

Regulation and Supply of Refurbished Medical Devices  
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# Pre-Owned Medical Equipment: Regulation & Markets

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Jeffrey Gren, Director

Office of Microelectronics, Medical Equipment  
& Instrumentation

International Trade Administration

U.S. Department of Commerce



# Topics of Discussion

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- The Market for Pre-Owned Medical Devices
- Types of Pre-Owned Equipment
- U.S. Internal Regulations
- Benefits & Risks / Concerns & Issues
- Import Regulations around the World



# Market Size

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- Data is essentially non-existent
- Most pre-owned devices circulate within unregulated national markets
- The United States is probably the largest single market
- China was major international market prior to 1998
- International trade statistics do not distinguish between new and pre-owned



# Sources of Pre-Owned Devices

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- Because most trade is within domestic markets, largest source is probably the each respective domestic market
- For internationally traded pre-owned devices, the United States is primary source



# Why the U.S. is Primary Source

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- The U.S. is major consumer of medical devices
- U.S. healthcare facilities often lease rather than purchase devices
- Leased equipment is replaced faster than purchased equipment
- Lessors recoup part of original capital costs by selling devices coming off lease

These practices generate a stream of well-maintained devices suitable for continued use



# Characteristics of the U.S. Remarketing Industry

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- Re-sale of approved devices is not regulated:
  - FDA does not inspect remarketers or products
  - FDA does not license remarketers
- Industry has many small firms, often run by former service personnel of OEMs
- The number of firms is estimated at 3,000 to 3,500
- Some OEMs have begun to refurbish and sell their own devices



# Characteristics of the U.S. Remarketing Industry (cont.)

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- Market for pre-owned devices is “Buyer Beware” and many buyers will only deal with vendors they know and trust
- Internet auction sites selling “as is, where is” devices have not generally succeeded
  - Were popular with facilities seeking to dispose of used equipment
  - Unpopular with buyers, who saw risks in buying as is/where is equipment



# Types of Pre-Owned Devices

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- Definition of terms related to pre-owned devices is problematic
- The industry has created a variety of terms to differentiate their products and overcome negative stereotypes
- Terms have no legally accepted meaning in the United States
- Translation of these terms into other languages creates even more confusion



# Defining the Secondary Market

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- Pre-owned
- As is/Where is
- Used
- Second-hand
- Spray & Pray
- Reconditioned
- Rebuilt
- Remanufactured
- Re-staged
- Re-marketed
- Refurbished
- Remarketed



# As Is/Where Is

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- Vendor makes no claims about the condition of the device
- Purchaser is buying the device where it is currently located (hospital, warehouse, etc.)
- If device has been removed from healthcare facility, it may be impossible to test the device
- Device may have been “cosmetically” enhanced (cleaned and painted)



# Refurbished/Reconditioned

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- No standard definition of these terms
- Generally imply (but do not guarantee) operation within OEM's specifications
- These terms may encompass:
  - Cleaning, painting, and/or decontamination
  - Calibration and preventative maintenance
  - Replacement of worn components
  - Installation of OEM's upgrades
- The device may or may not be sold with a warranty



# Remanufactured

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- Sometimes used as synonym for “refurbished” or “reconditioned”
- Sometimes used (e.g. by FDA) to mean that the purpose or operating parameters of the device have been altered, thus requiring a new 510K approval
- Devices altered to do something new or operate to other-than-OEM specifications are not considered “refurbished” by most regulators (or this presentation)



# Avoiding the Definitional Morass

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One proposed regulatory scheme for pre-owned devices sidesteps these problems:

- Does not define “Refurbished” or related terms
- Lists and defines terms describing things that could be part of refurbishing process
- Would require labeling based on those terms and definitions
  - “Say what you do, and do what you say”



# Internal

## Regulation of the U.S. Market

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- The FDA does not regulate the resale of approved, unaltered medical devices
- The FDA offers no certification of refurbished/reconditioned devices
- The FDA does not register or inspect refurbishers/reconditioners
- After reviewing safety concerns in late 1990s, FDA concluded registration and GMP regulation were not warranted



# Proposed Voluntary Regulatory System

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- In 1999, 9 organizations with interests/concerns about pre-owned devices proposed a voluntary regulatory system
- The FDA has had the proposal under consideration since late 1999
- FDA action on the proposal is expected this year

# Labeling Requirement

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- Name of the servicing or remarketing organization
- Toll-free telephone number or other contact information for the organization
- Documentation describing the work performed using standard terminology
- The date work was performed or transaction completed
- Device Condition code (DC 1 or DC 2)

