Competitive Conditions Affecting U.S. Exports of Medical Technology to Key Emerging Markets

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Abstract

The United States is the world's largest supplier of medical technology (medtech). At the same time, growth in key emerging medtech markets—especially China, India, and Brazil—represent significant export opportunities for U.S. manufactures to further bolster their competitiveness. Yet, import restrictions arising from onerous regulatory procedures in these countries limit U.S. exports to these markets, particularly by extending the time to market for these goods to gain approval for sale. Using a gravity model approach, we estimate ad valorem equivalents (AVEs) for non-tariff measures (NTMs) in 167 countries and find that China, India, and Brazil all rank in the bottom half in terms of import competitiveness. Further, we run a second stage regression to identify specific factors that depress advanced medtech exports. Our results show that the estimated competitiveness of each country is tied to regulatory measures rather than demand factors. In particular, lengthy time-to-market and regulatory complexity significantly reduce a country's import competitiveness. These findings suggest that the harmonization of China's, India's, and Brazil's medtech standards to internationally accepted best practices would likely translate into greater U.S. exports to these markets. This paper is the first to quantify the impact of regulatory procedures on the import competitiveness of various global medtech markets.

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1 Introduction

In recent years, the $400 billion global market for medical technology (medtech) has expanded rapidly as countries increasingly demand access to quality healthcare and the tools that provide it (Evaluate Medtech 2017). The United States, in particular, has benefitted from this market growth as it is the world's leading provider of medtech products, representing close to one-quarter of global exports in 2016 (Comtrade, 2018). However, with growth in established markets (e.g. Germany and Japan) likely to remain relatively stable in the near term, emerging markets—such as China, India, and Brazil—may suggest opportunities for the United States to maintain its competitive trade position. In addition to boasting large populations, growing GDPs, and rising GDP per capita, each of these three countries have sizeable disease burdens and relatively low per capita spending on medical devices (medical device density) (The World Bank, 2018). Yet, despite these factors, our analysis finds that China, India, and Brazil remain relatively small importers of medtech.

In order to better understand medtech trade and the factors that limit it, we estimate gravity trade models using bilateral trade data for each of a collection of medtech products. The results of the gravity models are used to rank countries based on their import competitiveness. Import competitiveness is a measure that reflects the value of imported medtech relative to a country's economic size; a country that imports large values of medtech given their GDP is considered highly competitive while a country that imports relatively little is considered uncompetitive.[1] To more concretely measure import competitiveness, we also calculate estimated ad valorem equivalent (AVE) trade costs that explain differences in competitiveness across 167 countries.[2] Using this methodology, we find that China (ranked 126), India (ranked 125), and Brazil (ranked 92) rank relatively low in terms of import competitiveness compared to the rest of the world, suggesting that there is considerable export potential for U.S. firms if the source of this lack of competitiveness can be addressed.

Next, we conduct a second regression using data that reflects regulatory requirements and medtech demand in order to identify the factors that influence import competitiveness. These estimates indicate that long and complicated approval processes significantly reduce import competitiveness, while key demand factors (per capita healthcare spending and medical device expenditures) have no effect. As the world's most innovative medtech producer, the United States is especially disadvantaged by regulatory delays (Torsekar, 2014; USITC, 2007). This concern is aggravated by the relatively short product lifecycle (18-24 months) of the most advanced medtech for which the United States is especially competitive in manufacturing. Therefore, our results provide strong evidence that the United States will stand to benefit significantly from the harmonization of policy measures in the Chinese, Indian, and Brazilian medtech markets to international best practices.

This work adds to the literature attempting to measure the impacts of trade restrictiveness measures. Kee, Nicita, and Olarreaga (2009) builds trade restrictiveness indices for 78 developed

[1] Similar gravity methods were used by USITC (2018).

[2] Because tariffs are generally low with respect to the global trade of medtech, trade costs in this context largely refer to non-tariff measures (NTMs), particularly in the form of onerous regulatory requirements that restrict trade. Examples include duplicative product testing, redundant clinical trial data submissions, and an inadequate pricing and reimbursement system (Johnson, 2008; Sunesen, 2009). These NTMs produce regulatory environments that correspond to high approval times, are costly to comply with, and are characterized by complexity. For example, imported medtech in China may face approval times that are more than double the global average of 10 months, generated more than $50,000 in compliance costs, and were listed (alongside Brazil) as the among the world's most complex (Emergo, 2017).

and developing countries. They estimate the trade restrictiveness indices (TRI) for countries by estimating AVEs of NTMs impact on imports, and then using that to observe the difference between a country's overall restrictiveness and its tariff rates. Moreover, Kee, Nicita, and Olarreaga (2008) use Feenstra's (1995) simplified trade restrictiveness index (TRI) at the country level rather than at the product level. Their results support the conclusion that poor countries have more restrictive trade policies and face higher export barriers. However, the quantitative analysis that has been done on the medtech sector specifically is quite limited. Sunesen, Francois, and Thelle (2009) find that medical device exports from the EU to Japan could increase by as much as 84 percent if the level of NTMs in Japan was comparable to that of the EU, but do not evaluate different types of NTMs. Additionally, a USITC (2007) study examining the competitive conditions affecting medtech trade identified "time to market" as a principal concern with respect to its effect on sales, but provided no empirical verification for this. To the best of our knowledge, our paper represents one of the first studies focusing entirely on quantifying policy barriers in medtech trade across multiple countries.

The paper proceeds as follows. Section 2 defines medtech and describes how it is regulated. Section 3 presents an overview of the U.S. industry, as well as the current markets and regulatory environment in the key emerging markets of China, India, and Brazil. Section 4 describes the empirical methodologies used to measure import competitiveness and restrictiveness and presents the estimated results. Section 5 concludes.

2 Medical Technology and Regulations

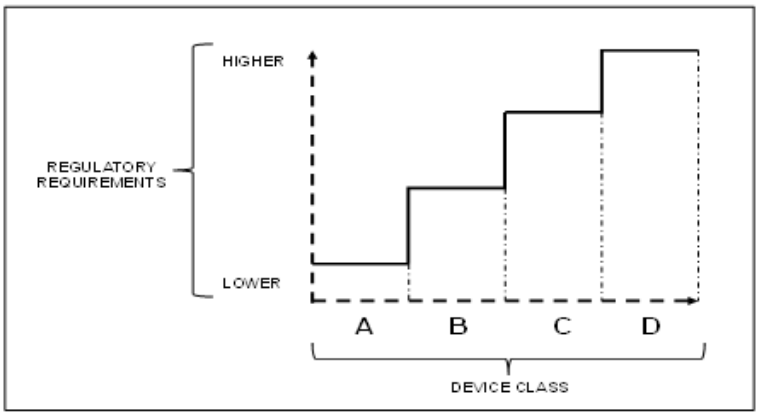
Medical technologies refer to the various implements, machines, appliances, and instruments that facilitate in the diagnosis, treatment, or alleviation of disease (WHO 2003). The products included in the medtech industry range in complexity from relatively unsophisticated goods, such as bandages and other hospital supplies, to high-tech capital goods, such as diagnostic equipment. Although there are several ways to classify medtech, recent research by Torsekar (2018a, 2018b) has applied a similar framework developed by Bamber and Gereffi (2013), which identifies four major product groupings, ranging from least to most sophisticated: (1) disposables (bandages, surgical gloves, and plastic syringes); (2) surgical and medical instruments (devices used in surgeries and cosmetic procedures); (3) therapeutics (includes implantable devices like hearing aids and prosthetics and non-implantable devices such as ventilators and infusion pumps); and (4) diagnostic equipment (capital equipment that is technologically complex). For the purposes of this paper, we emphasize trade in therapeutics and diagnostics because the majority of regulatory procedures apply to these devices. A full list of products included in the study can be found in table 4 in the appendix.

2.1 Regulating Medtech

Regulatory practices are critical determinants of overall trade competitiveness for a given country, influencing market access for foreign producers and guiding pricing decisions of products within these markets. In the global medtech industry, nearly all major markets apply a risk-based classification system to regulate these goods, similar to the recommendations of the International Medical Device Regulators Forum (IMDRF), a voluntary international association aimed at harmonizing international medical device standards. The IMDRF builds upon similar efforts made by the The Global Harmonization Task Force (GHTF) which, prior to being disbanded in December 2012, recommended dividing medical devices into four categories based on the relative harm posed to

patients; regulatory requirements are ideally supposed to increase in accordance with the device risk (figure 1).[3]

Figure 1: Conceptual illustration of the device class and corresponding regulatory requirements, as stipulated by the GHTF.



