis added)]. A lease “means a contract or agreement, written or verbal, which gives the lessee an *exclusive, continuous right to the possession* or use of a particular article for a period of time.” [Treasury Regulation §48.4217-1 (emphasis added)].

⁷⁷ 1972-2 C.B. 568

⁷⁸ Under Revenue Ruling 72-563, a gasoline and lubricating oils producer furnishes products ‘free of charge’ (within its advertising and sales promotion program) to a stock car operator for his use in stock car races. In return, the recipient agreed to display the producer’s identifying trademark and other promotional material in such a manner as to indicate his using the producer’s products for racing purposes.

But what if a dental device manufacturer makes donations to a volunteer program such as Give-Kids-A-Smile or the Missions of Mercy, valued at more than \$1.6 billion a year⁷⁹? Title passes from the manufacturer to dental volunteers and then to patients for the donated medical devices. There is also an indirect promotional benefit in kind to the manufacturer (goodwill developed with certain dentists). Does Revenue Ruling 72-563 indicate that this donation is taxable under the MDET? Plain reading the ruling seems to indicate the answer is “yes”. AdvaMed made similar comments in a broader context:

Medical device companies commonly support disaster relief and similar charitable missions through the donation of medical devices. For example, many companies contributed volumes of medical device products to support Hurricane Katrina relief. Sometimes these products are provided to volunteer U.S. healthcare professionals engaged in charitable missions for people in crisis in the U.S. and abroad. Product donations for bona fide charitable purposes should not be subject to the Medical Device Tax as a taxable use.⁸⁰

Under-reaching - In March 2010 the Staff of the Massachusetts Medical Devices Journal set out to check how accurate was the \$20 billion revenue estimate (\$2 billion per year for 10 years) the Congressional Research Service provided for the MDET⁸¹. Using gross revenue figures from medical device companies in the US market and isolating sales from companies with multiple product lines as best as possible, they concluded:

The 57 companies we looked at would have generated about \$1.87 billion in excise taxes last year [2009], had the law been in effect then. That’s on track to meet the prediction that the tax will generate \$20 billion over 10 years, once it goes into effect in 2013.⁸²

Did the Congressional Research Service assume, as the Massachusetts Medical Devices Journal apparently did, that the full final price paid for medical devices, *goods and related services*, was subject to the MDET? Gross sales figures undoubtedly include the value for software and services commonly sold in conjunction with tangible medical devices.

⁷⁹ See: Academy of General Dentistry (and others), *Letter: Internal Revenue Service Notice of Proposed Rulemaking, Taxable Medical Devices* REG-113770-10 (May 7, 2012) at 4, available at TAX ANALYSTS, Doc 2012-9985 or 2012 TNT 93-89, *Dentistry Groups Comment on Proposed Regulations on Medical Device Excise Tax*.

⁸⁰ AdvaMed (the Advanced Medical Technology Association) Stephen J. Ubl, *Letter responding to Notice 2011-89’s request for comments specifically on §4191(b)(2)(D)*, March 22, 2011, at 4 available at TAX ANALYSTS, Doc 2011-6160 or 2011 TNT 58-12.

⁸¹ Janemarie Mulvey of the Congressional Research Service indicates that MDET should raise \$20 billion over ten years, in *Health-Related Revenue Provisions in the Patient Protection and Affordable Care Act (PPACA)* R41128 (February 10, 2011) at 6.

⁸² Staff of Massachusetts Medical Devices Journal, *Medical device tax would mostly hit the biggest firms*, MEDCITY NEWS, March 24, 2010, <http://www.medcitynews.com/2010/03/medical-device-tax-would-mostly-target-the-biggest-companies/>.

If software and services can be separated from the tangible medical device as set out in the Rocen and Gerson hypothetical above⁸³, then the MDET's tax yield may be much lower than projected. By not reaching this value, the regulations appear to be under-reaching.

If Congress intended MDET to include in the tax base both the hardware and right-to-use license for embedded object code medical device software, then the regulations need to define a sale to include the (a) hardware components based on title passage and (b) software components on right-to-use software licenses because software is not captured under the title passage rule.