# Standard Terminology

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- Calibration
- Cleaning
- Cosmetic Restoration
- Decontamination
- Installation
- Performance Verification
- Preventative Maintenance
- Remarketing
- Repair
- Safety Testing
- Scheduled (Planned) Maintenance
- Service

# Device Condition Codes

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- DC 1

- Device may have received cosmetic restoration but otherwise is in as is or unknown condition
- Prior to use, device must be checked for proper performance and safety

# Device Condition Codes (cont.)

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- DC 2

- Device is performing properly and safely, and is ready for clinical use.
- If installation is required, the device must be checked again after installation.
- Users and purchasers should refer refer to the Service Documentation for additional information on the service(s) performed.



## Details of the Proposed Voluntary Regulatory System

# Registry

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- Registry would be operated by third party
- Purpose would be to make hazard, recall, and safety related service notices available to all participants
- Remarketers would have been obliged to make information on FDA and manufacturer hazard, recall, and safety related service notices available to their customers



# Purchasing Pre-Owned Devices: **Benefits**

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- Offer good functionality at low cost
- Minimize staff-training costs
- Provide a low-cost supplement to the primary unit
- Match acquisition costs to the revenue stream that device will generate
- Provide better healthcare for patients at facilities that can not afford new devices



# Purchasing

## Pre-Owned Devices: Risks

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- Device may not have warranty
- Parts, service, manuals may be difficult to obtain
- Condition of machine (reliability, safety, etc.) may be difficult to ascertain
- Buyer may not be able to determine trustworthiness of seller



# Imported Pre-Owned Devices: Governmental Concerns

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- Are pre-owned devices safe and reliable?
- How are safety alerts and recall notices sent to buyers?
- Are pre-owned devices technological obsolete?
- Do they compete with domestic products?



# Imported Pre-Owned Devices: Governmental Concerns (cont.)

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- How can unsophisticated buyers be protected?
- Do import restrictions protect buyers from unethical vendors, or just keep the ethical ones out?

These concerns may apply equally to devices that remain in use by the original purchaser or re-sold domestically



# Issues for Industry

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- Can service be provided across borders?
- Can parts be supplied?
- Can the buyer acquire the manual at reasonable cost?
- Can recall and safety notices be forwarded?
- How can the buyer be educated about benefits **and** risks of pre-owned devices?
- How can the buyer be protected from unethical vendors?



# Global Regulatory Report

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- U.S. Department of Commerce prepares annually report on import regulations
- Available on the web at:  
[www.ita.doc.gov/td/mdequip](http://www.ita.doc.gov/td/mdequip)
- Update for 2002 is now in final editing



# Report Methodology

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The report is based on information submitted by:

- U.S. Foreign Commercial Service specialists based in U.S. embassies
- Other interested parties



# Report Summary

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Of the world's 199 countries/markets, U.S. Dept. of Commerce has information on 100:

- 78 appear to permit unrestricted importation on same terms as new
- 17 restrict importation
- 5 prohibit importation



# Unrestricted Importation on Same Terms as New

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If device has received regulatory approval for sale, in a market, then ...

- The device can be imported either new or pre-owned
- The pre-owned unit is subject to the same taxes, duties, etc. as new unit
- The pre-owned unit is not subject to any additional safety review or registration to which a new unit is not also subject



# Unrestricted Does Not Mean...

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- Exemption from a country's medical-device regulations
- Exemption from duties, taxes, tariffs, etc.
- Exemption from government procurement laws or policies



# Government Procurement Policies

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- Government procurement policies may bar public entities from purchasing used equipment
- If the healthcare sector is dominated by public sector, such procurement rules can severely undercut liberal importation laws
- 22 countries have been identified that allow unrestricted importation, but have restrictive government procurement policies



# The U.S. Import Regime: Uncertain

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- Only FDA-approved devices may be imported
- U.S. law has no clear statement on importation of pre-owned devices
- No official FDA policy approving or restricting
  - Individual FDA districts impose own interpretation
  - Some districts allow importation of an pre-owned and unaltered unit of an approved device, while others do not
  - Some districts require that a pre-owned device being imported for parts first be disassembled



# Example of Unrestricted Access: The European Union

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The EU permits importation on same terms as new, but...

