Understanding the Medical Device Excise Tax (MDET)

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pwc

Agenda

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Medical Device Excise Tax - Overview

- Health Care and Education Reconciliation Act of 2010
- Established a 2.3% excise tax imposed on the <u>first sale</u> in the US of <u>taxable medical devices</u> effective 1/1/13.
- ***Taxable medical device*** - any device defined in section 201(h) of the Federal Food, Drug and Cosmetic Act intended for humans
- Certain sales of taxable medical devices are exempt –
  1. For further manufacture
  2. For export
- Tax not imposed on items available for purchase by the general public (e.g., eyeglasses, contact lenses, hearing aids)
- Many open issues still exist, including significant complexities surrounding determination of taxable price issues surrounding product "kitting," etc.

Washington Update: MDET – Legislative Repeal Activities

- Efforts continue to grow around legislative repeal of the tax.
- The Advanced Medical Technology Association (AdvaMed) is leading an initiative to repeal the tax.
- More than 400 companies signed a letter to leaders of Congress stating that the tax would "stifle innovation and US competitiveness."
- The case for repeal:
  - Tax is having an adverse impact on R&D investment and job creation.
  - Cost cutting measures will lead to job losses (public announcements have already been made in this regard)
  - Tax will adversely impact patient access to new and innovative medical technologies.
- Repeal efforts continue to advance (*H.R. 436, the Protect Medical Innovation Act of 2011,* introduced by Representative Paulson.
- Likelihood of repeal in 2012?

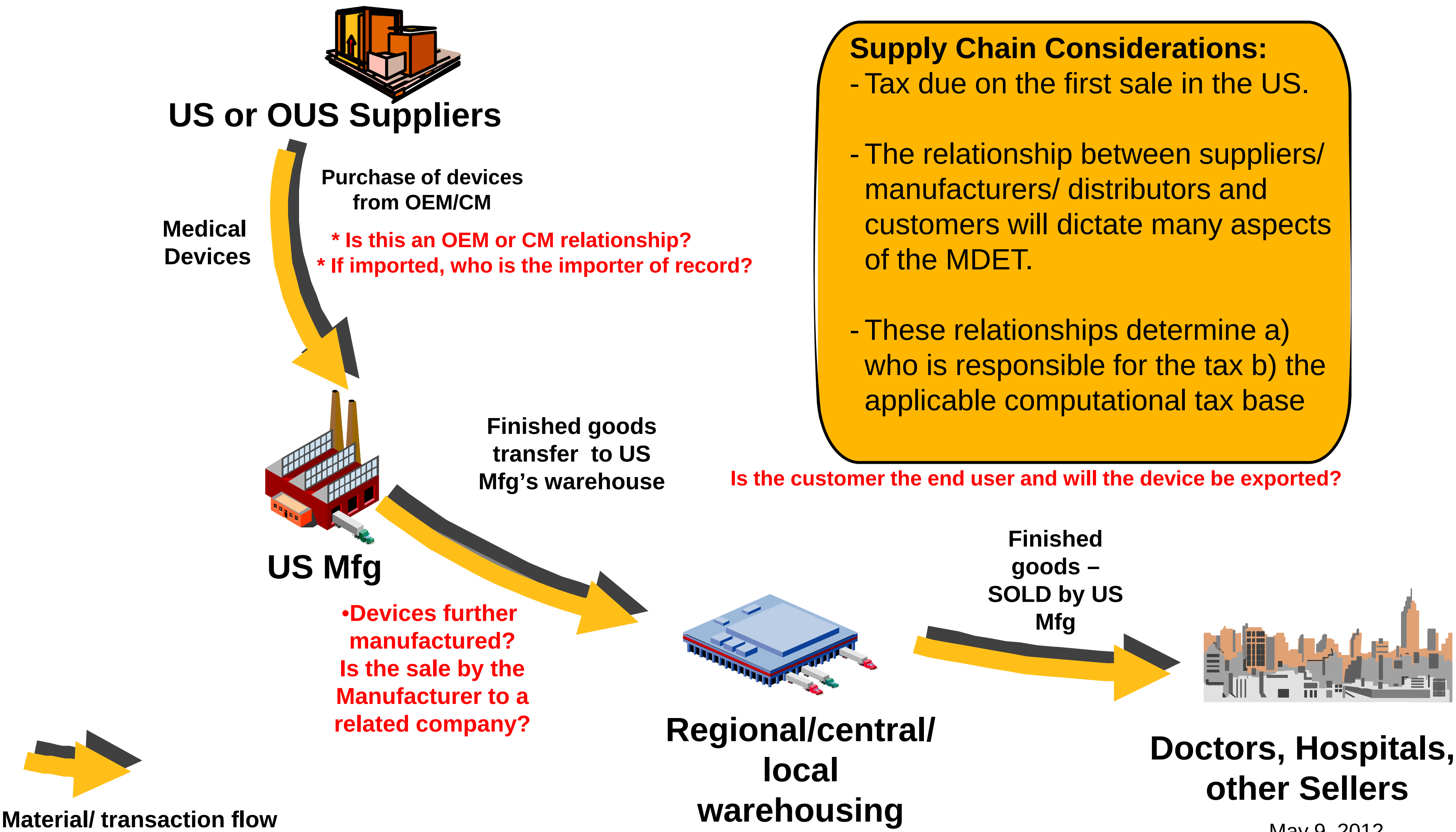
Washington Update: Supreme Court Challenge to Healthcare Reform