Because the proposed regulations do not contain language that could include right-to-use software licenses, the medical device industry argues that MDET does not tax the medical device software value if the software is incorporated into the device after the manufacturing process is completed. For example the Medical Imaging and Technology Alliance emphasized at the May 16th hearings that,

the long lifecycle and high technology nature of [medical devices manufactured by medical imaging, radiopharmaceutical and radiation therapy manufacturers] typically offer customers a service contract which is voluntary and separate from the purchase of the device. In the course of such servicing by the manufacturer, replacement components may be installed in the medical imaging or radiation therapy systems. Clearly a service contract is not an FDA listed device and thus, is not a taxable medical device.

... similarly, we request clarification that upgrades to the software of overall FDA listed devices should not be subjected to tax because the software is not listed and is a component of the overall listed device.⁸⁴

Paul A. Smith, representing McKesson Technology Solutions, made similar observations that title to medical software does not transfer. Licensing agreements are drafted independent from the device sale. These agreements are non-exclusive, non-transferrable contracts that the FDA does not define as a medical device under §201(h). Smith indicated that based on the way that McKesson does business,

... medical software is licensed, not sold, to a customer via a nonexclusive license agreement. Customers may also obtain optional information technology (IT) services from McKesson for software installation on its systems. Additionally, customers may sign an optional maintenance agreement whereby McKesson maintains and updates the software. These agreements may be part of the license agreement, or may be a separate agreement.

Licensed software is either provided to customers under a perpetual software license (the right to use the software indefinitely) or a

⁸³ Rocen and Gerson, *supra* notes 67 and 70

⁸⁴ David Fisher, Siemens Healthcare comments on the Medical Imaging and Technology Alliance behalf at Public Hearing on Proposed Regulations 26 CFR Part 48 "Taxable Medical Devices" [REG-113770-10] (May 16, 2012) *unofficial transcript available at* TAX ANALYSTS, Doc 2012-2232 or 2012 TNT 24-20.

term software license (the right to use the software for a fixed period of time) ... title to the software does not transfer and the license is indefinite and non-exclusive.

McKesson arrangements may also include maintenance contracts related to perpetual software licenses. The maintenance contracts are for a specific period of time and are generally renewable annually. Such maintenance contracts include providing upgrades, new releases, patches that correct software programming bugs, software information updates, new computer code enhancements, and corrections to programming errors in the software or interface, as well as transportation, delivery, insurance, IT and help desk services. The maintenance contract may be optional; McKesson may not require the customer to purchase the maintenance contract in order to license the medical software. ...

The licensing of software via nonexclusive license agreements and the treatment of IT services and maintenance does not fit squarely within the rules related to sales or leases. Accordingly additional guidance is requested.⁸⁵

Conclusion – Unanswered Question (3)

It is not clear how the IRS will respond to the issues developed around the Chapter 32 title passage rule and once again there are revenue and policy implications.

Revenue - It seems unlikely that the \$20 billion revenue projection for the MDET can be met if the goods-only, Chapter 32 title passage rules are followed.

Policy - The MDET is not an original provision in the PPACA but rather replaced the §9009 fee contained in an earlier PPACA Senate version. Under §9009, a two billion dollar annual fee was established applicable to the country's largest medical device-manufacturers⁸⁶. This is not only the MDET's stated revenue goal, but based on the Massachusetts Medical Devices Journal study, the same medical device manufacturers would be the primary taxpayers. Only the method for determining the tax was supposed to change⁸⁷. Because the fee reached both goods and services, should we assume that the

⁸⁵ Paul A. Smith, (McKesson Corporation), *Letter: Comments on Proposed Regulations for the Medical Device Excise Tax* (May 7, 2012) at 3-4, available at: available at TAX ANALYSTS, Doc 2012-9989 or 2012 TNT 93-93 *Company Requests Clarification in Proposed Regulations on Medical Device Excise Tax*.