Source: (GHTF, 2012, p. 11).

Despite the prevalence of risk-based classification standards for medtech and escalating regulatory requirements for higher-risk devices within most international markets, differences in the application of specific measures can restrict trade by imposing NTMs, thereby limiting or delaying market access to foreign manufacturers (Johnson, 2008, p. 1). According to UNCTAD (2012), there are 16 recognized NTMs, of which technical barriers to trade (TBTs) are most germane to the global medtech market. TBTs typically refer to three types of measures (UNCTAD 2012; WTO 1995):

- Technical regulations—documents which describe product characteristics and detail production methods. These may also address requirements for labelling. Compliance is mandatory.
- Standards—similar to technical regulations, but with which compliance is not mandatory (i.e. voluntary standards).
- Conformity assessment procedures—regulations detailing the sampling, testing, inspection, certification, and registration requirements for approval. These are the most common TBTs in the global medtech industry (Sunesen, 2009).

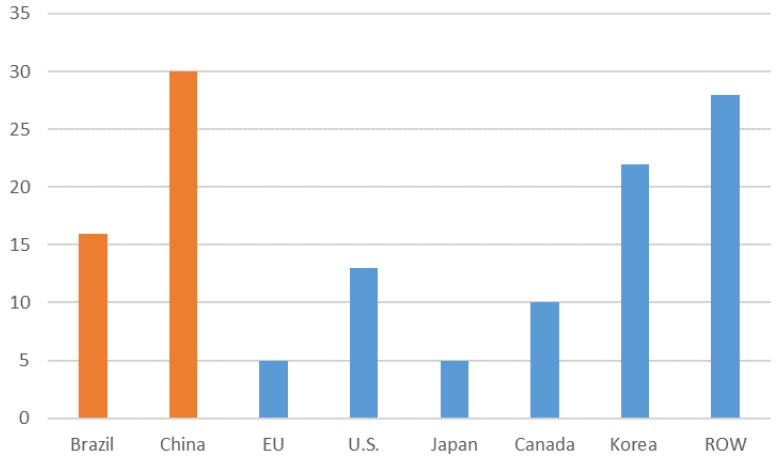
While the 1995 WTO Agreement on TBTs (TBT Agreement) permits countries to implement their own regulations, standards, and conformity assessment procedures to fulfill legitimate regulatory concerns, countries are encouraged to accept other member countries conformity assessment

[3]However, variations in the categorization of devices varies across countries. For example, in the United States, the Food and Drug Administration (FDA) identifies three classes of medtech, which range from basic hospital supplies and other disposables (class I), to therapeutics and other devices that carry slightly elevated health risks but are similar to existing devices on the market (class II), to diagnostic devices which exhibit a high risk of injury or illness to a patient (class III).

procedures. With regard to medtech production, class C-D devices are subject to the highest regulatory scrutiny; manufacturers are required to submit to on-site audits of production facilities, submit documentation detailing the product design, provide data from product testing, and maintain a quality management system (QMS) (GHTF, 2012, p. 8-17).[4] However, these procedures can run afoul of the TBT Agreement when they are deemed discriminatory, conferring an advantage to domestic producers at the expense of foreign manufacturers. Further, conformity assessment procedures requiring duplicative testing or product certifications and technical regulations imposing onerous labelling standards that require unnecessary information beyond the basics of what is needed to use the product are examples of likely TBT violations (UNCTAD, 2012).

When signatories of the TBT Agreement consider updating their regulations in ways that may significantly impact trade or diverge from international standards, they must notify the TBT committee; these notifications can serve as a proxy for understanding a country's overall regulatory market (Okun-Kozlowicki, 2016). During January 2013–August 2018, China and Brazil ranked first and third (behind South Korea), respectively, as having the highest number of medical device notifications submitted to the TBT Committee (figure 2); India did not have any notifications during this time. It should be noted that while these notifications don't necessarily connote TBT violations, they can suggest additional trade costs and possible delays in securing approval for sale, arising from the demands of adapting to changing regulations upon implementation. Many of the provisions that Brazil and China raised during this time ranged from labeling requirements, to inspection and auditing standards. An additional caveat is that countries with relatively immature regulatory systems who are seeking to adopt international standards will notify the TBT Committee to confirm that they are following best practices. Encouragingly, industry representatives report that this is more often than not, the case with Brazil and China's notifications to the Committee.[5]

Figure 2: Number of Medical Device TBT Notifications for Selected Countries and the Rest of the World (ROW), January 2013-August 2018.



Source: TBT Information Management System (2018, accessed August 11, 2018).

[4]The most common QMS in the medtech industry is the ISO 13485 certification, which satisfies most of the quality assurance requirements for regulatory approval in the EU (BSI, 2016, p. 5).

[5]Industry representative, e-mail correspondence with authors, August 20, 2018.

3 Overview of U.S. Industry and Key Emerging Markets

The U.S. medical device industry, which is valued at more than $153 billion in 2016, is the world's largest (EY, 2017). Moreover, seven of the world's ten largest medical device original equipment manufacturers (OEMs), by revenue, are headquartered in the United States (table 1). Although large firms command the greatest domestic market share, more than 80 percent of the industry's 1,500 firms are small and medium-sized enterprises (SMEs) that employ less than 50 people (Carusi, 2014). Nonetheless, it is typically the larger OEMs that commercialize most medical devices due, in large part, to their financial resources. Despite producing devices across 90 distinct categories of products, U.S. firms specialize in high-value-added technologies requiring a highly skilled workforce of engineers and technicians. The U.S. medical device industry accounts for more than two million jobs (both indirectly and directly) throughout the country, paying wages that exceed most manufacturing jobs by 30 percent and 9,800 manufacturing facilities both in the United States and around the world (AdvaMed, 2017).

Table 1: Top 15 global medical device manufacturers in 2017 by revenue, headquarters, and 2015 market share

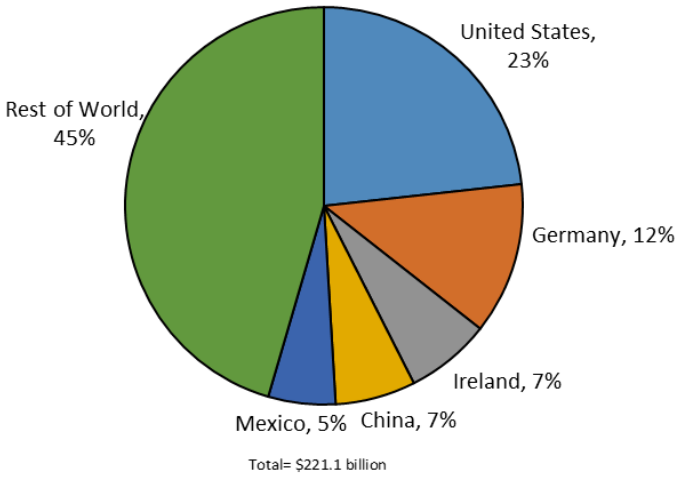
Company	Headquartered	Revenue ($ bn)	Global Market Share (%)
Medtronic	Ireland	28.8	8
Johnson & Johnson	United States	25.1	6
Siemens Healthineers	Germany	15.2	3
Becton Dickinson	United States	12.5	3
Cardinal Health	United States	12.4	3
Phillips HealthTech	The Netherlands	12.4	3
Stryker	United States	11.3	3
Baxter	United States	10.2	2
Abbot Laboratories	United States	10.1	2
Boston Scientific	United States	8.4	2
Danaher	United States	7.8	2
Zimmer Biomet	United States	7.7	2
Essilor	France	7.5	2
B.Braun	Germany	6.8	2
Top 15 totals		176.2	43

Source: Fenske et al. (2017) and Snyder (2017). Note: Market share data presented for 2015, the most recent year for which these data were available.

