



**AdvaMed**

Advanced Medical Technology Association

# SMTA Annual Fly-in

BRINGING INNOVATION TO PATIENT CARE WORLDWIDE

March 1, 2016

## Significant progress made on key industry priorities in 2015

- Enactment of Trade Promotion Authority and finalization of Trans-Pacific Partnership Agreement
  - Industry played key role in Hill advocacy and grassroots on TPA
- Significant progress on FDA regulatory reform
  - Key industry proposals included in 21<sup>st</sup> Century Cures Act as passed by the House
- Enactment of a 2-year suspension of the medical device tax
  - Major step towards full repeal

➤ **THANK YOU!**

- Medical device tax:
  - Saying “thank you”
  - Communicating on the use of saved revenue to build the case for repeal
- FDA regulatory reform:
  - Finishing the job on 21<sup>st</sup> Century Cures
- Coverage and reimbursement reform:
  - Educating policymakers on CMS process flaws and the impact on innovation
  - Guarding against bad proposals
- *TPP*

- 2016 Goal: creating an environment for further relief
  - Q1-Q3: Say thank you and describe positive impact of tax suspension
- How we talk about use of saved revenue will be key to maintaining industry credibility and positioning for further relief
- Message focus: innovation, investment, research and growth
  - Use anecdotes wherever possible
  - Link relief to investments that will grow jobs, strengthen industry in the U.S., and lead to benefits for patients.

- House passed 21<sup>st</sup> Century Cures initiative in July: 344-77. Bill includes all AdvaMed regulatory reform proposals.
- Senate Healthier Americans initiative moving in phases.
  - Progress on package impeded by disagreement over mandatory NIH / FDA funding, concerns around drug price debate.
  - First mark-up 2/9: passed Burr/Franken bill on least burdensome, CLIA waiver, and central IRBs. Mark-up also included Murray scopes legislation.
  - Future mark-ups tentative for March 9 & April 6
    - Breakthrough pathway, combination products, and software proposals slated for March
- Key message: support mark-ups, Burr/Franken bill breakthrough pathway bill

- Primary Goal: create understanding and awareness of coverage and reimbursement obstacles to patient access to medtech.
  - Secondary Goal: remind policymakers on the value of medtech to patients and the economy.
- Key messages: patient access, not reimbursement, to avoid pivot to price / cost issues.
- Pursuing stand-alone bills:
  - Breakthrough Pathway (Sen. Coats, Reps. Boustany & Bilirakis)
  - Automatic coverage of IDE clinical trials (Sen. Coats, Reps. Young & Peters)
  - LCD process reforms (Reps. Jenkins & Kind)
  - Telehealth (Sens. Gardner & Peters)

# Engaging in Value Discussions



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## THE VALUE OF MEDTECH MEDICAL TECHNOLOGY CREATES JOBS



## THE VALUE OF MEDTECH MEDICAL TECHNOLOGY DELIVERS VALUE AND SAVINGS



The medical technology industry has a healthy economic future. Medical technology is one of the few manufacturing sectors still expanding in the U.S., and the industry continues to innovate and grow. Patient activity in the medical technology sector increased 18.7 percent from 2010 to 2012, representing the strongest growth in patient activity among 12 leading technology sectors.<sup>8</sup> Medical technology not only creates jobs, but its use helps keep the American workforce healthy.

- Between 1980 and 2010, advanced medical technology helped reduce the number of days spent in hospitals by **59 percent**.
- The use of minimally invasive surgical procedures reduced workplace absenteeism by **53,000 person-years**.<sup>4</sup>
- The use of key medical technologies in four disease areas (diabetes, colorectal cancer, musculoskeletal disease, and cardiovascular disease) expanded U.S. GDP by **\$106.2 billion** and provided a net annual benefit of **\$23.8 billion** to the economy due to better treatment, reduced disability, and increased productivity.

Studies show that investing in access to medical technology in just four disease categories (diabetes, colorectal cancer, heart disease, and musculoskeletal disease) yields economic returns that far exceed their costs.<sup>1</sup>

- For patients with musculoskeletal diseases, use of medical technology **saved an average of \$24,518** per patient per year.<sup>2</sup>
- Colonoscopy/sigmoidoscopy screening tests **prevented 560,000** people from developing colorectal cancer, resulting in **\$12.2 billion in savings**.<sup>3</sup>
- Use of heart disease diagnostics and surgery technology **saved an average of \$1,930** per patient per year.<sup>4</sup>
- Insulin pumps improved diabetes management, **saving an average of \$5,886** per patient per year.<sup>5</sup>

## THE VALUE OF MEDTECH MEDICAL TECHNOLOGY SAVES AND IMPROVES LIVES



Medical technology is used at different points along the disease continuum—providing earlier diagnosis, improved surgical methods, or innovations in disease management. These all lead to markedly improved clinical outcomes and quality of life in a number of disease categories.

Tremendous progress has occurred in the development of advanced medical technology in the last 50 years. Medical progress and improvements in the technologies that physicians, nurses and other care-givers use to treat patients allow for improved outcomes, health system savings, and even stimulate the U.S. economy. Here's how:

- Medical technology helped **add five years** to the average U.S. life expectancy since 1980.<sup>1</sup>
- Disability rates **declined by 25 percent** from 1982 to 2000, and disability-free life expectancy has **increased** over time.<sup>2</sup>
- Between 1980 and 2010, advanced medical technology helped reduce the number of days spent in hospitals by **59 percent**.<sup>3</sup>

Since 1980, medical technology has reduced fatalities from heart disease and stroke by more than half, and deaths from breast cancer by more than a third.<sup>4</sup>

**Heart Disease:** Angioplasty and stenting saves lives and heart muscle for patients suffering a heart attack, and improves quality of life for patients suffering from symptomatic coronary artery disease.<sup>5</sup>

**Diabetes:** Studies have shown that insulin pump usage results in better blood sugar control, resulting in fewer clinical complications, reduced emergency room visits, and decreased hospital admissions.<sup>6</sup>

**Osteoarthritis:** Patients who received total hip replacements and total knee replacements transitioned away from disability within one year.<sup>7</sup>

**Breast Cancer:** Since 1975, medical advancements have helped increase the five-year survival rate for breast cancer patients by 40 percent.<sup>8</sup>

**Colorectal cancer:** It is estimated that the use of colonoscopy/sigmoidoscopy screening tests prevented 560,000 people from developing colorectal cancer.<sup>9</sup>

**Telemedicine:** The use of telemedicine expands access to health services for people living in rural or remote areas, and can facilitate health care outreach to those who are infrequent users of health care and may be vulnerable to untreated chronic conditions.<sup>10</sup>