⁸⁶ The §9009 fee was set at two billion dollars from 2011 through 2017. After 2017 it was slated to increase to three billion dollars. Joint Committee on Taxation referenced estimates (March 20, 2010, JCX-17-10) Janemarie Mulvey of the Congressional Research Service indicates that MDET should raise \$20 billion over ten years, in *Health-Related Revenue Provisions in the Patient Protection and Affordable Care Act (PPACA)* R41128 (February 10, 2011) at 6. Note however, that the Treasury Department has a higher estimate of \$30 billion over the 2013-2022 period. Office of Management and Budget, *Budget of the U.S. Government, Fiscal Year 2013, Analytical Perspectives*, at 224.

⁸⁷ The fee was allocated across the industry based on market share and would not apply to companies with medical device US sales below five million dollars. [§9009(b)] The fee did not apply to Class I or Class II products sold to consumers at retail of no more than \$100 per unit. [§9009(d)(1)] As a result pregnancy tests, contact lenses, and blood pressure monitors were exempt. The principle behind imposing a fee was the belief that major medical device companies stood to benefit substantially from the PPACA and should therefore be required to pay something extra.

excise tax would reach the same values or should the change to the manufacturer's excise tax be presume to convey intent to exclude services?

(4) *Unanswered Question – Objective Valuation*

The MDET is not an invoice based tax. Although the invoice price may be the starting point, most prices will be determined under the IRC §4216(b) and Treasury Regulation §48.4216(b)-1 constructive price rules⁸⁸ because this is how the medical device market is structured⁸⁹.

Thus, prices in most cases will be determined based on an objective valuation. This means that the tax will be imposed on the fair market value for the items sold and the actual price paid will be irrelevant. If the invoice price controlled, then valuation would be subjective, that is, tax would be imposed on the amount the buyer is willing to pay.

Under traditional manufactures excise taxes, constructive pricing is the exception rather than the rule⁹⁰ but under the MDET the exception has become the rule. This makes the MDET both (a) an exceptionally complex levy, open to tax planning among related parties, and (b) an exceptionally unfair tax when imposed on charitable donations, or devices provide for demonstration, evaluation, test, and development purposes. These results are unfortunately unavoidable under an objective valuation regime.

Complexity - The tax planning opportunities under the title passage rules have been considered above. Corporate groups' ability to structure sales among related parties to reduce the impact of the MDET is well understood⁹¹.

Even without tax planning in mind, the constructive pricing objective valuation approach brings with it considerable complexity because constructive pricing rules apply on a product-by-product basis. They require access to industry-wide proprietary pricing information or develop detailed device-by-device comparable wholesale prices. This approach is neither practical nor feasible in a highly competitive, differentiated global market⁹². AdvaMed argues that,

the determination of the price to which the tax attaches likely will be a complex determination for many companies, large and small, across the range of their product lines.

This determination and others (e.g., what constitutes a "sale", who is the manufacturer, what devices are exempt from tax, what uses are taxable and nontaxable) will require substantial analysis by companies on

⁸⁸ See: text at *supra* note 58.

⁸⁹ See: text at *supra* note 59.

⁹⁰ Sport fishing equipment, archery equipment, coal, tires, gasoline guzzling automobiles, and vaccine manufacturers are normally selling to independent third party distributors, not wholly owned service or sales subsidiaries as is the case in the medical device market.

⁹¹ See: text from *supra* note 80 to *supra* note 85.

⁹² AdvaMed (the Advanced Medical Technology Association) Stephen J. Ubl, *Letter responding to Notice 2011-89's request for comments specifically on §4191(b)(2)(D)*, March 22, 2011, at 17 available at TAX ANALYSTS, Doc 2012-9995 or 2012 TNT 93-99.

a *device-by-device basis* and the development of recordkeeping systems consistent with those determinations. The basic premise of the constructive price rules, that the tax should be determined based on a price that represents an arm's length fair market price.⁹³

With respect to the timing for booking rebates and discounts, constructive pricing will require recordkeeping systems inconsistent with Generally Accepted Accounting Standards (GAAP) and International Accounting Standards (IAS)⁹⁴.

Fairness - The consequences attributable to providing medical devices at no additional charge under IRC §4216(b)(1)(C) and Treasury Regulation §48.4216(b)-2(e) are clear. Title passage determines that a sale has occurred⁹⁵ and the sale price is determined via constructive pricing rules because the exchange was at less than fair market value in a non-arm's length transaction⁹⁶. MDET is due on the fair market value of the device.

