Table 7. Implications for biopharma and medical device companies

Goal of Cures	Implications for biopharma	Implications for medtech
Faster drug approvals		
Enable faster drug approvals by modernizing the approach to clinical trials—incorporating new sources of evidence and new tools to shorten the drug development process	Engage in proactive conversations with the FDA early on in development to understand which innovative tools or sources of evidence might apply to their program and expedite development Expand capabilities required to access, collect, and analyze RWD Leverage incentives to develop drugs for specific populations, including pediatric rare disease and antimicrobials Continuing to work with the FDA, patient advocacy groups, and provider groups to delineate pathways for patient and caregiver involvement	No direct impacts from Cures. Medtech companies should however continue to work with the FDA to understand how to incorporate patient-centered approaches and RWE into product development plans
Health care economic information communications		
Provide clarity on certain HCEI communications between biopharma and health care stakeholders	Expand the dialogue on economic evidence with health care stakeholders and explore value-based contracting	No direct impacts from Cures. Medtech companies should, however, continue to work with stakeholders to determine how to best structure value-based contracts within current regulatory constraints
Regenerative medicine		
Establish approval pathway for regenerative medicine	Engage in a dialogue with the FDA on how to advance regenerative medicine products while guidance on approval pathways are being developed	

Table 7. cont.

Goal of Cures	Implications for biopharma	Implications for medtech
Medical device innovation		
Clarify and improve existing approval process, create regulatory flexibility for devices that treat life-threatening conditions or impact small populations	No direct impacts from Cures	Encourage greater investment in medical technology innovation and consider partnerships with companies that are developing life-changing innovations Generate data to support regulatory approval but also market access—consider investing early in evidence that supports coverage and reimbursement as well as regulatory approval Invest in RWE capabilities to incorporate new sources of data into the device development and approval process
Improve access to POC diagnostics	Biopharma companies should consider how POC diagnostics could be used to increase patient engagement and drive utilization of products, especially for chronic disease	Take advantage of opportunities to advance POC diagnostics that can expedite diagnosis in lower cost care-delivery settings and get treatments to patients faster
Combination products		
Improve regulation of combination products and increase opportunity for sponsor engagement in dispute resolution	Take advantage of the opportunity to advance combination products through increased dialogue with FDA, leveraging evidence that supports a product's primary mode of action	
Regulation of medical software		
Clarify regulation of medical software	Engage in ongoing dialogue with the FDA to develop the framework for the regulation of software that will be regulated as a medical device, particularly devices that might be used to drive greater patient engagement	
Advance interoperability initiatives	Deepen partnerships and collaborations with health systems to access RWE	