The competitiveness of the U.S. advanced medtech industry is also reflected in their status as the world's largest exporter of these goods (figure 3). U.S. medical device OEMs earn between 40 and 50 percent of their revenues outside the United States, which reflect a combination of exports and activities by foreign-based subsidiaries (SP, 2014). Export decisions are largely influenced by the ease of foreign market entry. This is because, given the relatively short lifecycle of these technologies (18-24 months), U.S. firms may forgo significant potential earnings if a device is undergoing a lengthy review in a foreign country (USITC 2007). To that end, U.S. manufacturers have commonly generated roughly 30 percent of their revenues from the European Union (EU)—led by

Germany—which have the lowest reported times to market of any of the world's major medical device markets (Emergo, 2017a).[6] In addition, a principal advantage of maintaining a presence in a variety of international markets is the ability for firms to mitigate the effects of currency swings by focusing on markets that benefit from the current value of the U.S. dollar at a particular moment in time;[7] in recent years, an estimated 40 percent of revenues garnered by the top 10 U.S. medical device OEMs stemmed from beneficial foreign exchange rates (EY, 2012).

Figure 3: The world's largest exporting countries of advanced medtech, 2016 (%)



Source: Comtrade (2018, accessed June 18, 2018).

Alongside Germany, Japan has also served as a leading destination for U.S. medtech. However, these established medtech markets are relatively mature,[8] which implies relatively stable market growth. In contrast, the rapid expansion of key emerging medtech markets, led by China, India, and Brazil, may suggest substantial opportunities for U.S. manufacturers (Francis et al.,. 2011; Agarwal et al.,. 2016). Growth in these three countries reflects a combination of demographics (especially ageing populations in China), highly urbanized populations, and the growth and prevalence of non-communicable or lifestyle-related afflictions. At the same time, these three medtech markets remain chronically underserved. For example, medical device density for China, India, and Brazil each ranked in the bottom quartile according to a 2013 study by CHPI; out of the 67 countries studied, the three countries ranked 63rd, 58th, and 50th respectively.

The United States has been the largest supplier of medtech to China, India, and Brazil for the past decade. More specifically, the United States has represented more than one-quarter of each of these countries' medtech imports during this time (Global Trade Atlas, 2018).[9] However, our

[6] According to Emergo Group, the EU's maximum time to market estimates for the highest risk medtech was 9 months in sharp contrast to Japan (16 months), China (22 months), and the United States (30 months), for example.

[7] A strengthening U.S. dollar makes U.S. goods relatively more expensive and generally translates into reduced sales and revenues in overseas markets. Conversely, U.S. medical device OEMs benefit from a weakening U.S. dollar when entering foreign markets.

[8] For example, both countries fell within the top ten of medical device density out of the 67 countries profiled in a study (CHPI, 2013), suggesting relatively saturated medical device markets.

[9] As of 2018, the United States' exports of medtech to each of these countries was: India (26 percent), Brazil (31

analysis (which will be discussed in section 4) finds that these key markets rank low in import competitiveness, especially when compared to established medtech markets (as depicted in table 2). In particular, each of these countries maintains regulatory structures that are associated with extensive times to market for high-risk devices. The regulatory obstacles mostly fall under the purview of TBTs (especially conformity assessment procedures and technical regulations), but also include other NTMs (such as price controls), as summarized below:

- Duplicative certification and testing procedures (China and Brazil).
- Excessive data submission requirements (China and Brazil).
- Documentation (including labelling) that must be transcribed in local languages (China, India, and Brazil).
- Policies that privilege domestic production over foreign imports (China and India).

Table 2: Comparison of regulatory factors, demand factors, and overall barriers in advanced medtech for key emerging medtech markets and established medtech markets

	Key emerging medtech markets			**Established medtech markets**	
	China	**India**	**Brazil**	**Germany**	**Japan**
Regulatory Factors					
Maximum time to market	High	High	High	Low	Moderate
Regulatory Complexity	High	Moderate	High	Moderate	Moderate
Regulatory Cost	High	Moderate	High	Moderate	High
Demand Factors					
Medical Device Density	Low	Low	Low	High	High
Per capita Healthcare spending	Low	Low	Moderate	High	High
Overall Barriers					
Import Competitiveness	Low	Low	Moderate	High	High

Source: Compiled by authors from Emergo (2017a).
Note: Ratings (low, moderate, high) for maximum time to market, import competitiveness, and medical device density were assigned based on quartile rankings of these respective data sets. Quartile rankings of 4 were ranked "low" for time to market and import restrictiveness and "low" for medical device density. The country data on regulatory complexity and cost was ranked from 1–5, with 1 being the lowest and 5 the highest. In these cases, we assigned a rating of "moderate" to countries assigned listed as a 3 or 4 and a "high" to countries with a ranking of 5. Per capita healthcare spending of below 5 percent of GDP were considered low, spending between 6–10 percent were considered moderate, and anything at or exceeding 11 percent was deemed high.

percent), and China (33 percent).

3.1 China

3.1.1 Market Overview

As of 2016, China's medical device market was valued at $8.7 billion (Emergo, 2017b) and ranked second behind Japan as Asia's largest market. In particular, China's rapid rate of urbanization, aging population, and increasing incidence of lifestyle-related afflictions has created substantial demand for various categories of advanced medtech (Luo, et al. 2014). For example, unprecedented urbanization (Roxburgh, 2017) has heightened the need for diagnostic technologies, pacemakers, dialysis systems, and intravenous diagnostic technologies. This trend reflects the various public health risks that accompany city dwelling.[10] For example, 1 in 10 adults (110 million people) in China are estimated to have been diagnosed with diabetes (WHO, 2016). Further, China's elderly population (those aged 65 and above)—already one of the world's largest—is generating growing demand for orthopedic devices within the country; China may become the world's largest orthopedic device market within 10 years, according to recent projections (Liu, 2017). Elderly populations are generally the largest consumers of these devices, due to the degradation of the musculoskeletal system and loss of bone strength generally associated with aging.

At the same time, government policies have helped expand the growth of China's healthcare market. In an attempt to redress the country's historically inequitable healthcare system, China implemented healthcare market reforms in 2009. According to the EIU, these have since been associated with improvements in the country's primary healthcare system, having achieved near-universal health insurance through the expansion of basic health insurance, limiting out-of-pocket expenses, and reforming public hospitals. Further, in late 2016, China unveiled the country's first long-term strategic health plan ("Healthy China 2030"), which aims to build off of previous initiatives to extend life expectancy among its citizens, increase the number of doctors, and reduce out-of-pocket expenses (EIU 2018a). In accordance with these plans, China has steadily increased its healthcare spending, which reached a historic high of 6 percent of GDP in 2016 (EIU, 2017a). Nevertheless, China's per capita total healthcare spending remains low compared to other leading markets, such as the United States (17 percent), Germany (11 percent), and Japan (10 percent), for example (EIU, 2018b,c).

3.1.2 Regulatory Overview

China is estimated to have the second longest time to market (behind the United States) and ranks among the world's most complex and costly regulatory systems (Emergo, 2017a). China's chief medical device regulatory agency, the China Food and Drug Administration (CFDA), is responsible for approving all devices for sale within the country. Much as in other markets, China requires foreign manufacturers to appoint an agent to liaise with the CFDA and an after-sales service representative after approval. The device registration process in China can be especially onerous and time consuming due to the requirement that foreign firms provide a file listing technical information, test reports, clinical data, and a document attesting to the quality of the device with all documentation provided in "simplified Chinese." During this review, the CFDA reserves the right to perform audits of foreign manufacturers, which may entail an on-site review of production facilities (Emergo,

[10] Urbanization is often associated with many public health risks—including various non-communicable diseases such as lung cancer, cardiovascular disease, diabetes, and hypertension. These risks largely reflect the increased consumption of high-calorie, processed foods; the transition away from farming towards more sedentary occupations; and the relatively poor air quality that often accompanies city living (Torsekar, 2014).

2016); these steps are often duplicative, as they have more than likely been performed in order to achieve market entry for sale in other countries (USTR 2016, 87).

Of particular concern to U.S. industry is China's March 2014 revision of medical device regulations.[11] These polices principally apply to conformity assessment measures and introduced two requirements on medical devices that have raised concerns from U.S. manufacturers. The first policy requires medtech exporters to be registered in their country before being eligible for registration in China. The second policy imposes new clinical trial requirements for the most advanced medical technologies. Both of these policies are believed to be associated with market delays and represent more stringent departures from previous policies (USTR, 2016, p. 88). For example, with regard to the new clinical trial requirements, China had previously permitted foreign firms that had obtained market clearance in other countries to sell in China without having to conduct multiple clinical trials (Luo et al., 2014). This practice was consistent with that applied in other leading markets, such as the EU, for example. In addition to adding to the overall approval times, this measure imposes high costs of between $1 million to 1.5 million (Giger, 2017). These high costs would likely discourage small producers in the United States, who lack the financial resources of their larger counterparts.