Charitable donations, demonstration devices, medical devices provided for evaluation purposes, and test or development products provided at no additional charge are all subject to MDET. This outcome could, however, be avoided under subjective valuation.

At the proposed regulations May 16th hearing, Christopher White from AdvaMed put a medical device in a Ziplock bag and brought it through IRS security to make a point. He passed the device around the hearing room and stated:

I would encourage you to open the bag and to kind of handle this, this is an orthopedic implant from one of our fine orthopedic members, and it is marked for demonstration purposes only, and this is to illustrate our first priority issue concerning nontaxable uses.

As we state in our comments, there are many noneconomic uses of medical devices, including samples, demonstration products, evaluation products, and many others, and these are educational arrangements, there's no consideration provided, there's no economic value. These are so that, just as you can hold this medical technology and assess its unique features, so can a patient, so can a doctor.

So we see that there's a value to having a patient feel and understand the functionality, the range of motion and other unique features of medical technology, and so a medical device company would provide a demonstration unit or an evaluation product. And these are provided

⁹³ AdvaMed (the Advanced Medical Technology Association) Stephen J. Ubl, *Letter: AdvaMed Comments on Implementation of Medical Device Excise Tax Provisions of the Affordable Care Act*, May 3, 2012, at 17 available at TAX ANALYSTS, Doc 2011-6160 or 2011 TNT 58-12.

⁹⁴ *Id.*, at 9

⁹⁵ IRC §4191(a); Treasury Regulation §48.4191-1(a); Treasury Regulation §48.0-2(b)(1).

⁹⁶ IRC §4216(b); Treasury Regulation §1.48.4216(b)(1).

without charge. Under a reading of the proposed regulation, it could be that these uses are deemed taxable.⁹⁷

Conclusion – Unanswered Question (4)

It is not clear how the IRS will respond to the issues developed involving objective valuation in the final regulations. There are revenue and policy implications.

Revenue - Objective valuation makes the MDET a very complex tax to comply with and administer. It is difficult to determine if this complexity will produce a larger or smaller revenue stream for the government and the net revenue (after deducting compliance costs) may well be less than expected.

Policy - From a policy perspective, the MDET runs into fairness issues because it taxes charitable donations at fair market value. While subjective valuation would solve this problem, IRC §4216(b)(1)(C) is clear that an objective valuation is required when an exchange is at less than fair market value in a non-arm's length transaction.

MDET RECAST – A MARKET-SPECIFIC VAT

The MDET, like the former New York HROT, is a single stage transaction tax imposed in a limited, clearly defined market⁹⁸. Despite this similarity, these taxes are very different because the MDET is imposed on the manufacturer (at the commercial chain summit) while the former New York HROT is imposed on the final consumer (at the commercial chain abyss). Consumers bear the HROT's full burden while the intent is for manufacturers to bear the MDET's full weight⁹⁹.

Converting a consumption tax like the HROT to a standard European style VAT is easy to imagine. Value can be taxed as it is added at each stage along the commercial chain until the transaction sequence reaches the final consumer. The tax can be withheld in slices and remitted in full when final consumption occurs.

Converting the MDET to a VAT, however, is more difficult to imagine. We want the tax determined and due when manufacturing ends, which is not necessarily when consumption begins. Neither the institutional consumer such as hospital chains, nursing homes, health maintenance organizations, and other large-scale institutional healthcare users nor the individual consumer at retail is supposed to pay the tax. In fact, the tax is supposed to be completely removed when individual consumers make purchases for personal consumption. A VAT can do this, but the design will not be standard.

⁹⁷ Christopher White (AdvaMed) Public Hearing on Proposed Regulations 26 CFR Part 48 "Taxable Medical Devices" [REG-113770-10] (May 16, 2012) *unofficial transcript available at* TAX ANALYSTS, Doc 2012-2232 or 2012 TNT 24-20.

⁹⁸ The HROT market is entire room accommodation market in the State of New York. The MDET market is any device as defined the Federal Food, Drug, and Cosmetic Act section 201(h) intended for humans.

