AdvaMed

Advanced Medical Technology Association

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Auto-ID Working Group

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**

2005 Active Members
By Company Size

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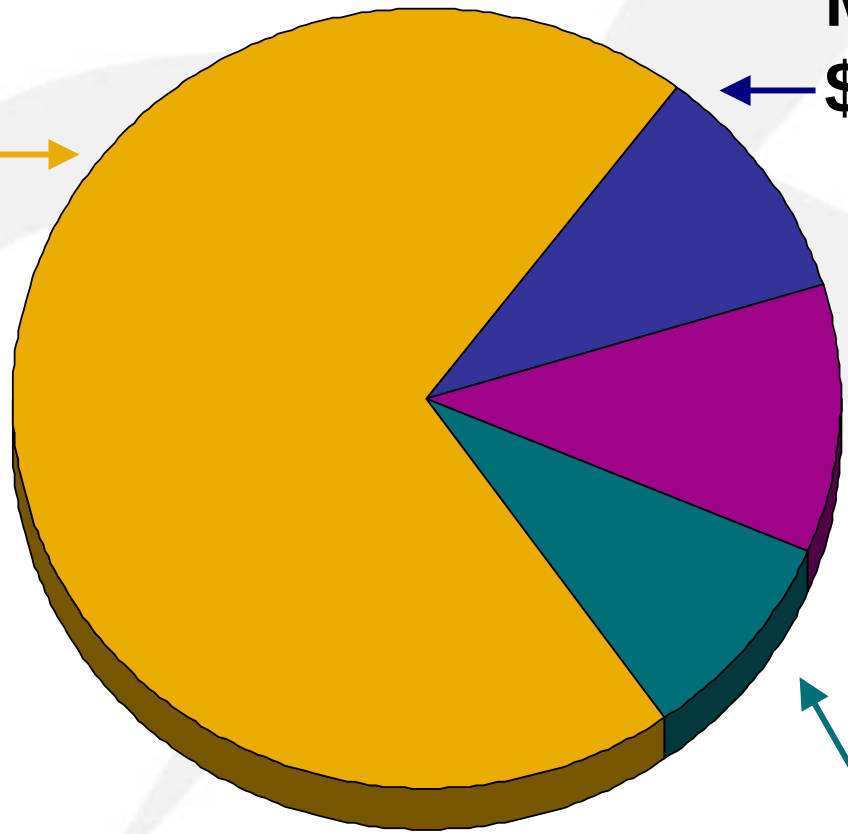

Small
<$30 mil
(70%)

Medium
$30-100 mil
(10%)

Large
$100-500 mil
(11%)

Very Large
>500 mil
(9%)

Member Companies *By Region*

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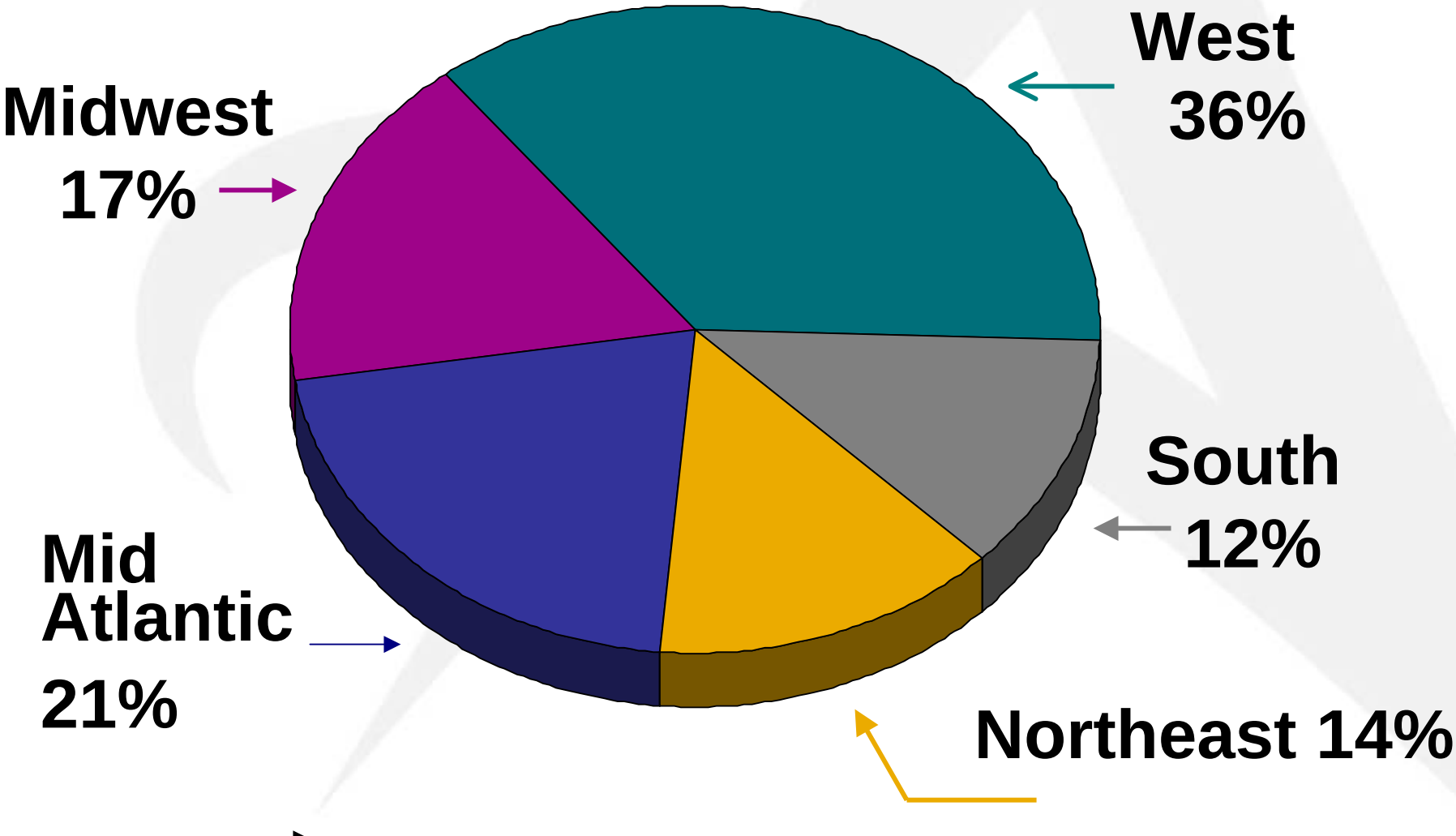