- In March 2012, the Supreme Court heard three days of oral arguments on the constitutionality of the minimum coverage provision (e.g., individual mandate) of Healthcare Reform.
- Severability of the individual mandate is the most relevant issue for the medical device industry.
- If the individual mandate is considered severable, the MDET would continue to exist (even if the individual mandate is ruled unconstitutional)
- A ruling a) against the constitutionality of the individual mandate and b) that it cannot be severed from the rest law would bring down the entire act—and the device tax with it.
- The Supreme Court's decision is expected in June 2012

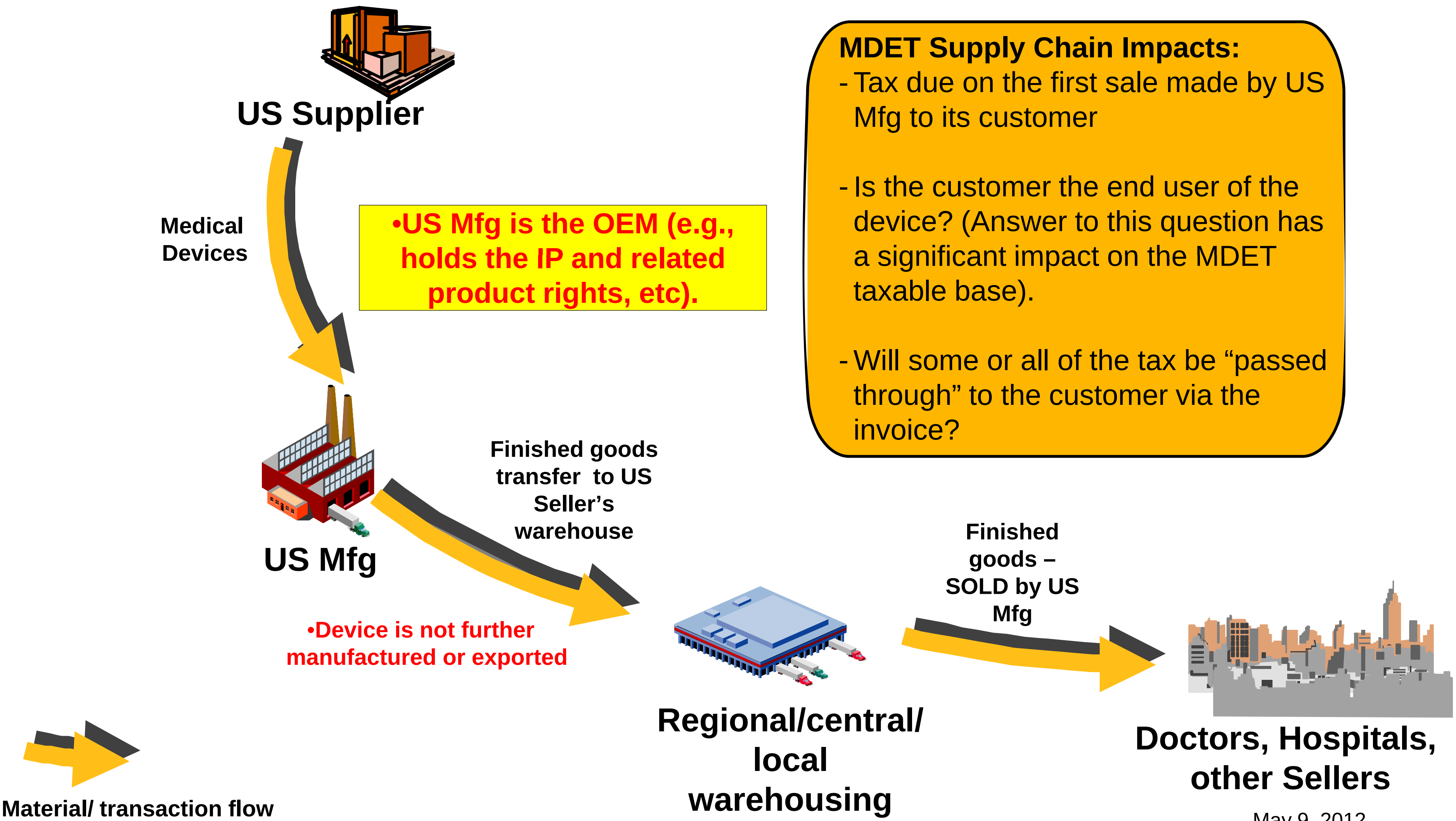
Washington Update – What is a Company to Do?