⁹⁹ The Federation of American Hospitals made the case that the MDET regulations needed to contain provisions that would prevent manufacturers from passing this tax through to customers. It is difficult to see how this could be accomplished. Federation of American Hospitals (and others), *Letter: Notice of Proposed Rulemaking and Notice of Public Hearing on Taxable Medical Devices* (77 Fed. Reg. 6.028 [Feb. 7, 2012]) at 3-5.

Policy Background

Tax policy should guide tax design. MDET's policy concerns are derived from its origin as a funding provision for the PPACA. MDET reflects health care stakeholders effort to "share responsibility" for implementing healthcare reform¹⁰⁰. MDET is intended to "bring in" the medical device manufacturing industry's contribution.

This funding provision began as a targeted \$4 billion fee over 10 years¹⁰¹ and the amended PPACA Senate version §9009 increased this fee to \$20 billion over 10 years¹⁰². Both fees targeted the largest medical device manufacturers. This was perceived to be unfair so the provision was converted to the current broad-based 2.3% excise tax.

The problem with an excise tax solution is that traditional manufacturer excise taxes do not successfully secure an *industry-wide contribution*. They are quite narrow. They focus on the *last manufacturer* rather than all manufacturers in a chain and they tend to be concerned with simple commodity-type goods rather than high technology devices that rely on software and services to deliver a completed product.

The excise tax model is not a good fit for Congress's intent so adjustment is warranted. Congress wanted a transaction tax that would fairly assess the manufacturing segment output in the medical device supply chain at 2.3% of sales. The underlying concept is that this contribution (tax) would be proportional to the increase in benefits (sales) that device manufacturers were expected to realize from healthcare reform.

Recasting MDET

Recasting the MDET is not difficult. Two changes are needed. First, the MDET needs to be applied to *each* taxable medical device sale and to the sale of *each* discrete component of a taxable medical device within the manufacturing segment of this commercial chain. Secondly, the tax must be imposed on the increase in price (subjectively valuation) as the medical device passes through the commercial chain.

The proposed revised statute would read as follows [additions in italics; omissions crossed out]:

¹⁰⁰ Senator Max Baucus, Chair of the Senate Finance Committee, *Letter to President Obama*, (November 6, 2008) available at: <http://www.finance.senate.gov/newsroom/chairman/release/?id=b7fe3588-4028-4484-b0fd-f4c90632db36>

Shared Responsibility: Individuals, employers, and the government must all play a part in the creating and funding of a new health care system. I intend to enumerate specific roles and opportunities for all to share the burden.

¹⁰¹ Senate Finance Committee, *Framework for Comprehensive Health Reform* (September 9, 2009) 18, available at: <http://www.himss.org/content/files/SenateFrameworkComprehensiveHealthReform.pdf>

¹⁰² The §9009 fee was set at two billion dollars from 2011 through 2017. After 2017 it was slated to increase to three billion dollars. Referencing estimates by the Joint Committee on Taxation (March 20, 2010, JCX-17-10) Janemarie Mulvey of the Congressional Research Service indicates that MDET should raise \$20 billion over ten years, in *Health-Related Revenue Provisions in the Patient Protection and Affordable Care Act (PPACA)* R41128 (February 10, 2011) at 6. Note however, that the Treasury Department has a higher estimate of \$30 billion over the 2013-2022 period. Office of Management and Budget, *Budget of the U.S. Government, Fiscal Year 2013, Analytical Perspectives*, at 224.

§4191 Medical devices

(a) In general

There is hereby imposed on the sale of any taxable medical device by *each the* manufacturer, producer, or importer a tax equal to 2.3 percent of the price ~~for~~ *which so sold or in the case where a device or portion of a device is resold among a manufacturers, producers, or importers, the increase in price, as invoiced.*

(b) Taxable medical device

For purposes of this section—

(1) In general

The term “taxable medical device” means any device *or portion of a device* (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act) intended for humans.

(2) Exemptions

Such term shall not include—

- (A) eyeglasses,
- (B) contact lenses,
- (C) hearing aids, and
- (D) any other medical device determined by the Secretary to be ~~of a type which is generally~~ purchased by the general public at retail for individual use.

