AdvaMed

Advanced Medical Technology Association

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GS1 HUG™

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BRINGING INNOVATION TO PATIENT CARE WORLDWIDE

AdvaMed Growth

AdvaMed
Advanced Medical Technology Association

- **Founded in 1974 as the Health Industry Manufacturers Association (HIMA)**
- **Now grown to 1,300 + member companies and subsidiaries (devices, diagnostics, HIS)**
- **Nearly 90% of domestic market**
- **$20 million budget, 60 staff with global expertise**
- **45 - member Board of Directors**

2007 Active Members
By Company Size

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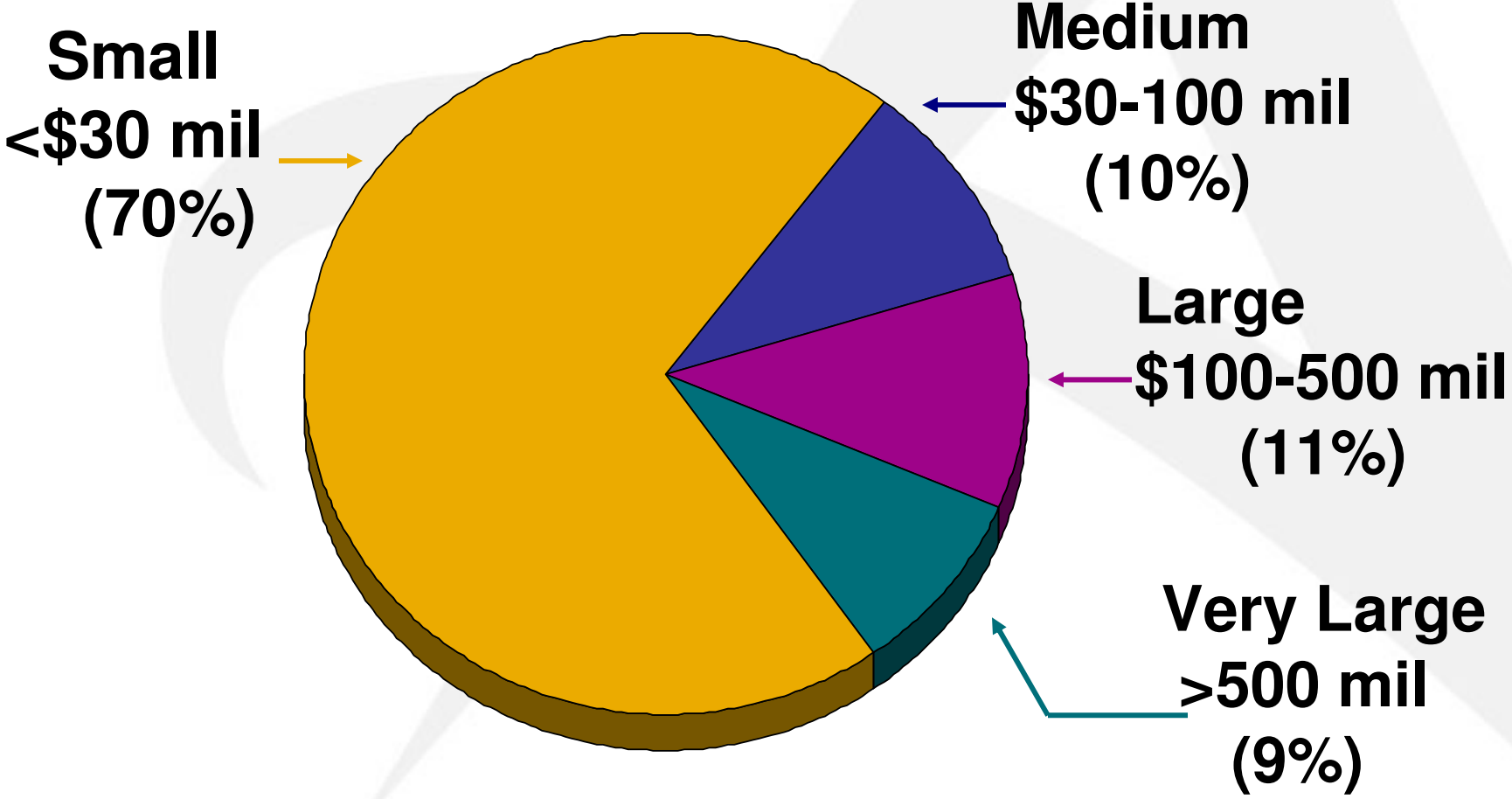

The Issues We Work On

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Goals

- **Gaining rapid clearance by FDA**
- **Ensuring adequate payment**
- **Speeding coverage determinations**
- **Accessing international markets**

Primary Goal

- Work to ensure an appropriate premarket and postmarket regulatory environment both domestically and globally