- Given the potential for repeal, why do I care right now??
- Good question… But keep listening…
- Do you consider your supply chain similar to that of a fishing lure manufacturer?
- Archaic IRS rules, thus… are you IT systems ready?? (More on that later…)

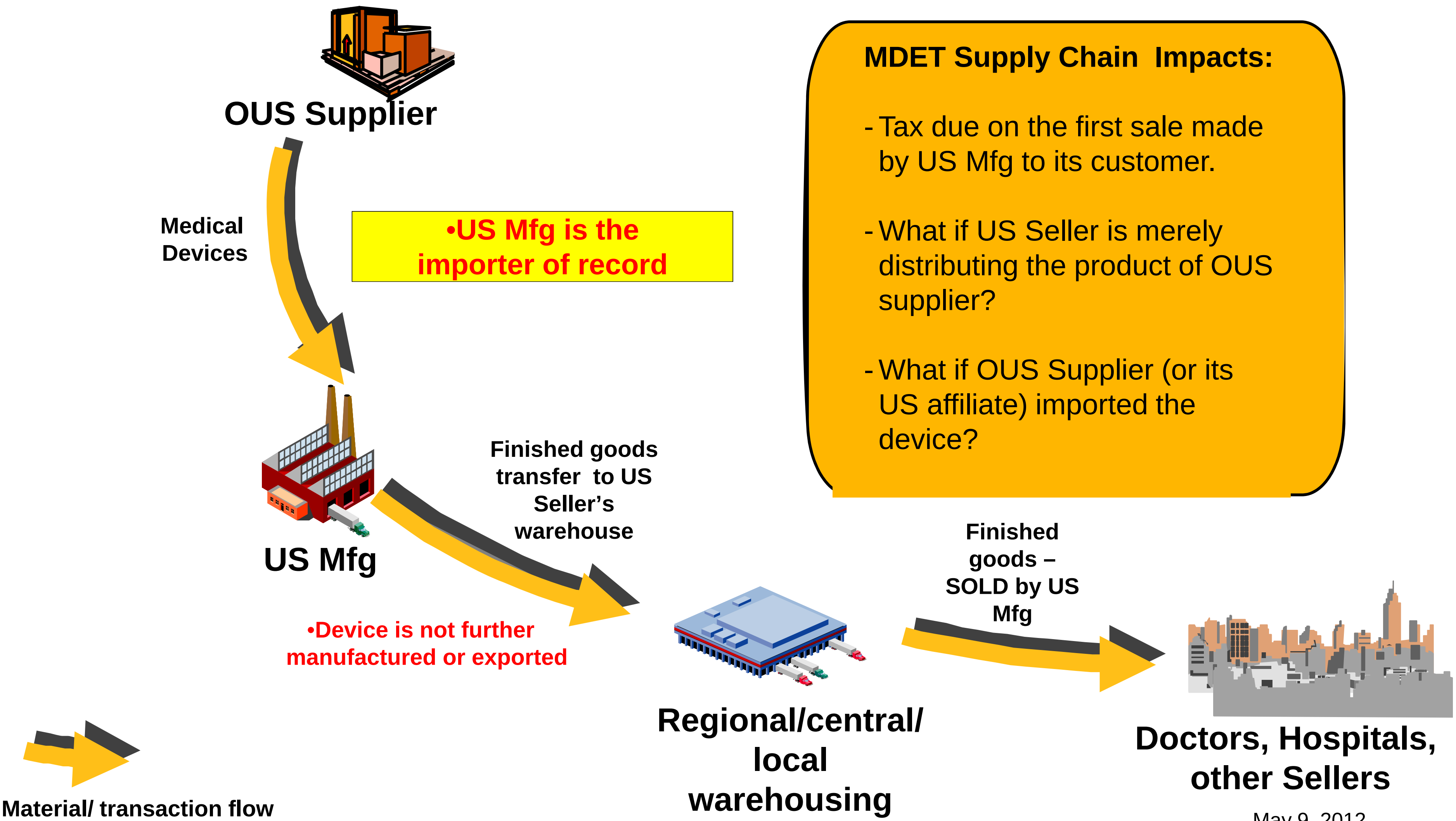
The Supply Chain from 10,000 feet ……



Example 1 – US Contract Manufacturer Supplier



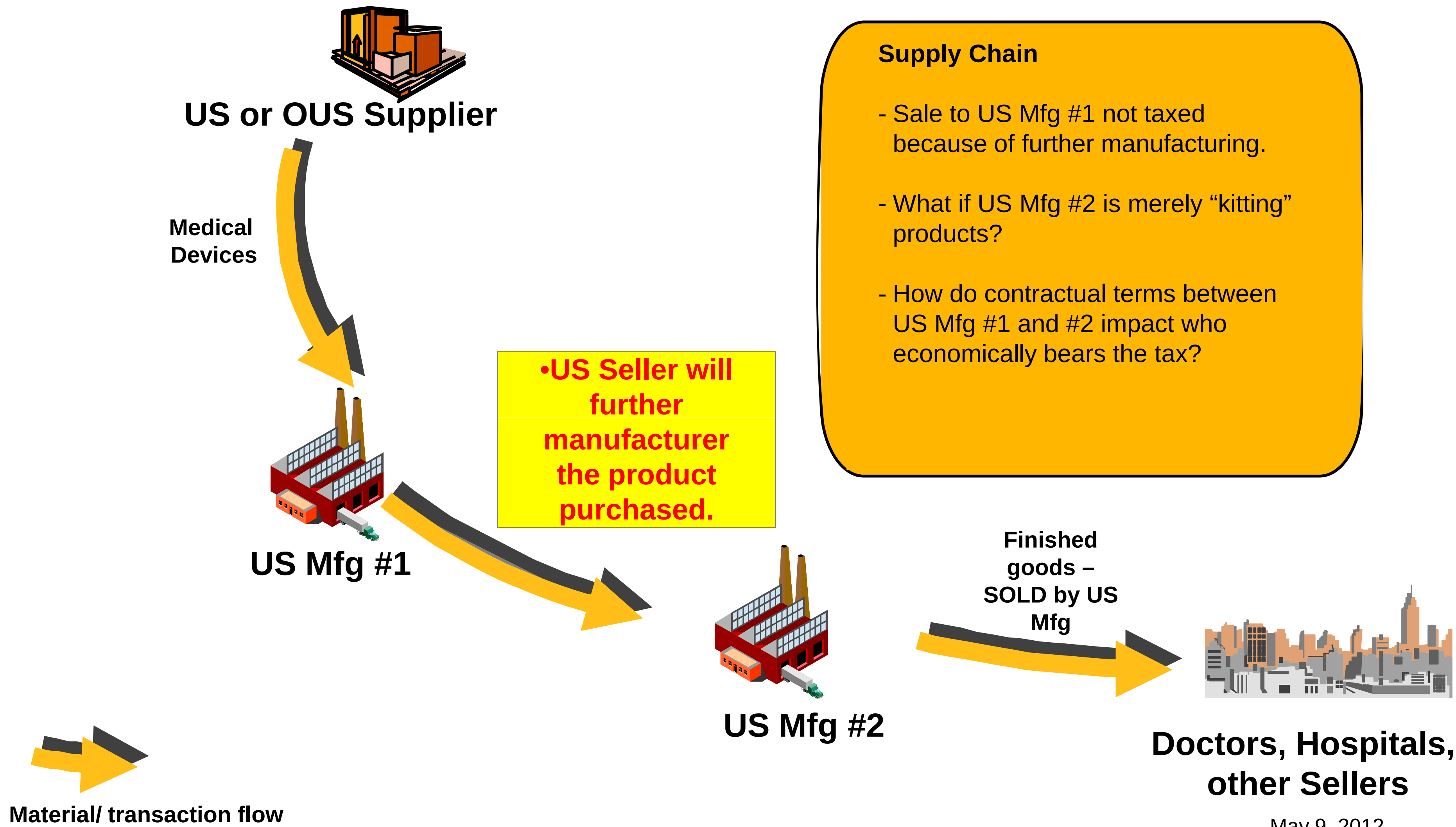
Example 2 – Imported from OUS Supplier



Example 3 – Sale for Further Manufacturing