The recast MDET recognizes that there are multiple manufacturers in a single commercial chain and each manufacturer contributes to the whole. The “manufacturer” definition in the regulations will be broadly construed.

A manufacturer will include goods providers including those providing parts, replacement parts, components, sub assemblies¹⁰³ and services including warranties, training, software, software updates. A *medical device* will be defined to mean a fully functional, operational, updated, and subsequently modified medical device that qualifies as a device under section 201(h). A *taxable medical device* will be defined as any final device, device part, replacement part, component, sub assembly, warranty, training, software, software update necessary to make a *medical device*.

¹⁰³ David Fisher at Siemens Healthcare, speaking on the Medical Imaging and Technology Alliance behalf went to great lengths to emphasize that the manufacturing supply chain was exceedingly complex, involving multiple partially completed device sales and component acquisitions.

As a general matter [imaging and radiation therapy equipment] are very large machines with many components. As many as a thousand, thousands at times. ... [There are] complex corporate and manufacturing structures to facilitate global sales. In some cases, dozens of corporate affiliates manufacture different medical devices or components, transferring components to each other for incorporation into finished products, and then transferring the finished product among each other again. In other cases components may just be purchased from third party vendors.

Public Hearing on Proposed Regulations 826 CFR Part 48 “Taxable Medical Devices” [REG-113770-10] (May 16, 2012) at 8, *unofficial transcript available at* TAX ANALYSTS, Doc 2012-2232 or 2012 TNT 24-20.

It will be clear in the regulations that any article (tangible good, service or software supplied) that is necessary for a medical device to achieve or maintain certification under the Federal Food, Drug, and Cosmetic Act is included within the *taxable medical device* definition.

Procedural regulations will explain that the MDET will be charged on the invoice price (subjective valuation) for every transaction a manufacturer made. In cases where a manufacturer:

- (a) purchases a taxable medical device (component) from another party, and then
- (b) integrates this component into another (larger) medical device, and finally
- (c) sells the completed device onward, that
- (d) the tax will be due on the increase in value between the purchase price (a) and the onward sale price (c).

The tax due will be identified, but not “passed though” to the buyer on each invoice.

For example, if X sells a taxable medical device to Y for \$100 and Y incorporates it into another medical device who sells the larger device to Z (a hospital that will use the medical device to provide care, and is not a manufacturer) for \$1,000, then:

- X will determine a \$2.30 tax on its \$100 sale and note tax paid on the invoice. The tax does not “pass-through” to Y. The invoice will be for \$100. X will also provide its tax ID number.
- Y will determine a \$23.00 tax on its \$1,000 sale, deduct \$2.30 based on X’s invoice note, leaving \$20.70 due. The invoice from Y to Z will be for \$1,000 but will record the \$20.70 due and the \$2.30 already paid. The tax ID numbers for both X and Y will be provided on the invoice.
- If X does not record the \$2.30 on the invoice or if X does not provide a tax ID number, then Y will not be allowed a deduction and will owe the full \$23.00 tax.
- If the invoice Y issues to Z (a hospital that is not a manufacturer) does not include X’s tax due note and Y’s tax due along with their tax ID numbers then Z will treat the invoice as “tax inclusive.” Z will be required to withhold the tax from its invoice payment. Most likely a corrected invoice will issue, if not then after a period of time Z will be required to remit the tax withheld (perhaps on its annual income tax return). It will be clear that Z does not bear the tax burden.

The exemption under IRC §4191(b)(2)(D) will be streamlined under the recast MDET. Rather than a difficult product exemption exercise under the current law, it will not be necessary for the Secretary to determine that a medical device is “of a type which is generally purchased by the general public.” The recast MDET allows exemptions to be more precisely targeted so the exemption can be applied to “purchases by the general public at retail for individual use.”

A further procedural regulation example substitutes ZZ (a retail pharmacy) for Z (the hospital) in the example used above. The requirement is to remove the MDET from the entire commercial chain. ZZ will be required to provide certification that the purchase was for resale to the general public for individual use”.