At the same time, China has implemented policies aimed at bolstering the domestic manufacturing sector. As part of their "Made in China 2025" campaign, the country has prioritized the production of advanced medtech to meet their domestic requirements. By 2025, China has established a semi-official target of supplying 70 percent of their domestic market for these goods with local production (Wubbeke, 2016). In particular, their innovation policies appear to favor domestic production over foreign (EIU, 2017b; Agarwal, 2015). For example, Chinese companies have been the principal beneficiaries of the country's expedited review process for the most innovative devices; 90 percent of the 117 approved devices under this procedure have been produced by Chinese firms as of 2017 (EIU, 2017b).

These policies are consistent with China's pricing policies, which are believed to disadvantage the types of advanced medical technology commonly supplied by the United States. China's provincial tendering process, which determines the price at which medtech is sold, is associated with high administrative requirements that translate into lengthy delays for foreign manufacturers. For example, advanced medtech manufacturers must provide detailed specifications of their products and often enter into lengthy negotiations with the government in order to justify the higher prices that these goods command; it can take years before a device is priced for sale in a particular province (Torsekar, 2014). At the same time, U.S. industry representatives have suggested that price controls are applied in the tendering process, with ceiling prices that discourage the adoption of foreign medtech (USTR, 2017, p. 57).

3.2 India

3.2.1 Market Overview

India's medical device market is valued at roughly $5-6 billion[12] and ranks as Asia's fourth largest medical device market behind Japan, China, and South Korea (Emergo, 2017b). The market is largely being driven by rapid urbanization, the emergence of non-communicable diseases (e.g. cardiovascular disease and diabetes), and a growing middle class (Dey, 2017; SKP, 2017). Because

[11] Officially known as Order No. 650, the Regulations for the Supervision and Administration of Medical Devices.
[12] Industry representative, e-mail correspondence with authors, August 28, 2018.

domestic production is concentrated in disposables and other low-end segments, roughly three-quarters of its medical device market is supplied by imports, with the United States being the largest supplier (Torsekar, 2017). The highest imported categories of devices include therapeutics (especially hearing aids, pacemakers, and stents) and diagnostic equipment (SKP, 2017). Despite the large potential market opportunity, India's healthcare system is chronically underfunded, spending less than five percent of its GDP on healthcare (EIU, 2018d).

3.2.2 Regulatory Overview

In contrast to all of the twenty foreign markets for which time to market data was available, India has been unique in its absence of a risk based classification structure. Instead, the country's regulations have only extended to 22 types of devices, a process that created ambiguity with respect to classifying devices outside of these categories. Further, India has typically regulated medical devices as analogous to pharmaceuticals despite the notable differences between the two products, including the way that these products are designed, manufactured, and administered to patients, for example.

A report from the USITC from 2014 noted that the disparity between regulated and unregulated devices, along with the requirement to comply with standards more appropriate for pharmaceuticals than medical devices created substantial burdens on foreign manufacturers. For example, producers of unregulated devices could be compelled to provide various documentation and paperwork at any time even after a device has been placed in the market; each document required of these firms was estimated to cost $1,000 (USITC, 2014).

In addition, during 2014, India's Central Drugs Standard Control Organization—a regulatory body that governs the imports of medical devices—implemented India-specific labeling requirements for exporters of medtech. These standards list 14 steps that must be placed on a medtech label, including the date and place of manufacture, the maximum retail price, and manufacturing license numbers, to name a few (Morulaa, n.d; USITC, 2014). These requirements exceed GHTF recommendations, which advise that country-specific labeling be "kept to a minimum" or removed entirely (GHTF, 2011).

In response to these challenges, the Ministry of Health and Family Welfare in India began implementing the Medical Devices Rule of 2017 on January 1, 2018. Encouragingly, the policy has established the country's first risk-based classification system for all medical devices and distinguishes these goods from pharmaceuticals. At the same time, these measures eliminate onerous procedures, such as the requirement for foreign manufacturers to register medical devices intended for sale and the periodic renewal of licenses (SKP, 2017; IQVA, n.d.).

Yet, even as India has made advances in standardizing its regulatory regime with international practices, the country has also pursued policies aimed at reducing its reliance on foreign imports while bolstering its domestic industry. According to SKP (2017), the country decided in February of 2017 to impose price controls on coronary stents,[13] reducing their prices by nearly 75 percent. In August of 2017, a similar policy on knee implants reduced prices by as much as 87 percent depending on the type of device. Both policies have faced strong objections from U.S. manufacturers. For example, leading U.S. producers including Abbot Vascular and Boston Scientific attempted to withdraw their products from the market as a result, despite prohibitions against such actions for 12 months from the date of the notification. Further, in March of 2018, India's Department

[13]It should be noted that price controls are classified as a type of NTM that is distinct from the conformity assessment procedures discussed earlier (UNCTAD 2012).

of Pharmaceuticals issued a public procurement order which includes local content requirements ranging from 25 to 40 percent on various high-value medtech, such as implants.[14] Taken in sum, these policies may place U.S. firms at a competitive disadvantage, as they are the leading suppliers of these high-end devices to India's market (Torsekar, 2017).

Beyond the imposition of NTM's India has also raised tariffs on medtech during 2016 in an effort to further dampen the country's import dependence. Medtech tariffs increased from 5 percent to 7.5 percent, with the list of medtech including pacemakers, coronary stents and stent grafts, surgical equipment. In addition, by placing higher tariffs on finished medtech, as opposed to intermediate goods and parts (which are used in the production of finished goods), these policies are expected to further advantage domestic producers at the expense of foreign manufacturers (USTR, 2018, p. 225). While these measures don't necessarily add to the complexity or extend time to market, it should be noted that policies that benefit local producers at the expense of foreign producers would likely discourage U.S. exports.

3.3 Brazil

3.3.1 Market Overview

Brazil is the largest medical device market in Latin America and was valued at $4.7 billion in 2016 (Emergo, 2017d). During the past decade, Brazil remained a top 15 destination market for exports of advanced medtech from the United States, though a recent economic recession has translated into declining exports for the past five years; according to GTIS (2018), U.S. exports of advanced medtech to Brazil declined by 17 percent during 2012–17 to $1.1 billion. However, the 3 percent expansion of U.S. exports of these products to Brazil's advanced medtech market during 2016–17 suggests a reversal of the previous five-year trend.

The domestic market for disposables and other low-end hospital equipment is largely supplied by the domestic industry, presenting opportunities for U.S. manufacturers to supply the high-end of the market. The demand for these devices will likely grow as rising incomes in the urban south of the country translate into the emergence of non-communicable diseases (e.g. cardiovascular disease and cancer) which account for nearly three-quarters of deaths in the country (EIU, 2018e; WHO, 2014). As a result, Brazilian imports of diagnostic equipment, ranging from electrocardiographs, MRI machines are all projected to experience the double-digit import growth in both value and quantity in the near future (Roy, 2017).

3.3.2 Regulatory Overview

The process of registering a medical device for sale in Brazil ranked among the world's most complex, due largely to the frequently changing regulations and a relatively under-resourced Brazilian Health Surveillance Agency (ANVISA) (Emergo, 2017e; Dun, 2015). Brazil regulatory regime ranks among the world's highest in both complexity and cost (Emergo, 2017a). There are several key measures associated with complying with the country's medtech regulations. First, exporters need to appoint a Brazilian Registration Holder who acts as a regulatory liaison through the process and obtain a license to sell medtech within the country. This process alone can average more than one-year for the highest risk devices.[15] All documents, including product identification, labeling, instructions

[14] Industry representative, e-mail correspondence with authors, August 28, 2018.
[15] Industry representative, e-mail correspondence with author, August 7, 2018.

for use of the product, and legal documentation, device descriptions, and manufacturing stages of the devices, provided during the process must be translated into Portuguese, which can be lengthy.