2007 Policy Focus

MDUFMA Reauthorization

- Improved Performance
- Stable and Predictable Fees
- Third-Party Review
- Third-Party Inspection
- Appropriate Regulatory Scheme for IVDs

Postmarket

- Risk Communication
- Adverse Event Reporting
- Recalls
- Unique Device Identification
- Post Approval Studies (CoA, 522)
- Annual Reports

Combination Products

- Cross-Labeling
- Adverse Events
- GMP's

Critical Path

- Device Development Models
- Surrogate Endpoints for Drug-Eluting Stents
- Other Initiatives

Standards Involvement

- Member - ISO TC 212 Clinical laboratory testing and in vitro diagnostic test systems
- Clinical Laboratory Standards Institute
- Member US National Committee of the IEC Technical Management Committee
- US Technical Advisor for IEC TC 62 and SC 62A - IEC 60601-1 general standard for the safety of electrical medical devices, and associated collateral standards - US Chief delegate at TC/SC meetings
- Member - IEC TC 62 Chairman's Advisory Group - main strategy group for international committee
- Co-Chair of AAMI Electrical Safety Committee

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Auto-ID Working Group

- Co-chairs: Tom Werthwine (J&J) & Jackie Elkin (Medtronic)
- 90+ Individuals representing 40+ AdvaMed Members Companies
- Support Standards Development: GS/1, EPCglobal, HIBCC
- Oppose legislative proposals to restrict the use of RFID
- Support FDA as the most appropriate vehicle for development and implementation of UDI System

Auto-ID Working Group

- AdvaMed supports the development of Auto-ID technology and standards that address specific patient and public health safety problems
- FDA Stakeholder Meetings on UDI (April, October 2005)
- FDA Public Meeting on UDI (October 2006)
- FDA Docket on UDI (November 2006)

What are the Problems?

- Eastern Research Group Report on UDI (March 2006)
  - Use Error
  - Device interactions
  - Counterfeiting
  - MDR Analysis
  - Recalls Tracking

Attacking the Problem

- Root Cause Analysis
- Risk Analysis
  - Severity
  - Frequency
  - Mitigation
- Solution
  - Device
  - Use
  - Unintended Consequences

Device Characteristics

- Risk Class
- Physical – size, material
- Packaging
- Use

Use Characteristics

- Professional
- Self /Family
- Care setting
- Processing – Disposable, Reusable

Unintended Consequences

- Technology limitations
- Implementation costs
- Adoption by Users

Elements of Device Identity

- What is it – Category
- Who made it – Manufacturer
- What was made – Model, packaging
- How/When was it made – LOT / Serial Number
- Other info – expiration, materials, reprocessing, handling

F D A
Current Regulations –

- **Design & Manufacturing**
  - 21 CFR 820 Quality System Regulation
- **Labeling**
  - 21CFR 801: General Provision for Labeling
    - 21 CFR 801.400 Special Requirements for Specific Devices
  - Section 301: Prominent and Conspicuous Mark of Manufacturers Who Reprocess Single-Use Devices
- **Adverse Event Reporting**
  - 21 CFR 803: Medical Device Reports (MDR)
- **Recalls**
  - 21 CFR 806: Corrections & Removals
  - 21 CFR 810: Recall Authority
  - 21 CFR 821: Device Tracking (SMDA:1990)

F D A
Current Authority Applicable to UDI

- **Registration Of Producers Of Drugs And Devices**
  - **SEC. 510.** [21 U.S.C. 360] (e) "The Secretary may by regulation prescribe a uniform system for the identification of devices intended for human use…"
- **Misbranded Drugs And Devices**
  - **SEC. 502.** [21 U.S.C. 352] A drug or device shall be deemed to be misbranded … (o) "…if it does not bear such symbols from the uniform system for identification of devices prescribed under section 510(e) as the Secretary by regulation requires."

Concluding Points

1. Work with all Stakeholders to identify specific safety problems that can be mitigated by the application of Auto-ID

2. Support the develop of consensus standards for different modes and applications of Auto-ID

3. Propose UDI solutions to patient safety problems, including a clear plan for adoption by device users

4. Medical devices are extremely diverse in size, materials, processing, use, and criticality

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Bringing innovation to patient care worldwide

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AdvaMed 2007 The MedTech Conference

October 1-3, 2007, Washington, DC
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Upcoming Events and Meetings

Private Payer and other Non-CMS Reimbursement for Medical Technology , June 12-13, 2007, Chicago, IL

Medical Device Clinical Trials and Biosafety Monitoring, June 26-27, Palo Alto, CA

11th Conference of the Global Harmonization Task Force October 3-4, Washington, DC

AdvaMed 2007 Trade Show, October 1-3, Washington, DC

THANK YOU !