The Issues We Work On

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Goals

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

Government Affairs Department

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- **Lobbying Congress**
  - **Hill meetings,**
  - **Briefings on issues,**
  - **Med Tech Caucus**

State Affairs

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- **Represent industry before legislative committees and regulatory agencies**
  - **Track and Report on Priority Initiatives**
  - **Convene ad hoc issue-specific committees**
  - **Submit comments**
  - **Organize member-legislator meetings**

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2006 Policy Focus

- Medicare Inpatient Payments
- Medicare Hospital Outpatient Payments
- Secure an Adjustment to Medicare Inpatient and Outpatient Rates to Account for Charge Compression
- Develop Policies to Make Possible Passage of Legislation to Update/Reform the Clinical Laboratory Fee Schedule (CLFS)
- Medicare Remote Monitoring Services Legislation
- Engaged in Developing Quality Standards to Ensure the Medical Technology Industry Issues are Reflected in the Measures

2006 Policy Focus

- Reorient Japan policies to recognize value of technology
- Gain recognition of the value of technology (VOT)
- Establish appropriate reimbursement systems
- Accelerate efficient and effective regulatory regimes
- Develop close international policy collaboration
- Substantial Reduction of trade barriers

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Strategic Imperative

Communicate the value of medical technology through developing, supporting and conveying a compelling message to patients, health care providers, government officials and the media

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Primary Goal

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

2006 Policy Focus

MDUFMA Reauthorization

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

Postmarket

- Recalls
- Unique Identifiers
- Condition of Approval/522 Studies
- Annual Reports
- MDRs
- Risk Communication

Combination Products

- Cross-Labeling
- Adverse Events
- GMP's
- Number of Submissions

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

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 Auto-ID

Auto-ID Working Group

- FDA Stakeholder Meeting on UDI (April, October 2005)
- Supports the development of Auto-ID technology and standards that address specific patient and public health safety problems

Auto-ID Working Group

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

Auto-ID Working Group

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

Auto-ID Working Group

- Device Characteristics
  - Risk Class
  - Physical – size, material
  - Packaging
  - Use
  - Distribution

Auto-ID Working Group

- Use Characteristics
  - Professional
  - Self /Family
  - Care setting
    - Hospital
    - Non-hospital institution
    - Home
  - Processing – Disposable, Reusable

Auto-ID Working Group

- Unintended Consequences
  - Technology limitations
  - Implementation costs
  - Adoption

Auto-ID Working Group

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
C D R H – 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)

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. Solutions to patient safety problems must include a clear plan for adoption by the users
4. Medical devices are extremely diverse in size, materials, processing, use, and criticality
5. Mandatory bar code rule for medical devices will increase cost and complexity for users, with little assurance of improving patient safety

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THANK YOU !