Next, foreign companies are required to comply with a local quality management system requirement called the Brazilian Good Manufacturing Practice (BGMP) for all devices. However, the most risky devices require an audit by Brazil's National Health Surveillance Agency (ANVISA),[16] and producers need to submit clinical data for regulatory compliance which can be a lengthy process (Emergo, 2017d; USTR, 2016, p. 54). For most implantable devices, the data that is submitted must also include pricing comparisons to other markets where the device is sold, along with pricing comparisons of analogous products that are being sold in Brazil. Further, with regard to testing requirements, Brazil applies a mandatory electrical safety testing and certification standard to selected devices. These requirements have raised concerns from U.S. industry representatives within the past decade as being excessive and unrelated to verifying the product safety (Johnson, 2008, p. 19).[17] Reportedly, industry representatives have suggested that these challenges have been less of a problem in recent years.[18]

Delays in the overall approval process have been compounded by the lack of ANVISA federal inspectors to implement the program; during a 2012 meeting to discuss international TBTs, the EU argued that the timelines for registering medical devices in Brazil were too long, with delays being driven by the failure of Brazilian inspectors to conduct factory inspections of foreign producers in a timely fashion (WTO 2012).[19] In particular, the final stages of review can result in significant delays, owing to the backlog of devices under review; the most risky devices can range from 8-15 months, or extend beyond 4 years (Emergo, 2017d). Moreover, backlogs in regulatory inspection procedures have also translated into customs delays for admitting imported medtech into Brazil. For example, in 2016 the time to import medical technology was estimated to be one of the highest in Latin America (Advamed, 2016). U.S. manufacturers have reportedly complained about the extensive documentation, which Brazil requires to import medtech (USTR, 2018, p. 67); the peak time for ANVISA to issue an import license for medtech in 2016 was 60 business days.[20] Although ANVISA has recently been able to reduce this delay to a 15 business-day average, they are still not consistently meeting their target of 3-5 days.[21] Notably, industry representatives report that Brazil's medtech market is more accessible to U.S. manufacturers than China's and India's, respectively, despite these delays.[22]

4 Gravity Estimation of Competitiveness

To evaluate import competitiveness for medtech, we employ a gravity modeling approach that estimates the factors that determine trading patterns. The modeling approach identifies and ranks countries based on their global competitiveness as importers given their respective GDPs and relationships such as distance, common languages, and trade agreements with exporters. Countries that import large volumes of medtech given these factors are considered highly competitive while those import relatively little are considered uncompetitive. Using these measures of competitiveness, we

[16] Brazil uses a similar risk based classification as the EU and categorizes devices into four classes.

[17] Industry representative, e-mail correspondence with author, August 7, 2018.

[18] Industry representative, e-mail correspondence with authors, August 20, 2018.

[19] Industry representatives note that this has been less of a problem in recent years. Industry representative, e-mail correspondence with authors, August 20, 2018.

[20] Industry representative, e-mail correspondence with author, August 7, 2018.

[21] Industry representative, e-mail correspondence with authors, August 20, 2018.

[22] Industry representative, e-mail correspondence with authors, August 20, 2018.

calculate an ad valorem equivalent (AVE) trade cost that explains each country's import activity relative to the most competitive country. To better explain the relative competitiveness of each importer and the implied AVE, we conduct a second estimation that relates the competitiveness of each country with factors that might explain these trends. The results suggest that barriers to importation in the form of long or complicated medtech approval processes significantly decrease the competitiveness of importers.

4.1 Data

The analysis is primarily based on international trade data made available by the United Nation's Comtrade database.[23] The data covers all reported trade in each of 42 different 6-digit, HS12 codes that we have categorized as advanced medtech for the years 2012–2015.[24] The trade data is squared so that zero trade flows are reconstructed and included where no trade has been reported. Doing so helps better identify factors that prevent trade from occurring all together. To the trade data, we add a collection of gravity variables from the Dynamic Gravity dataset that reflect relationships between countries (Gurevich and Herman, 2018). These variables include the population-weighted distances, shared common borders, common languages, colonial relationships, preferential trade agreements, and GDP. Together, this results in data used to estimate import competitiveness for 167 countries.

4.2 Estimating Competitiveness

The methodology for estimating import competitiveness follows the work of Fontagné et al. (2011) who propose the use of importer fixed effects in a gravity model to calculate AVE trade costs. Similar approaches have been taken in several other papers by Park (2002) and Fontagné et al. (2016), for example. In a gravity model, country fixed effects are used to capture all country-level characteristics that determine trade patterns. These country-level characteristics include factors such as market demand, non-tariff measures, and other forms of restrictions that affect a country's propensity to import. If factors governing demand have been suitably controlled for outside of the fixed effects, they can be used to analyze aspects of trade restrictiveness and measure import costs.

We begin by estimating a typical gravity model, similar to those described by Fontagné et al. (2011) as well as numerous general gravity surveys such as those by Piermartini and Yotov (2016) or Head and Mayer (2014). The model takes the following form:

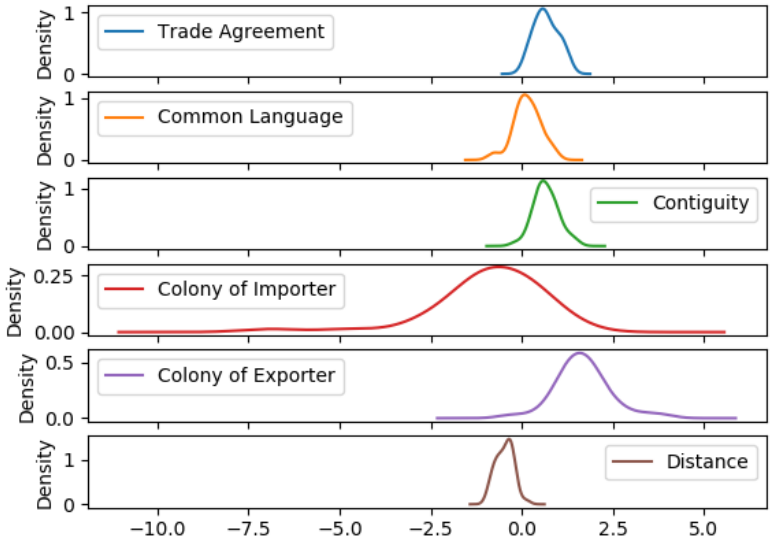
$$\frac{X_{ijs}}{Y_j} = \exp\left\{\sum_k a_s^k z_{ijs}^k + \nu_{is} + \mu_{js} + \epsilon_{ijs}\right\}. \tag{1}$$

Trade values from exporter j to importer i in product s are denoted by X_{ijs}. Unlike in many contemporary gravity models, the importing country's GDP, which is reflective of market demand, is moved to the left hand side of the equation prior to estimation so as to remove it from the importer fixed effect. Doing so improves the connection between the estimated fixed effects and unobserved import restrictions. On the right hand side of the equation, z^k denotes a collection of conventional gravity variables as described above, ν_{is} denotes an exporter fixed effect, and μ_{js} denotes an importer fixed effect.

[23] United Nations Statistics Division. UN Comtrade. `https://comtrade.un.org/`

[24] The years 2012–2015 were chosen based on the availability of HS12 classified trade data, available after 2012, and GDP data, which was only widely available up to 2015 at the time of writing.