Supply Chain

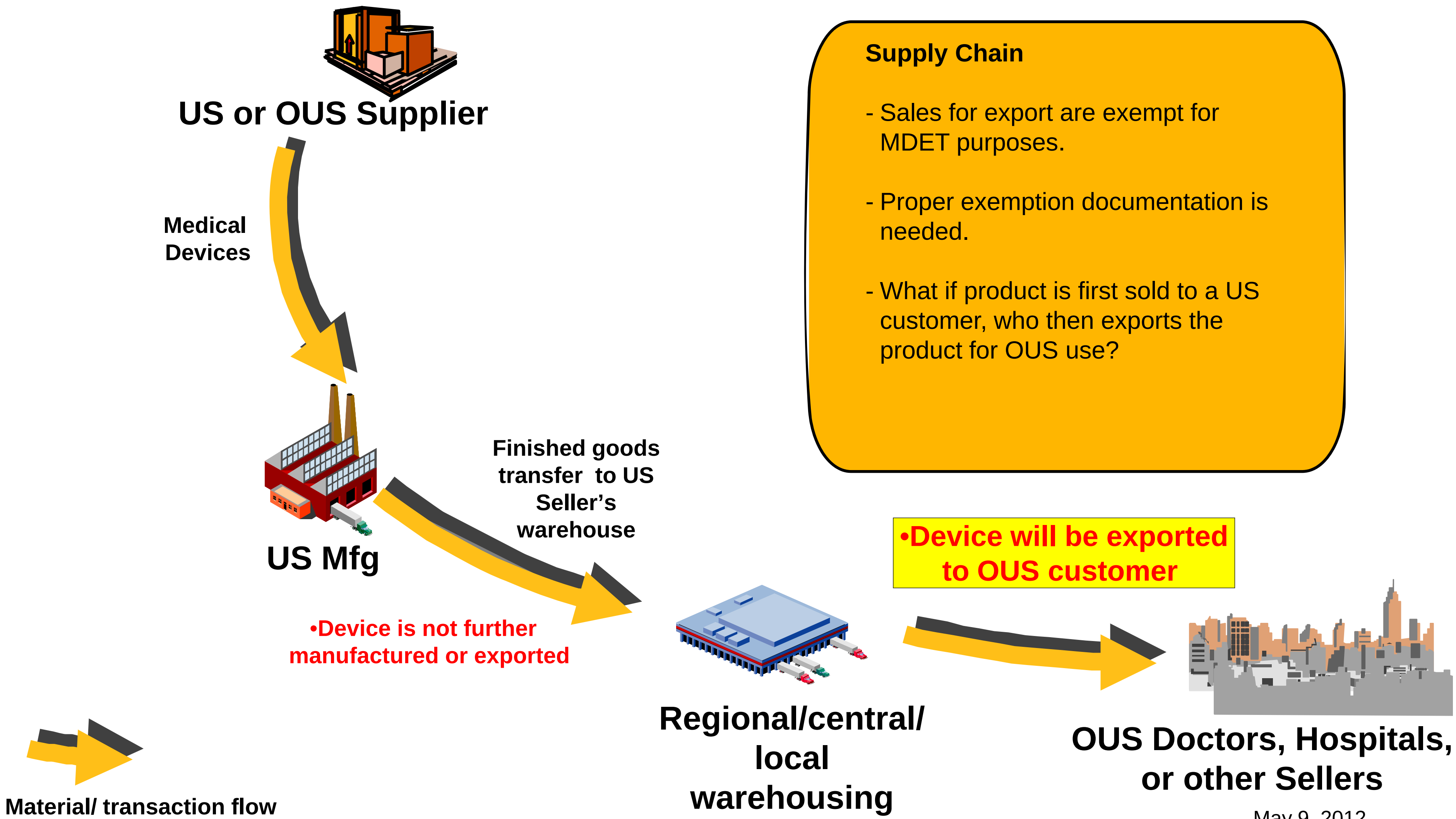
- Sale to US Mfg #1 not taxed because of further manufacturing.
- What if US Mfg #2 is merely "kitting" products?
- How do contractual terms between US Mfg #1 and #2 impact who economically bears the tax?



