

AdvaMed Priority Issues

Washington, D.C.

June 22, 2017



AdvaMed

Advanced Medical Technology Association

Federal Priorities

- Medical Device Tax
- MDUFA
- Breakthrough Pathway



Medical Device Tax

- Full repeal included in health care reform
 - H.R. 1628, the American Health Care Act of 2017
 - Anticipate repeal will be included in Senate bill
- CBO score could impact repeal inclusion
 - Higher than expected coverage losses
 - Lower total savings
 - Both would require additional votes
- Effective Date
 - January 1, 2018

MDUFA

- FDA Reauthorization Act of 2017 passed key committees
 - H.R. 2430; Passed House E&C 54-0; S. 943; Passed Senate HELP 21-2
- Key policy riders
 - Included in both House & Senate versions
 - Accessories
 - Streamlines classification process for accessories
 - Inspections
 - Reforms device inspection process
 - Contrast agents
 - Change regulation of contrast agents used in imaging devices
 - Included in one chamber
 - Diagnostics reform (Senate version)
 - FDA guidance on regulation of instrument families
 - Third Party Servicing (House version)
 - FDA study on third party servicing
- Timing & Outreach
 - Expect floor votes in late June/early July
 - Urge members to ignore Administration's call to double user fees
 - Swiftly pass User Fee Package as negotiated

Breakthrough Pathway

- Establish accelerated transitional coverage for new med tech which FDA has designated as “breakthrough”
 - Current pathway takes 3 years
- Breakthrough must meet following conditions:
 - Provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions
 - Has no approved alternatives
 - Offers significant advantages over existing approved alternatives
 - Availability is in the best interest of patients.
- SMTA Sign-on Letter
 - BioFlorida one of 32 associations to support