Figure 4: Kernel Density Plots of Estimated Gravity Coefficients for Medical Devices

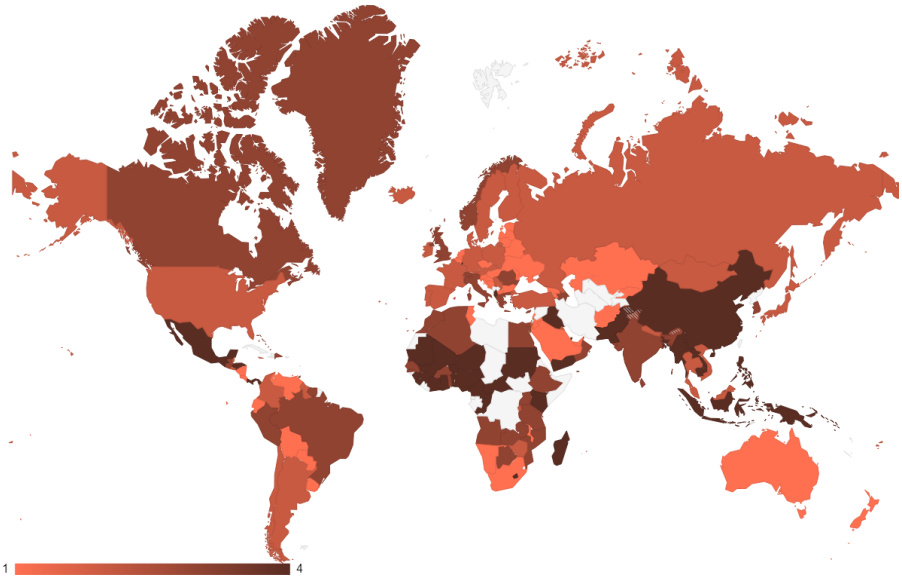


A gravity model is estimated for each of the product codes separately using a PPML estimator as described by Santos Silva and Tenreyro (2006). PPML estimation offers several advantages over linear methods such as improved handling of heteroscedasticity and the ability to include zero-trade flows. The results of these estimations are depicted if figure 4, which present kernel density plots for the coefficients of the gravity variables across each of the 42 estimated products. As can be seen from the kernel density plots, the estimated values are generally in line with prior gravity research. Distance is consistently inversely related to trade (the coefficient is less than zero) while belonging to a trade agreement, sharing a common language, sharing a border, or being a colony of the exporter are positively related (greater than zero). Interestingly, the estimates for the effect of being a colony of the importing country features a very wide spread covering both positive and negative values, suggesting that it does not have consistent impact medtech trade flows.

We use the estimates for the importer fixed effects μ_{js} analyze each sample importer's relative restrictiveness. The importer fixed effects provide a measure of an importer's competitiveness given their market size as measured by GDP. Countries with larger fixed effects tend to import more on average than those with smaller fixed effects, which implies that they are relatively more competitive. Because this competitiveness already accounts for market demand as proxied by GDP, we assume that competitiveness is largely governed by unobserved import restrictions. Further evidence supporting this assumption is provided later in this section.

Using the importer fixed effects, we are able to rank countries based on their estimated competitiveness and, implicitly, their estimated restrictiveness. Figure 5 provides a map in which this ranking, averaged across all estimated medical devices, is depicted. A full listing of the overall rankings can be found in table 5 in the appendix. In figure 5, countries are broken into four quantiles such that lighter countries such as Belarus (rank 1), Nicaragua (rank 6) and New Zealand (rank 11) are those that are least restrictive. Darker countries such as China (rank 126), Indonesia (rank

Figure 5: World map of relative import restrictiveness



Note: 1 denotes the most competitive quartile of importers, 4 denotes the least competitive. Uncolored countries are not ranked due to a lack of available data.

153) and Mali (rank 167) are the most restrictive.[25]

The estimates of import competitiveness highlight that the key markets of Brazil (rank 92), China (rank 126), and India (rank 125), rank relatively poorly compared to the rest of the world. Given a sample of 167, these three are in the bottom half of the countries considered. Given the relatively large GDPs and populations of all three countries, as well as their bilateral relationships with exporters of medtech products, all are expected to import much more than they have been in recent years. These empirical findings are consistent with the factors influencing medtech imports noted in table 2, which suggest that NTMs affecting medtech are particularly severe in these countries compared to others.

In addition to creating a ranking of countries based on estimated restrictiveness, the importer fixed effects can be used to derive AVE trade costs associated with unobserved trade distortions. Fontagné et al. (2011) do this by comparing each country's fixed effect with that of the most competitive country and identifying the trade cost that would explain this difference. Because we cannot observe the cost-free importation of medical devices, the use of the least restrictive country as a benchmark for cost-free imports is the best available comparison. As such, all computed cost values are relative to that least restrictive, benchmark country.[26] For example, Malawi and Belgium are each benchmark countries in two different product codes. Using this comparison and

[25] Uncolored countries are those for which insufficient data was available for estimation.

[26] That is, the AVEs are effectively normalized to the benchmark estimated AVE countries. The benchmark country will have an AVE cost of zero percent and estimates for other countries should be interpreted as being in addition to the unidentifiable AVE of the benchmark.

the structure of the gravity equation, we can calculate an AVE trade cost using the following equation:

$$AVE_{js} = \exp\left\{\frac{\mu_{js} - \mu_{*s}}{1-\sigma}\right\} - 1. \tag{2}$$

As before, μ_{js} denotes the fixed effect for importer j of product s and μ_{*s} denotes the corresponding fixed effect of the benchmark country. The calculated AVEs can be interpreted in the following way. For product 901839 (a subcategory of medical instruments), Belgium is the least restrictive importer while Brazil has an estimated AVE of about 34 percent. In this case, an additional tariff rate of 34 percent in Brazil above the costs present in Belgium would explain the difference between Belgian and Brazilian imports.

One additional parameter is needed in order to complete the calculation, an elasticity of substitution σ. The elasticity of substitution captures the extent to which an importer is likely to substitute between exports in response to price changes. Because it is not possible to directly estimate an elasticity of substitution using the specification of gravity model employed here, we draw on an estimate from the literature. Specifically, we use a value 0f 8.98, which was estimated for "medical devices" broadly by Caliendo and Parro (2015). While the selection of this elasticity does not affect the general ranking of countries based on restrictiveness, it has a large effect on the magnitude of the implied AVE costs. It is likely that this estimate is too low for any particular product category with in the general grouping of "medical devices", resulting in particularly large estimated AVEs. Broda and Weinstein (2006) discuss the nature of substitution elasticities as goods become increasingly disaggregated, noting that higher levels of disaggregation result in greater substitutability due to the larger number close substitutes available. Put simply, substituting between products within the category of "medical devices" can be done much more readily than substitution between "medical devices" and some other product category. As such, the AVE estimates we present can be reasonably considered a high end of those face by exporters.

The estimated AVEs, averaged across products, are listed in table 5.[27] The average AVEs tend to vary between about 30 percent to 130 percent, suggesting that even in the least restrictive countries, imports of medical devices face costly frictions. Individually, the average AVE for a medical device is about 59 percent, the median value is 55 percent, and the standard deviation is about 42 percentage points. In the key markets of Brazil, China and India, these AVEs are high relative to many other countries, which is consistent with their rankings noted above. The AVE for Brazil is 57 percent, China is 67 percent, and India is 60 percent. As before, all three countries exhibit estimated relative import costs above the median rate, indicating higher restrictions faced by medtech products than in other markets.

4.3 Determinants of Import Competitiveness

A limitation of this method for estimating import competitiveness and AVE costs is that it inherently attributes many aspects of a country's import size other than GDP and the bilateral gravity variables to unobserved restrictiveness. It may be the case that relatively small import values given market size are the results of factors other than trade restrictions. In order to better validate the notion that our reporter competitiveness measures reflect import costs, we introduce a second regression that tests whether the estimated importer fixed effects, and therefore the calculated AVEs, are related to known restrictions that affect medical device trade.

[27] A more complete listing of computed AVEs by country or product is available by request.

Heid, Larch and Yotov (2017) note that the literature has long used a two-step approach to estimating the effects of non-discriminatory policies, specifically highlighting the methodologies' used by Eaton and Kortum (2002), Head and Reis (2008), Anderson and Yotov (2012), and Head and Mayer (2014). In many of these papers, the two stages involve the initial estimation of a structural gravity model with the appropriate fixed effects. Second, the fixed effects are regressed against the policy variables of interest that could not be included in the initial gravity model.

To provide evidence that the estimated import restrictiveness and AVEs of each country described above are related to restrictions rather than demand, we regress the estimated fixed effects of each country and product against a collection of variables that more directly reflect the medtech regulatory environment in each country. The first measure reflects the number of months it takes a medical device to gain regulatory approval for importation in each country. The second measure is a categorical variable that ranks the complexity of the approval process from 1 to 5. Both measures are based on information made available by Emergo Group, a consultancy that gathered this information from nearly 1,000 industry professionals worldwide.[28] In both cases, these measures differ based on the country importing the device as well as the device being imported. Each HS code is classified into one of several device classes, which reflect the relative health risk of the device. In general, riskier devices are subject to stricter and lengthier approval processes. In addition to these regulatory measures, we include two measures that are reflective of the demand for medical devices in order to also identify demand influences in the estimated fixed effects. Specifically, these measures reflect the per capita healthcare spending (EIU 2018) and medical device density in each country (CPIA 2013). Due to limitations in the availability of this data, we are only able to study the relationship between them and the estimated fixed effects for a subset of the countries in the first stage gravity estimation.

