



December 21, 2025

Dear \_\_\_\_\_:

I write to you today in support of Congressional efforts to advance [H.R.5343](#), the Ensuring Patient Access to Critical Breakthrough Products Act. This legislation, which advanced out of the Ways and Means Committee on September 17 with strong bipartisan support, seeks to increase access to breakthrough medical devices for Medicare patients. As you know, the New England Council is a non-partisan alliance of businesses, academic and health institutions, and public and private organizations throughout New England. Our mission is to promote economic growth and a high quality of life in the region, and it is with that background that I urge you to consider supporting the Ensuring Patient Access to Critical Breakthrough Products Act.

In 2016, the 21st Century Cures Act created a new pathway for “breakthrough” medical devices to receive expedited Food and Drug Administration (FDA) approval. To be eligible for the Breakthrough Devices Program, the device must utilize novel technology to treat a condition that has no other approved alternatives or the device’s technology provides a significant benefit above existing therapies. However, numerous challenges have emerged since the bill’s initial passage, namely, that there are multi-year delays in Medicare coverage following FDA approval, which significantly impacts patient access to potentially lifesaving treatments.

The Ensuring Patient Access to Critical Breakthrough Products Act provides a clear pathway for four years of transitional Medicare coverage of breakthrough devices upon the manufacturer's application and requires CMS to make a permanent coverage determination by the end of the temporary period. This expedited coverage pathway will encourage more innovative medical devices to come to market and provide quicker access to treatments for Medicare patients.

The New England Council believes that the bipartisan Ensuring Patient Access to Critical Breakthrough Products Act can play a pivotal role in improving access to cutting-edge healthcare across the region and the country, and we urge you and your colleagues to consider supporting this legislation now that it has advanced out of the Ways and Means Committee. If you have any questions, please feel free to contact our Director of Federal Affairs Sean Malone [smalone@newenglandcouncil.com](mailto:smalone@newenglandcouncil.com).

Sincerely,

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**The New England Council**

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A handwritten signature in black ink, reading "James T. Brett". The signature is fluid and cursive, with the first name "James" and last name "Brett" clearly legible, and "T." as a small initial between them.

James T. Brett  
President & CEO  
The New England Council

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