- Under EU Directive 93/42/EC, medical devices must bear the CE Mark, indicating approval for sale in the EU
- Like the new unit, pre-owned units can not be sold in the EU unless they carry the CE Mark



# Restrictive Import Regimes

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Restrictions vary in severity:

- The OEM, holder of registration, or end-user may enjoy liberal rules, while others face restrictions
- Some restrictions discourage, but do not impede importation
- Some restrictions are tantamount to a total prohibition



# Examples of Restrictions

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- Taxes on pre-owned device or device over a certain age
- Ban on devices older than a certain age or beyond a set percentage of estimated useful life
- Requirement that device be refurbished by original manufacturer
- Requirement for warranties



# Examples of Restrictions (cont.)

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- Requirement that parts and service be available
- Restrictive rights for importation (e.g., only by holder of registration or by end-user)
- Requirement for licensing/approval
- Bureaucratic obstructionism not codified in law



# Countries that Restrict

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Argentina	Japan	South Africa
Brazil	Korea, South	Turkey
Canada	Mexico	Uruguay
Colombia	Moldova	Uzbekistan
Croatia	Pakistan	Vietnam
India	Peru	



# Countries that Prohibit

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China

Syria

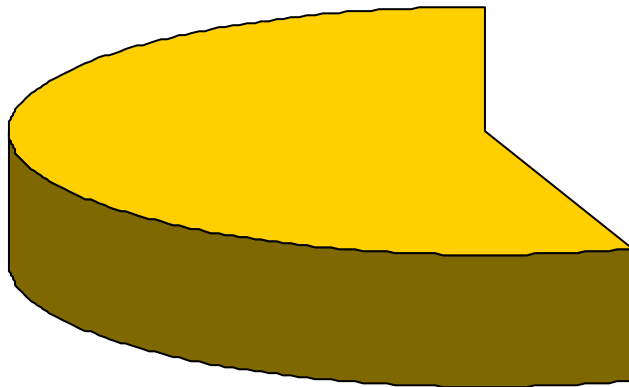
Egypt

Thailand

Kuwait

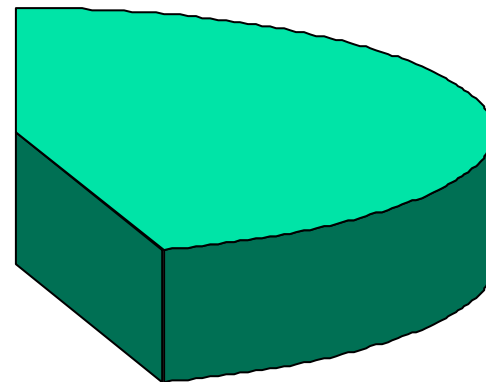
# Impact of Restrictions on Access to Pre-Owned Devices

Percent of World Population



Known Restricted or Prohibited Markets

55%



Rest of World  
(Unrestricted or Not Known)

45%



# Observations on Regulation of Import Market

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- Import regulations for pre-owned devices are often vague and ill-defined
- Although relatively few countries restrict or bar importation, those that do account for a high percentage of world population
- Import restrictions are often paired with unregulated domestic market



# Observations on Regulation of Import Market (cont.)

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- Government procurement policies may have unintentional impact on healthcare
- When restrictions exist, they seem more based on risk-avoidance than effort to balance risks against possible benefits
- No model legislation exists to address legitimate safety concerns while fostering access to improved healthcare



# Contacting OMMI

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- General Phone Number: 202-482-2470
- Web Site: [www.ita.doc.gov/mdequip](http://www.ita.doc.gov/mdequip)
- Steven R. Harper  
International Trade Specialist  
Tel: 202-482-2991  
Fax: 202-482-0975  
E-Mail: [Steven\\_Harper@ita.doc.gov](mailto:Steven_Harper@ita.doc.gov)



# Summary

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- Market

- Size of market is unknown
- U.S. is key supplier and major market in absence of China
- Domestic markets are generally unregulated

- Types

- Little agreement exists on how to define or describe refurbished equipment



# Summary (cont.)

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- U.S. Internal Regulations
  - Resale of *unaltered* devices is unregulated
  - FDA is considering a Voluntary Regulatory System
- Benefits/Risks & Concerns/Issues
  - Pre-owned devices have benefits for both patients and healthcare institutions
  - No agreement exists on how to deal with risks



# Summary (cont.)

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- Import Regulations
  - Import regulations are often vague
  - No model legislation exists to guide countries wishing to draft rules
  - Relatively few countries restrict or prohibit importation, but these countries account for over 50% of world population