The estimates for the second stage regression are present in table 3. We report six different specifications testing the robustness of the estimates with several different combinations of regulatory and demand measures. Regressions (1)–(3) include combinations of the two measures of regulatory challenges. Regressions (4)–(6) include the factors that are likely to reflect demand for medtech: medical device density and healthcare spending. Each specification was estimated using OLS. Differences in the number of observations in each specification are due to the availability of data. In each case, we used the maximum number of observations available given the respective data requirements. Because the purpose of these regressions is to show the robustness of statistical relationships rather than to compare models, we believe this is a reasonable approach in this case.

These results provide strong evidence that the competitiveness rankings of countries are reflective of the restrictiveness of each importer rather than demand for medtech. The statistically significant, negative relationship between approval time and importer competitiveness confirms that longer delays in product approval reduce competitiveness. Additionally, we find some evidence that approval complexity reduces competitiveness. Complexity, which is ranked from least complex (0) to most complex (5), appears to have some connection with competitiveness. Lower levels of complexity are associated with higher competitiveness, suggesting that moderate levels of regulation are import promoting. This finding is consistent with the work of Chen et al. (2008) who find that certain policy measures are trade improving because the increase consumer demand for the product. However, level 4 complexity significantly reduces competitiveness. The most restrictive category (5) shows no statistical relationship with competitiveness. The coefficients for medical device density and health care spending are both insignificant, lending support to the assumption that demand

[28]These data are available at the Emergo website: `https://www.emergobyul.com/resources/worldwide/global-regulatory-comparison-tool?field_market_tid=All&cost=All&field_device_risk_value=3`.

Table 3: Regression of fixed effects on medical device regulatory and demand measures

Variable	(1)	(2)	(3)	(4)	(5)	(6)
Approval Time	-0.16***		-0.16***	-0.16***		-0.14***
	(0.04)		(0.08)	(0.05)		(0.05)
Approval Complexity (2)		0.72***	0.32		-0.14	
		(0.35)	(0.57)		(0.61)	
Approval Complexity (3)		0.76***	0.26		-0.16	
		(0.11)	(0.44)		(0.42)	
Approval Complexity (4)		-1.61***	-1.65***		-2.05***	
		(0.45)	(0.70)		(0.60)	
Approval Complexity (5)		0.23	1.03		-0.48	
		(0.41)	(0.97)		(0.59)	
Medical Device Density				0.000	0.002	0.002
				(0.001)	(0.003)	(0.003)
Health Care Spending					0.000	0.000
					(0.000)	(0.000)
Constant	-19.28***	-20.62***	-19.42***	-19.18***	-19.96***	-19.37***
	(0.21)	(0.07)	(0.41)	(0.27)	(0.43)	(0.29)
R^2	0.006	0.009	0.017	0.007	0.013	0.006
Obs.	2764	7303	2764	2316	1941	1941

Note: *** $p < 0.01$, ** $p < 0.05$, * $p < 0.10$. Robust standard errors in parentheses.

factors are being properly controlled for using GDP. Neither factor appears to impact the competitiveness of importers, suggesting that the rankings do accurately reflect trade restrictiveness rather than weak demand for the product.

4.4 Implications for Key Emerging Markets

Our analysis suggests that the United States would likely experience a marked improvement in medtech exports to key emerging markets following the harmonization of regulatory procedures to international standards by these countries. These policies largely pertain to the conformity assessment procedures and technical regulations of China, India, and Brazil, which are characterized by duplicative testing or certifications, redundant clinical trials for high risk devices, and the imposition of onerous labeling standards; each of these requirements likely adds substantial delays to gaining market approval. Further, each of these markets would likely reduce the perceived complexity of their regulatory regimes by adopting registration procedures, such as the Regulated Product Submission (RPS), a document drafted by the IMDRF. In particular, RPS advances an electronic protocol for the submission of registration requests and standardizes the process of obtaining pre-market approvals among markets (IMDRF, 2015). Brazil and China are both members of the forum, suggesting the possibility of adopting these protocols.

Another critical finding from our analysis is that regulatory policies associated with time-delays and complexity are of more importance than demand factors within these markets. As such, key emerging markets with especially low per capita healthcare expenditures, such as China and India,

would likely achieve greater import penetration by standardizing their regulatory procedures rather than simply increasing their healthcare spending.

5 Conclusion

As the United States seeks to maintain its competitive leadership within the global medtech industry, the ability to export to key emerging markets will remain an important strategy. Chief among these markets are China, India, and Brazil all three of whom maintained regulatory regimes characterized by either a moderate or high times to market and complexity. Our analysis has found that these regulatory factors exert a statistically significant impact on reducing import growth. The United States, which is the world's largest single-country exporter of these goods and widely considered the world's most innovative producer, is uniquely impacted by these market restrictions due to the high opportunity costs incurred from foregone revenue as devices undergo lengthy reviews in foreign markets.

As a consequence, all of these countries ranked in the bottom half of our calculations of the world's most import competitive markets for advanced medtech, with China and India ranking especially low. This suggests that efforts by the IMDRF (and prior work of the GHTF) to harmonize international standards across global medtech markets are likely facilitate greater global trade for these products. Encouragingly, China, India, and Brazil have each adopted portions of the guidance documents from these committees in constructing their respective regulatory systems (USDOC, 2016).

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Appendix

Table 4: Medtech Products by HS 6-digit code, product description, and total global trade in 2016 (actual dollars)

HS 6-digit code	Description	Trade Value ($)
300510	Adhes Dressngs Coated or Impreg With Pharma Substs	3,201,771,010
300590	Sterile Surgical Catgut, Similar Sterile Sutur,Etc	3,671,327,509
300610	Sterile Surgical Catgut, Similar Sterile Mater Etc	3,896,848,419
300620	Blood-Grouping Reagents	375,434,186
300630	Opacifying Preparations For X-Ray Examinations Etc.	2,678,230,645
382100	Prepared Culture Media For Devel Of Microorganisms	1,765,260,653
382200	Composite Diagnostic/Lab Reagents, Exc Pharmaceut	22,626,700,000
401519	Gloves, Except Surgical Etc., Vulcan Rubber, Nesoi	4,497,962,713
420600	Articles Of Catgut,For Mfg Of Sterile Surgical Sut	61,206,061
841920	Medical, Surgical or Laboratory Sterilizers	856,961,115
841990	Parts Of Medical, Surgical or Laboratory Sterilize	5,109,526,528
871390	Invalid Carriages, Mechanically Propelled	417,059,634
900130	Contact Lenses	5,097,971,625
901811	Electrocardiographs, and Parts and Accessories	840,650,228
901812	Ultrasonic Scanning Apparatus	3,868,010,497
901813	Magnetic Resonance Imaging Apparatus	4,195,833,524
901814	Scintigraphic Apparatus	324,965,239
901819	Electro-Diagnostic Apparatus Nesoi, and Parts Etc.	8,534,230,304
901820	Ultraviolet or Infrared Ray Apparatus, & Pts & Acc	252,671,071
901831	Hypodermic Syringes, With or Without Their Needles	4,502,403,000
901832	Tubular Metal Needles & Needles For Sutures &Parts	2,413,295,532
901839	Med Needles. Nesoi, Catherers Etc and Parts Etc	23,588,000,000
901850	Other Ophthalmic Instruments & Appliances & Parts	3,662,549,794
901890	Instr & Appl F Medical Surgical Dental Vet, Nesoi	46,239,700,000
902110	orthopedic or Fractre Appliances, Parts & Accessor	8,193,266,851
902131	Artificial Joints and Parts and Accessories Therof	8,691,496,629
902139	Artificial Joints & Parts & Accessories Therof,Nes	11,242,800,000
902140	Hearing Aids	3,762,185,043
902150	Pacemakers For Stimulating Heart Muscles	5,239,728,643
902190	Appliances Worn,Carried,Implanted In Body&Pt,Nesoi	11,743,500,000
902212	Computed Tomography Apparatus	2,841,837,916
902213	Appts Base On X-Ray For Dental, Uses, Nesoi	821,580,865
902214	Appts Base On X-Ray, Medical,Surgical,Vetnry,Nesoi	4,332,388,108
902221	Appts Base On Alpha,Beta,Etc. Radiation,Medical,Etc.	301,444,488
902230	X-Ray Tubes	1,830,476,471
902290	X-Ray/Hi Tnsn Genr Cntr Pnl & Dsk Exm/Trtmnt Tb Pt	6,694,386,764
902511	Clinical Thermometers Liquid-Filled	125,094,373
902519	Clinical Thermometer, Nt Combined W/Oth Inst,Nesoi	2,583,094,128

Source: USITC, *Harmonized Tariff Schedule of the United States*, 2018.

