MEDICAL DEVICE REGULATION-
BUILDING BRIDGES: EU, MDR, AND U.S.

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ISSUES FOR DISCUSSION

- What is the impact of these new EU medical device regulations on U.S. manufacturers and steps they are taking to address them within their companies?
  - Challenges
  - Results/Unintended Consequences
  - Impact on Clinicians
  - Advantages

- Case studies in advocacy: How the Alliance of Wound Care Stakeholders work with U.S. regulators to ensure clinicians, patients and manufacturers have access to wound care procedures and services
ALLIANCE OF WOUND CARE STAKEHOLDERS

Who is the Alliance?
- A non-profit, multidisciplinary “umbrella” trade association of physician specialty societies and clinical associations, whose members treat patients with wounds
  - Includes non-clinical associations and manufacturers
- Unified voice for wound care as regulatory policies are developed and implemented

Mission of the Alliance
- An active advocate to promote quality care and access to wound care products and services for people with wounds.
- Focus on compelling issues of commonality to the organizations in the reimbursement, government and public affairs affecting wound care.

Unique credibility of the Alliance with policymakers
Academy of Nutrition and Dietetics
American Association of Nurse Practitioners
American Board of Wound Medicine and Surgery
American College of Foot & Ankle Surgeons
American College of Hyperbaric Medicine
American Diabetes Association® Interest Group on Foot Care
American Physical Therapy Association
American Podiatric Medical Association
American Professional Wound Care Association

American Society of Plastic Surgeons
American Vein and Lymphatic Society
American Venous Forum
Amputee Coalition of America
Association for the Advancement of Wound Care
National Lymphedema Network
Society for Vascular Medicine
Society for Vascular Surgery
Undersea & Hyperbaric Medical Society
Visiting Nurses Association of America
Wound Ostomy and Continence Nurses Society
Focus of the Alliance

- Purpose: Alliance exists to reduce barriers to patient access to wound care procedures or care as it relates to:
  - Reimbursement issues: Acceptable coverage, coding, and payment
    - Submit comments to federal agencies and their contractors:
      - Centers for Medicare and Medicaid Services (CMS)
      - Food and Drug Administration (FDA)
      - Agency for Health Care Research and Quality (AHRQ)
  - Wound care quality measures
  - Wound care research

- Serve as educational resource to FDA and CMS staff that focus on Medicare coverage, coding, and payment for wound care products and services
Expensive! This initiative is extremely expensive to the US companies since they need to do the following:

- Prepare for MDR
  - Educate senior management, budget, impacts every dept.- distribution, manufacturing, design development, research, change labeling
  - Hire many consultants and staff (this touches probably every person in the company)
  - 5-8% of sales devoted to MDR project in some companies

- Impacts entire whole product lifecycle
  - R&D discovery; Clinical trial testing
  - Supply chain- labeling, UDI
  - Manufacturing & Distribution
  - Commercial & Customer (portfolio rationalization)
  - Post Market
Evaluate entire product line- Review data on existing products

- Evaluate the data they have on each product- look at low sales vs. investment
- If there is not great data on the product, determine whether the company wants to invest to create the data or eliminate it from the product line
- Evaluate what the impact is on patient care and to physicians and clinician’s practice if the product is eliminated

Liability concerns- MDD- manufacturer was liable/ MDR- entire supply chain liable- have responsibility to ensure upstream economic operator meets requirements of regulation

New Labeling requirements

- Supply chain challenges- gauge sales- don’t want to have extra stock in warehouse that are not compliant regarding new labeling requirements
Notifying Bodies (NB)

- Decrease in number of NB - US companies worried which may still be in existence?
- Most notifying bodies are not yet certified for MDR and can’t guarantee that they will be certified by the time frame to help the companies for the deadline (BSI- accept new applications June 3 and coming out with approvals Jan 2020)
- Can’t get answers from NB - overwhelmed with questions from thousands of MedTech companies
- New and emerging technologies - the number of notifying bodies have decreased and they will be competing with larger well established companies for the time and attention of notifying bodies
- Logistical issue - BSI UK and BSI Netherlands - have different NB numbers and need to change labeling on products
- What is impact of Brexit on UK’s Notifying Bodies?
Clarification and more information needed from European Commission:

- Data- what kind and how much is sufficient
  - Varies depending on risk and class of product- up to company to do it
  - How low can we go?

- Secondary legislation and implementing acts still being formulated

- Eudamed- central database- when will it be ready?

- Summary of safety and clinical performance- how does it work realistically?
  - Address giving options to providers/patients and compare with other options to use to treat for that particular indication
  - Prove product state of the art- substantiate product claim; clinical evaluation of safety and benefits to patient
  - Guidance to patients- what form being published- what language

Bottom line- Is timeline too rushed?
Results of New EU MDR on U.S. Companies-
Unintended Consequences

- Longer approval process- from 3-4 months to one year
- Cycle of innovation much slower pace
- Decrease in company’s product line
- Decrease in research and development since the dollars will be dedicated to this project;
- Increase cost for market access; Potential job loss
- By every product needing clinical data, it could make every product more expensive
- US companies may renew MDD certificates on older products to buy time/companies not anxious to be the “first” ones to get products approved under MDR since rules are higher and confusion on labeling
- Private labeling may end for manufacturers since must be in full possession of technical documentation
- Companies will launch in other countries such as the U.S. first since the FDA has clearer regulations
Implications for Clinical Practice

- May be decrease in choice of products for clinicians to select to treat patients with wounds
  - What happens to wound care combination products (e.g. antimicrobial dressings? Products with silver?) More regulatory oversight