Example 4 – Sale for Export to OUS Customer

Supply Chain

- Sales for export are exempt for MDET purposes.
- Proper exemption documentation is needed.
- What if product is first sold to a US customer, who then exports the product for OUS use?



MDET – Compliance Challenges

- **Why is it important to focus on this tax now?**
- Taxable base computations are highly complex and frequently are not derived from the actual 3rd party sales price.
- Items such as rebates, discounts, leases, intercompany sales and numerous other factors must be addressed so that taxpayers are ready to comply with the new excise tax when it becomes effective on January 1, 2013.
- IT systems must be materially updated/modified in advance so that the correct amount of excise tax can be calculated, reported and paid.

MDET – Compliance Challenges – cont'd

- **Why isn't this a straightforward calculation??**

  e.g. Domestic sales $5B x 2.3% = $115M

- What about sales for export or for further manufacturing? How do I systematically capture that data for exemption purposes?

- What about sales where the supplier is the domestic manufacturer and subject to the tax? How do I make sure I don't pay tax on these sales?

- Also – the law allows reductions to the taxable base for: 1) rebates, 2) transportation costs incurred after title transfer – How do I capture this information?

- Is the product sold by the manufacturer to the end user (e.g., a hospital)? If so, the law allows a taxable base reduction (via highly complex rules) to arrive at a wholesale (vs. retail) price . These highly complex rules often require accessing 3rd party sales data to determine a highest (or lowest) wholesale price.

- Are sales made via a related party sales affiliate? If yes, a taxable base reduction (via highly complex rules) is also allowed.

- **Impractical?? Yes. Required – Yes. The above creates significant IT systems challenges.**

MDET – Savings Opportunities

- Significant Tax Savings opportunities exist with proper planning
- Examples include:
  - Bundled products (sales of products that include non-taxable elements – e.g., services, software, etc).
  - Consideration of related party sales company impacts (related party sales often materially impact the amount of tax due and payable)
  - Incorporation of transfer pricing concepts (to derive a sale by manufacturer value), where appropriate

MDET – Current State of MDET at Medical Device Companies

- It's quite varied…
- Companies are at various stages regarding the planning process.
- Some are taking more of a "wait and see" approach due to potential for repeal (<u>Not</u> recommended for any company where the MDET would have a material impact beginning 1/1/2013).
- Some have approached it from a more tax technical or academic level and have yet to consider a system-based solution
- Others are beginning to consider system requirements or are actively in the initial stages of a systems based implementation process.

MDET – Emerging Best Practices

1) Educate the organization to understand the tax.

2) Gauge the ability of your organization to pass the tax onto customers.

3) Approximate the financial impact of the tax for each business unit.

4) Perform a pre-implementation assessment of the information technology and business processes requirements in order to be compliant with the tax.

5) Implement a system-based solution that will allow compliance with the material aspects of the MDET.

Questions?

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Thank you!

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