The medical device industry has been driving the U.S. economy forward for years. Through direct and indirect employment the med tech industry accounts for nearly 2 million jobs, with a market for medical devices reaching $110 billion. This is spurred by 7,000 medical technology firms, 80 percent of which are small businesses—the backbone of our economy. Overall, these firms create stable careers and high-wage manufacturing jobs with an average salary of $58,000.

The U.S. medical device industry is one of the few American manufacturing industries with a positive balance of trade of $42 billion in U.S. exports. Markets outside the United States provide significant opportunities for growth with revenue surpassing U.S. revenue. While Europe and Japan add a combined 40 percent of global sales, there is positive economic potential in emerging markets such as China, India, and Brazil. Continued growth beyond our borders will depend on the development and approval of trade agreements that provides a level playing field for U.S. companies and improves access to the world’s consumers.

A vigorous trade policy can support export growth and provide a level playing field for U.S.-based manufacturing, and renewal of Trade Promotion Authority (TPA) will help to facilitate the development and approval of key trade agreements. TPA would strengthen the administration’s ability to negotiate free trade agreements with foreign countries based on goals and priorities set by Congress. Lawmakers in Congress would have the opportunity to thoroughly review Free Trade Agreements and approve or disapprove of an agreement based on the negotiating team’s ability to achieve congressionally established objectives. The TPA in effect sets guide rails for the negotiating team and lets the other countries at the table know the baseline parameters needed for congressional approval.

Currently under negotiation is the Trans-Pacific Partnership (TPP), a plurilateral trade agreement that includes 12 countries (U.S., Japan, Australia, New Zealand, Singapore, Malaysia, Vietnam, Brunei, Canada, Chile, Mexico, and Peru). The TPP is intended to liberalize trade among its members, leading to increased economic activity and growth. It will cover manufactured goods, services, government purchases, and agricultural products. The current TPP members account for 40% of global gross domestic product (GDP) and one-third of world trade.

Also under negotiation is the Transatlantic Trade and Investment Partnership (TTIP) with 48 other countries, including the EU member states. The U.S. and EU economies account for nearly half of world GDP, 30 percent of global trade, and have investments of more than $3.7 trillion in each other’s economies, supporting nearly 7 million jobs. Studies show that a successful TTIP
deal could increase the size of the US economy by $95 billion. The EU market for medical devices is over $100 billion.

Both TPP and TTIP are good examples of trade negotiations where passage of TPA can have significant implications for economic growth in the United States.

**Trade Promotion Authority Legislation**

There are specific negotiating principles in the TPA legislation aimed at government regulations that reduce market access for U.S. products. These negotiating principles are critical to ensuring a transparent and appropriate rate setting process, as well as more efficient regulatory cooperation.

First, the TPA legislation includes a principle negotiating objective that calls for transparency and procedural fairness in medical device reimbursement. Such a provision would provide transparency to the process by which the national health care authorities set reimbursement for medical devices. For example, this objective would allow for the rules national health care authorities use to make these decisions to be made public, that applicants can provide comments at appropriate times in the decision process, that the basis for decisions is made available to the applicants, and that an independent appeals process be available to the applicants.

The proposal would not require that covered products be reimbursed or that reimbursement be set at specific levels. It simply provides for procedural transparency. Similar provisions are included in the U.S.-Korea Free Trade Agreement.

Second, the TPA proposal includes an objective to achieve the elimination of government measures such as price controls and reference pricing, which deny full market access for American products. Use of reference prices does not adequately reflect the cost of doing business in certain countries, and suppresses and discriminates against innovation leading to less competition and less patient access to innovation. Foreign price controls and reference pricing result in a situation where patients in the United States end up shouldering the cost of medical technology innovation. Moreover, these controls act as market barriers that ultimately lead to a distortion of trade in medical technologies and discrimination against U.S. exports of medical technology.

Finally, the TPA proposal calls for regulatory convergence. This would allow for increased harmonization of cross-border regulatory requirements and could lead to reduced costs and administrative burdens for manufacturers, lower prices for consumers, and more efficient use of scarce regulatory authorities’ resources.