

India's Price Controls on Coronary Stents May Place U.S. Firms at a Competitive Disadvantage

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On February 13, 2017, the government of India began imposing national price reductions of between 75% and 85% on coronary stents (stents), an implantable medical device that ensures adequate blood flow to the heart. Although the current policy applies only to stents, the government has taken steps suggesting it may impose similar reductions on as many as 14 other types of medical devices, including catheters, syringes, needles, and orthopedic implants. Collectively, these goods represented more than two-fifths of India's medical device imports from the United States in 2016. As the leading supplier of medical devices—including stents—to India's market, the United States may be uniquely impacted by these measures; instead of trying to increase sales to India's burgeoning healthcare market, U.S. firms may opt to withdraw from it altogether, potentially reducing the supply of critical medical devices for Indian consumers.

India's price control policies have two likely drivers

In February 2017, India's National Pharmaceutical Pricing Authority (NPPA)—the agency that sets India's market prices for medical devices in India—began placing price controls on stents. NPPA is applying this policy to products on the market as well as to future imports. The policy places all stents into a single price category, regardless of their technological sophistication. It also prohibits manufacturers from withdrawing stents that are already in the market, while requiring them to maintain a supply of at least six weeks.

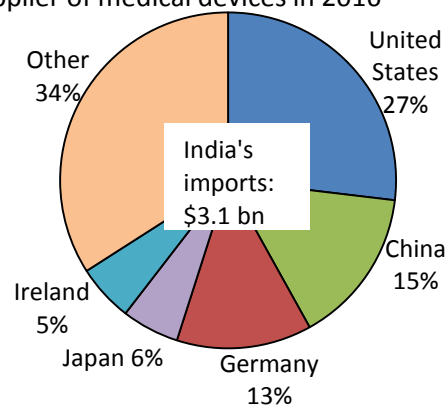
There are two likely motivations for this NPPA policy:

- (1) **Improving the affordability of stents.** In earlier years, Indian hospitals reportedly increased stent prices by more than 600%, which limited patient access.
- (2) **Supporting India's domestic industry.** Since 2014, the India has attempted to increase domestic production via its "Make in India" campaign. Price caps may allow more domestic companies to gain a foothold in India's stent market, as imports may decline due to price controls that would reduce profits or even cause a loss for exporting firms.

The United States Is India's Largest Medical Device Supplier

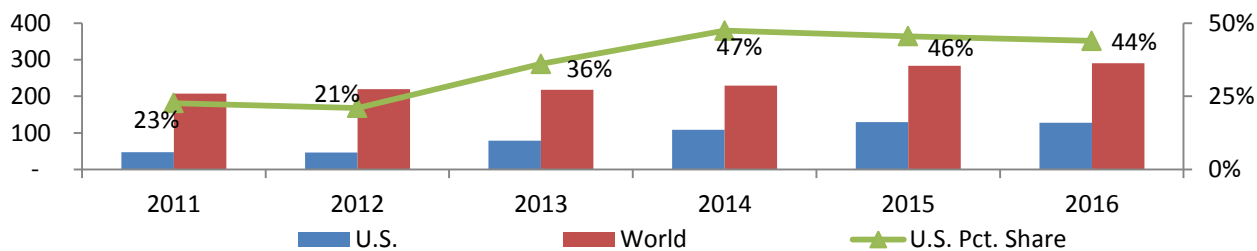
- An estimated 70% of India's medical device market is supplied by imports, of which the United States represented nearly 30% during 2016 (figure 1).
- Several leading U.S.-led firms—including Abbott, Boston Scientific, Johnson & Johnson, and Medtronic—also have substantial investments in packaging, assembly, and research and development facilities in India.
- India's largest import categories were instruments and intravenous diagnostic equipment (36%), implantable parts and equipment (22%), and diagnostic equipment (17%). The United States was the leading provider of the first two categories and was among the top three suppliers of diagnostic equipment during 2016.
- Imports supply 60% of India's stent market, which may partly reflect inadequate domestic capacity to meet demand; the United States was the leading provider during 2011–16 (figure 2).

Figure 1 The United States was India's largest supplier of medical devices in 2016



Source: IHS Markit, Global Trade Atlas database (accessed July 3, 2017).

Figure 2 The United States was estimated to be India's largest supplier of coronary stents during 2011–16, by quantity (thousands of units); its market share grew from 23% to 44% over this period



Source: Compiled by USITC staff from IHS Markit, Global Trade Atlas database (accessed July 3, 2017).

India's price controls may place U.S. firms at a competitive disadvantage

U.S. producers primarily supply the high-value-added niche (e.g., bio-absorbable and drug-eluting stents) of India's stent market. They are therefore likely to be competitively disadvantaged by these price controls, which disregard differences in quality and value-added production;¹ in some cases, they must sell their product at a loss. For example, Boston Scientific predicted losses of \$7 million this year, as the costs of exporting its drug-eluting stents could exceed India's price caps.

Thirteen more devices could be next . . .

Firms are concerned that this policy may eventually extend beyond stents to other devices. In March 2017, the NPPA began to evaluate prices on each of the 13 other categories of medical devices that India now regulates. Among the products included are catheters, surgical dressings, needles, syringes, orthopedic implants, and intravenous diagnostic devices. According to the Global Trade Atlas, the United States was India's largest supplier of these goods, which accounted for more than two-fifths of India's \$834 million of medical device imports from the United States in 2016.

. . . which may lead U.S. firms to withdraw various devices from the Indian market . . .

The price control policies have already caused leading U.S.-headquartered companies such as Abbott, Boston Scientific, and Medtronic to attempt a withdrawal of their various high-end stents due to forecasted lost revenue.

. . . possibly reducing the supply of critical medical devices within India

Rapid urbanization, poor air quality, and the emergence of lifestyle-related diseases are contributing to the rapid expansion of non-communicable diseases in India. Such diseases will likely increase the country's demand for various medical devices in the coming years. However, if the imposition of strict price caps on more devices led U.S. firms to withdraw from India's market, a substantial number of patients in India could lose access to critical medical technologies, assuming other countries are unable to fill the gap.

Sources: Enriquez, "After Slashing Cardiac Stent Prices," *MedDevice Online*, February 22, 2017 and "Medical Device Companies Cope," May 2, 2017; Banerjee, "India's Decision to Cap Coronary Stent Prices," *Michigan News U of M*, May 9, 2017; Datta, "Price Control Fallout," *Hindu Business online*, April 21, 2017; industry representative, interview by USITC staff, March 5, 2017; industry representative, interview by USITC staff, July 6, 2017; Kalra, "India Government Panel Rejects Boston Scientific Plea," *CNBC*, May 9, 2017.

¹ Compared to India's stents, U.S. products are technologically advanced and meet rigorous safety standards not found in India's regulatory regime, which lacks transparency. For example, the Indian government lacks a comprehensive regulatory system for medical devices; contrary to international standards, it regulates those devices as pharmaceuticals.