Table 5: Estimated restrictiveness rankings and ad valorem equivalents (AVE)

Country	ISO3 Code	Average Rank	Average AVE
Belarus	BLR	1	29.1%
Rep. of Moldova	MDA	2	33.5%
Armenia	ARM	3	35.3%
Georgia	GEO	4	35.1%
Lithuania	LTU	5	36.5%
Nicaragua	NIC	6	38.9%
Ecuador	ECU	7	38.1%
Bolivia (Plurinational State of)	BOL	8	38.9%
Netherlands	NLD	9	36.9%
Jordan	JOR	10	37.8%
New Zealand	NZL	11	39.8%
TFYR of Macedonia	MKD	12	39.9%
Malawi	MWI	13	42.2%
Bosnia Herzegovina	BIH	14	40.2%
Saudi Arabia	SAU	15	38.9%
Slovenia	SVN	16	39.1%
Belgium	BEL	17	39.6%
Latvia	LVA	19	41.3%
Bulgaria	BGR	20	40.1%
South Africa	ZAF	22	41.3%
Estonia	EST	23	40.8%
Cabo Verde	CPV	24	43.7%
Afghanistan	AFG	25	27.1%
Namibia	NAM	26	42.0%
Venezuela	VEN	27	39.3%
Singapore	SGP	28	42.3%
Lebanon	LBN	29	44.3%
Kyrgyzstan	KGZ	30	41.5%
Paraguay	PRY	31	46.2%
Czechia	CZE	32	42.2%
Samoa	WSM	33	46.3%
Ukraine	UKR	34	44.5%
Tunisia	TUN	35	43.6%
Australia	AUS	36	42.9%
Uruguay	URY	37	41.2%
Hungary	HUN	38	41.6%
Costa Rica	CRI	39	48.1%
China, Hong Kong SAR	HKG	40	47.6%
Kazakhstan	KAZ	41	45.2%
Croatia	HRV	42	46.5%
United Arab Emirates	ARE	43	44.5%

Continued on next page

Table 5 – continued from previous page

Country	ISO3 Code	Average Rank	Average AVE
Palau	PLW	44	44.1%
Zimbabwe	ZWE	45	48.0%
Malaysia	MYS	46	45.7%
Portugal	PRT	47	43.5%
Viet Nam	VNM	49	46.1%
Serbia	SRB	50	45.0%
Barbados	BRB	51	49.2%
Russian Federation	RUS	52	43.4%
Slovakia	SVK	53	45.2%
Mongolia	MNG	54	46.4%
Finland	FIN	55	49.5%
Colombia	COL	56	44.4%
El Salvador	SLV	57	48.8%
Mauritius	MUS	58	51.8%
Iceland	ISL	59	45.2%
Thailand	THA	60	47.6%
Sweden	SWE	61	44.6%
Rwanda	RWA	62	52.9%
Maldives	MDV	63	58.1%
Kuwait	KWT	64	46.2%
Ireland	IRL	65	48.1%
Fiji	FJI	66	61.5%
State of Palestine	PSE	67	51.4%
Chile	CHL	68	50.5%
Belize	BLZ	69	59.4%
Japan	JPN	70	49.1%
Turkey	TUR	71	48.5%
Germany	DEU	72	49.0%
Israel	ISR	73	50.1%
Spain	ESP	74	48.0%
Denmark	DNK	75	52.0%
USA	USA	76	48.1%
Austria	AUT	77	50.0%
Argentina	ARG	78	51.6%
Bahrain	BHR	79	49.2%
France	FRA	80	48.4%
Nepal	NPL	81	54.5%
Poland	POL	82	50.4%
Seychelles	SYC	83	64.9%
Burundi	BDI	84	62.5%
Guyana	GUY	85	60.1%
Jamaica	JAM	86	61.4%
Dominican Rep.	DOM	87	54.9%

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Table 5 – continued from previous page

Country	ISO3 Code	Average Rank	Average AVE
Saint Lucia	LCA	88	55.8%
Italy	ITA	89	49.5%
Greece	GRC	90	52.0%
Switzerland	CHE	91	52.5%
Mozambique	MOZ	92	58.2%
Cyprus	CYP	93	50.7%
Botswana	BWA	94	59.3%
Brazil	BRA	95	56.8%
Peru	PER	96	53.4%
Oman	OMN	97	54.4%
Ethiopia	ETH	98	57.2%
Suriname	SUR	99	58.5%
Malta	MLT	100	55.6%
Uganda	UGA	101	65.8%
Tonga	TON	102	62.5%
United Kingdom	GBR	103	54.3%
Canada	CAN	104	52.8%
Sri Lanka	LKA	105	58.5%
Togo	TGO	106	67.1%
Antigua and Barbuda	ATG	107	61.8%
Burkina Faso	BFA	108	71.3%
Senegal	SEN	109	58.5%
Rep. of Korea	KOR	110	59.8%
Egypt	EGY	111	56.5%
Bermuda	BMU	112	58.5%
Azerbaijan	AZE	113	56.6%
Angola	AGO	114	61.1%
United Rep. of Tanzania	TZA	115	65.1%
Sao Tome and Principe	STP	116	61.4%
Trinidad and Tobago	TTO	117	55.2%
Algeria	DZA	118	57.6%
Guatemala	GTM	119	57.9%
FS Micronesia	FSM	120	72.8%
Bahamas	BHS	121	58.3%
Norway	NOR	122	55.6%
Zambia	ZMB	123	64.8%
Greenland	GRL	124	68.0%
Morocco	MAR	125	59.8%
Romania	ROU	126	58.0%
Brunei Darussalam	BRN	127	61.3%
India	IND	128	60.2%
China	CHN	129	67.0%
Andorra	AND	130	73.3%

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Table 5 – continued from previous page

Country	ISO3 Code	Average Rank	Average AVE
Gambia	GMB	131	70.3%
Central African Rep.	CAF	132	60.4%
Albania	ALB	133	63.9%
Yemen	YEM	134	65.3%
Kiribati	KIR	135	70.2%
Côte d'Ivoire	CIV	136	72.6%
Niger	NER	137	78.2%
Qatar	QAT	138	66.0%
Honduras	HND	139	67.6%
Sierra Leone	SLE	140	68.2%
Mexico	MEX	141	64.1%
Panama	PAN	142	65.9%
Madagascar	MDG	143	73.6%
Luxembourg	LUX	144	70.5%
Saint Vincent and the Grenadines	VCT	145	70.7%
Cambodia	KHM	146	73.5%
Ghana	GHA	147	85.2%
Guinea	GIN	148	88.6%
Cameroon	CMR	149	84.9%
Mauritania	MRT	150	80.2%
Dominica	DMA	151	83.1%
Congo	COG	152	91.8%
Pakistan	PAK	153	81.9%
Bangladesh	BGD	154	83.7%
Papua New Guinea	PNG	155	97.8%
Indonesia	IDN	156	78.5%
Kenya	KEN	157	78.7%
Benin	BEN	158	106.4%
Philippines	PHL	159	78.3%
Myanmar	MMR	160	117.8%
Comoros	COM	161	122.4%
China, Macao SAR	MAC	162	95.0%
Lao People's Dem. Rep.	LAO	163	105.9%
Sudan	SDN	164	111.2%
Iraq	IRQ	165	132.0%
Solomon Isds	SLB	166	125.9%
Lesotho	LSO	167	119.8%
Nigeria	NGA	168	113.4%
Bhutan	BTN	169	119.4%
Mali	MLI	170	119.7%

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Table 5 – continued from previous page

Country	ISO3 Code	Average Rank	Average AVE

Note: The average rank and AVE are both independently calculated across all product codes and may not perfectly align. Because of the variance in estimated AVEs, a country's AVE may be slightly higher or lower than the countries ranked higher or lower that it.