Assume the same facts as in the prior example (except ZZ – a retail pharmacy – is substituted for Z). X sells a taxable medical device to Y for \$100, and Y incorporates it into another medical device and then sells the larger device on to ZZ (a retail pharmacy) for \$1,000, then:

- X will determine a \$2.30 tax on its \$100 sale, noting this on the invoice. The tax does not “pass-through” to Y so the invoice remains at \$100 and X provides its tax ID number on the invoice.
- Y will determine a \$23.00 tax on its \$1,000 sale, deducting \$2.30 based on the note on X’s invoice, leaving \$20.70 due. Y’s invoice to Z will be for \$1,000, recording both the \$20.70 due and the \$2.30 already paid and both X and Y’s tax ID numbers are provided on the invoice.
- If Y’s invoice to ZZ notes both X’s and Y’s tax due along with their tax ID numbers, then ZZ submits this record (taxes due and tax ID numbers) to the IRS and no withholding by ZZ will be required.
- If, however, the invoice Y issues to ZZ does not note X’s tax due, and Y’s tax due along with their tax ID numbers, then ZZ will treat the invoice as “tax inclusive”. ZZ will be required to withhold the tax from the invoice payment.
- Once the IRS receives from ZZ the taxes due from X and Y along with their tax ID numbers, the IRS will (a) confirm the tax received from X (\$2.30) and Y (\$20.70) and (b) deem these amounts to be an MDET pre-payment that can either be used to offset other taxes due or be refunded. A notice will issue from the IRS.

The recast MDET will be self-enforcing, flexible, and will solve the major issues currently facing the MDET: (1) a double taxation possibility, (2) related party pricing and the application of constructive pricing rules, (3) manipulation of values through exclusion of service / software attributes in the title passage rules, and (4) unfairness in forced application of objective valuation rules for charitable donations, educational uses, testing or no-cost replacement parts.

Double taxation is removed from the recast MDET because values are taxed in slices as they are added to the medical device, not absolutely on full value whenever a sale by a final manufacturer occurs. The tax is imposed throughout the commercial chain, as value is determined, not on the difficult to identify “last manufacturer” in line.

Constructive pricing will not apply under the recast MDET. Tax is imposed on the invoice price (the price the buyer pays) rather than a difficult to determine fair market value or what the medical device is worth on the open market under the same or similar circumstances of sale.

The incentive to migrate supply chain activities, placing services and software values outside the taxable base, is also eliminated once the definition of taxable medical device is expanded to include any device *or portion of a device*. This provision is not only designed to allow the MDET to be collected in slices, but it prevents goods-based distortions in the medical device’s true value. The tax base Congress intended to tax was the completed medical devices sales, not just the tangible property component.

Finally, the unfairness inherent in placing a tax on medical devices that for whatever reason are donated or contributed at no charge can also be eliminated. It is a simple matter to connect the charitable donations to sales at retail (as in the ZZ example above). The Red Cross or Katrina relief fund would simply need to be presented a “no charge” invoice and the tax is removed. It simply extends subjective valuation to indicate that if a final transfer is made for no consideration that the entire tax on prior slices in the manufacturing chain should be exempt. The ZZ example should be followed again.

CONCLUSION

MDET can be recast and made largely self-enforcing if it was approached as a multi-stage transaction tax with subjective rather than an objectively valued excise tax. A manufacturers excise tax simply does not fit in a high technology manufacturing sector like medical devices.

Although this paper has approached recasting the MDET by changing the statute, the same result could be achieved under the current statute through regulatory measures. That exercise has not been included here because doing so would significantly extend the text. The key to making this change through regulations would be to clearly articulate the tax policy objectives underpinning the MDET. An assessment of the medical device market would be necessary and it would be necessary to reach a conclusion that a multi-stage transaction tax is the best way to meet Congressional needs.

Action is needed before the final regulations are issued. There are at least four major areas where revenue and policy objectives may be in conflict and administrable solutions are needed. The overriding administrative advantage in recasting the MDET as a market-specific VAT is that it can be fully automated with off-the-shelf tax software applications in use today. These applications were designed for the VAT.