Advantage

- Benefit to patient- develop safe and effective products/ more robust in reporting, testing
- Product performance transparency which levels playing field for evidence
- If company has the data, it will make it easier to compete in Europe since products that are not made as well will not take the time to adhere to the new regulations; and won’t compete in the EU marketplace
- Eliminate substandard notifying bodies
**EXAMPLES OF SUCCESSES OF CLINICAL ASSOCIATIONS AND INDUSTRY COLLABORATION WITH REGULATORS**

- Demonstrates that Payers and Decision Making Organizations Listen to Physicians and Clinical Community
- If it wasn’t for the Alliance clinical specialty societies/associations and their leadership in making the decision to be proactive on behalf of their members, patients might not have access to the products and procedures that they need and patient care would be compromised

**Examples:**
- Organized Alliance members to speak at FDA Plastic Surgery Panel- wound care products with drugs (antimicrobial wound care dressings) result-recommend classification of them as “Class II (with special controls) and protecting access for patients
- Created new terminology of CTPs to replace clinically inaccurate term “skin substitutes” and adoption by payers and standard organizations; Address payment and coverage issues
- Education of Medicare contractors on chronic wound care
- Pneumatic compression issues- Delay of implementation of clinically inaccurate LCD on pneumatic compression devices; Correcting clinical inaccuracies in Milliman Care Guidelines (MCG)
- New coding for procedures using disposable NPWT and clarifying billing with payers
EXAMPLES OF COLLABORATION

- FDA and Alliance Members- classification of “wound care products with drugs” (antimicrobial wound care dressings)
  - Alliance key role in educating FDA and Advisory Panel by providing relevant information and perspective allowing the Panel to vote to recommend to the FDA that antimicrobial wound care dressings should be classified as “Class II (with special controls)”
  - Protecting access and availability to patients and clinicians
  - Submitted comments in advance of the meeting to provide relevant background information on wound care complexities.
  - Mobilized a team of well-known and respected clinicians, scientists, wound care registry data experts, design and endpoints data experts, former FDA official, clinical associations, and manufacturers with FDA expertise to testify at the public meeting, with supportive/complementary messaging.
  - Testified before Advisory Panel during public meeting
  - Educated clinical associations to also submit comments
  - Submitted post meeting follow-up comments reinforcing Panel’s recommendation
Cellular and/or Tissue Based Products for Wounds (CTP) Issues

Example of Payers and Standard Setting Organizations Adopting Alliance’s More Clinical Accurate Terminology

- Created Cellular and/or Tissue Based Products for Skin Wounds (CTPs) guidance document for standard setting organization ASTM F-04 committee and was adopted
- Currently 3 out of 4 Medicare contractors use this terminology in the body and/or title of their coverage policies in place of clinically inaccurate term “skin substitutes”

- 2019-Working with Payers to address appropriate coverage and payment for CTPs
EXAMPLES OF COLLABORATION - EDUCATION

- Successfully educated Medicare contractor through full day educational session about complexities of chronic wound care products and procedures
  - Alliance clinical associations with industry educated 50 staff and medical directors on the phases of wound healing; making the accurate diagnosis; wound and skin assessment; measurement and documentation; diagnosis and treatment of pressure, diabetic, vascular and arterial ulcers; wound bed preparation; and of course, clinical considerations when selecting products and procedures.
    - Provided “hands on” session in which 15 product categories of surgical dressings (collagen, hydrogel, foam, hydrocolloid, etc.) were passed around so that each attendee could see and appreciate the different sizes, shapes, etc. and understand better their uses.
    - Addressed NPWT (mechanisms of action, indications and components) and demonstrated NPWT and dNPWT devices for the audience.
  - Benefits:
    - Enabled more clinically-accurate policies moving forward:
    - Grew relationships: enhanced the Alliance’s recognition as a valuable, credible resource for wound care issues.

- 2019- Convene second educational session which will now include lymphedema
**Examples of Collaboration**

- **Pneumatic Compression**

  *Examples of Alliance Clinical Associations and Business Entities Working Together to Achieve Success with Payers*

  - Successfully delayed clinically inappropriate Durable Medical Equipment Administrative Carriers’ (DMEMAC) Local Coverage Determination on pneumatic compression devices thus allowing patients continuing to have access to them. Achieved through Alliance creating unified voice/quickly responsive to reach out to CMS senior staff, DMEMAC medical directors and legislative contacts to discuss the issue.

  - Due to Alliance’s advocacy in addressing the clinical inaccuracies in the 17th edition of the Milliman Care Guidelines (MCG) on Intermittent Pneumatic Compression, the next edition (18th) in 2014 was corrected. This allowed payers who use MCG for their coverage policies to have ones that are clinically accurate allowing for patient access.
Negative Pressure Wound Therapy Issues

Example of Clinical Associations and Business Entities Working Together to Achieve Access for Patients

- Alliance clinical specialty societies (AAOA, ACS, APMA ASPS) worked with business entities to establish new 2015 CPT codes for the procedure regarding disposable negative pressure wound therapy (dNPWT) 97607 and 97608.
- 2019- Working with Medicare to clarify how home health agencies can bill for dNPWT since the current instruction is confusing and incomplete
What Are We Working on Together in 2019?

- Anything that Impacts Patient Care!
- Wound care is now front and center for US regulators
- Alliance “Value In Health” article addresses Medicare expense for wound care – one in 15 Medicare patients has a chronic wound

Regulatory Issues
- Work with Medicare contractor to develop new wound care coverage policies
- Partner with Physician Focused Payment Model Advisory Committee to create wound care payment models
- Educate new Medicare contractor staffs and medical directors about complexities of wound care and lymphedema

Legislative Issues
- Educate new Congressional staff on wound care
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