

Advancing and Defending a Critical Manufacturing Sector

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Key Facts

- Hundreds of medical device manufacturers in New England sought advocacy strategy in Washington and Beacon Hill
- Working closely, our federal and state teams proactively advance positive policy and defeat problematic proposals
- We manage legislative, regulatory, reimbursement, and political strategy for the Massachusetts Medical Device Industry Council

The Situation

In 2020, facing unprecedented pressures and challenges related to the COVID-19 pandemic, MassMEDIC retained the services of ML Strategies' federal team. Facing supply chain disruptions, extraordinary customer demand, and a flurry of legislation and policymaking, our team helped the organization and its members navigate the pandemic, reach key decision-makers, and capitalize on opportunities presented. Since then, the relationship has grown to include state government relations in Massachusetts.

The Approach

Like any part of the health care system, or any manufacturing sector, medtech faces constant challenges that demand thoughtful policy solutions. ML Strategies has worked with MassMEDIC to build a thorough and durable government relations program. We have established open lines of communication with key policymakers, including members of the federal congressional delegation, committees of jurisdiction in Congress and the Massachusetts legislature, and officials throughout federal and state government. We stay in front of members and highlight the importance of the industry to their district with regular official and political engagement. We are active participants in state and federal policymaking, participating in legislative drafting and negotiations, providing testimony in hearings, and submitting comments on rulemakings. ML Strategies has also built an effective mechanism for collaboration and information sharing among the many internal lobbyists working on behalf of MassMEDIC's member companies. Finally, ML Strategies assisted MassMEDIC in the establishment of a federal PAC and advises and assists the organization on political activities at the federal and state levels.

The Outcome

ML Strategies continues to address challenges and seize opportunities for the medtech sector in New England. Among the notable achievements during our engagement with MassMEDIC are:

- The establishment of the Investor Catalyst Hub of the Advanced Research Projects Agency for Health (ARPA-H) in Massachusetts. Established in 2022, ARPA-H is a federal agency tasked with making high-risk, high-reward investments in health care research projects. After intense lobbying to spread agency resources and reach beyond the Beltway, ARPA-H solicited proposals to host two remote Hubs. MassMEDIC played a key role in convening and leading a team of Massachusetts research entities in pursuit of the Investor Catalyst Hub. With a strong proposal and dogged political support at the state and federal levels, shepherded by ML Strategies, Massachusetts won the Hub. Federal research funding continues to flow through it.
- Working to establish a Medicare coverage pathway for "breakthrough" devices. Medical devices that change the standard of care for a disease or condition can be cleared by the Food and Drug Administration under the expedited breakthrough pathway. Unfortunately, there is no similar pathway to coverage at the Centers for Medicare and Medicaid Services, which extends the timeline of bringing a cutting-edge product to market by years. This makes the industry unattractive to investors and stymies

innovation. To address the issue, Congress is working to pass the Ensuring Patient Access to Critical Breakthrough Products Act. MassMEDIC is a forceful advocate for the legislation and, with ML Strategies' help and guidance, has built significant support for the bill and cultivated strong champions in Congress, including members of the Massachusetts congressional delegation.

- Protecting manufacturers' intellectual property. Many states regularly consider so-called "right to repair" legislation, which gives consumers greater control over the products they purchase. Often unintentionally or inappropriately included in these policy proposals are medical devices, including in bills considered by the Massachusetts legislature. Working with MassMEDIC, ML Strategies has effectively advocated for thoughtful policy related to FDA-cleared devices that does not jeopardize patient safety or manufacturers' intellectual property.

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