

# Legal and regulatory issues to watch for in the medical technology industry: International trade — customs, export controls, sanctions, CFIUS and trade policy

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## SECTION 301 CUSTOMS DUTIES CONTINUE TO EXPAND — WITH THE POSSIBILITY FOR MORE IN 2020.

Since 2018, the Trump administration has engaged in its own “trade war” by using established statutory authority — Section 301 of the Trade Act of 1974 — to issue additional customs duties on various goods imported into the U.S. Although President Trump insists that Section 301 duties help American industry, many businesses, including ones in the medtech and health care sectors, have struggled to keep pace with the ever-changing Section 301 landscape.

In July 2018, President Trump first used Section 301 to impose additional duties against certain goods of Chinese origin. Now, the U.S. government has placed additional duties on almost all goods of Chinese origin.<sup>1</sup>

In mid-December 2019, there was some good news, as China and the U.S. reached a “phase one” deal, which resulted in the U.S. declining to add Section 301 tariffs to a final \$160 billion worth of Chinese-origin goods (which were originally scheduled to take effect on December 15th).<sup>2</sup>

However, this “phase one” deal is now on the brink of collapsing due to the impact of the COVID-19 pandemic on the US and China economies, and blame game that has ensued between the two countries.

Medtech companies should still carefully monitor the Section 301 China duties to ensure that they meet their legal requirement to pay any customs duties owed to the U.S. government — otherwise, they could be subject to severe penalties — but they should keep an eye out on whether more punitive tariffs are coming down the pipeline as a result of the collapse of the “phase one” deal.

If President Trump announces more tariffs, medtech companies should engage with the Administration and supporters in the US Congress to push back on any such increases.

And, while the COVID-19 pandemic may mean more punitive measures with respect to US-China trade, it has also resulted in certain trade facilitative measures for U.S. importers, including, but not limited to, the granting of additional Sec. 301 product

exclusions for medical goods (e.g., personal protective equipment and other medical and sanitizing goods) and temporary duty deferral.

The U.S. has also used Section 301 to issue duties on goods from other countries. In October 2019, it placed Section 301 duties on goods coming from various EU countries (e.g., Germany, United Kingdom),<sup>3</sup> and it has indicated that it may extend these duties.<sup>4</sup>

And, in December 2019, the U.S. government proposed another set of Section 301 duties, this time against French goods.

Some of the targeted tariff codes include ones that have been used by consumer health care companies on products like soap. And, although the U.S. government has not launched an official investigation yet, there have been rumblings of using Section 301 duties against India.<sup>5</sup>

In sum, there is a growing trend to use Section 301 as a means of molding trade and customs policy.

Medtech companies should consider ways to minimize Section 301 duty impact, including, but not limited to, product exclusion requests (which can mean big savings and retroactive refunds from U.S. Customs and Border Protection of already-paid Section 301 duties), country of origin and classification assessment and product sourcing modifications.

A thorough review of the related U.S. Customs legal principles may end up providing a duty mitigation strategy that could result in significant savings.

## HEIGHTENED SCRUTINY ON HEALTH DATA-RELATED TRANSACTIONS INVOLVING FOREIGN PERSONS.

Starting in 2020, the Committee on Foreign Investment in the United States (CFIUS) will have enhanced authority to scrutinize non-controlling foreign investments into the U.S. medtech sector that involves “sensitive personal data” regarding U.S. citizens.

CFIUS reviews focus on the national security concerns of such investments. These reviews can add time and costs to deal-making, require mitigating measures to be taken and even lead

to the blockage or forced divestiture of investments, which threaten U.S. national security.

In recent years, CFIUS has increased its focus on investments into businesses that collect or maintain sensitive personal data and/or large amounts of data, especially when Chinese investors are involved.

In September 2019, CFIUS issued proposed regulations that implement CFIUS reform legislation that was signed into law in 2018. Among other things, the proposed rules define what constitutes “sensitive personal data” of U.S. citizens.

This term will capture genetic information and categories of “identifiable information” (i.e., traceable to individuals), which would include health and insurance data, that is held by certain U.S. businesses.

Importantly, investments in such businesses that involve a “substantial interest” held by a foreign government may be subject to mandatory CFIUS reporting. The rules became effective in February 2020.

#### **U.S. SANCTIONS ACTIONS SHOULD BE CLOSELY WATCHED TO ASSESS MEDTECH BUSINESS CHALLENGES AND OPPORTUNITIES.**

The Trump administration has made significant use of economic sanctions to further its foreign policy goals, and it is likely to continue to do so this year, even amid the COVID-19 pandemic.

While medtech businesses should ensure they have established adequate measures to comply with all U.S. sanctions, those seeking to engage in dealings with Venezuela and Iran will want to be especially vigilant, as sanctions programs targeting these countries are particularly complex and continue to evolve.

The U.S. government’s sanctions regime against Venezuela has expanded significantly in recent months.

While the President, through U.S. Department of the Treasury, Office of Foreign Assets Control (OFAC), recently prohibited U.S. persons from dealing with the government of Venezuela, it also issued General License 4C,<sup>6</sup> which authorizes transactions involving medicine and medical devices to Venezuela, keeping the door open to opportunities for medtech companies to do business in Venezuela in compliance with U.S. sanctions.

In 2019, OFAC designated the Central Bank of Iran (CBI) as a Specially Designated Global Terrorist, but then issued General License 8 in February 2020 which authorizes the delivery of humanitarian goods to Iran if CBI is involved.<sup>7</sup>

Relatedly, in October 2019, the U.S. Treasury and State departments announced a new mechanism by which humanitarian goods, including medicine and medical devices, can be provided to Iran in compliance with U.S. sanctions.<sup>8</sup>

The mechanism requires certain enhanced due diligence and reporting from foreign financial institutions serving as channels to effectuate the transactions, but so long as these are met, medtech companies may find a permissible path to continue to provide medicine and medical devices to Iran.

In April 2020, OFAC issued consolidated guidance highlighting the most relevant exemptions, exceptions, and authorizations for humanitarian assistance and trade (including medicine and medical devices) under the Iran, Venezuela, North Korea, Syria, Cuba, and Ukraine/Russia-related sanctions programs.<sup>9</sup>

#### **EXPORT CONTROLS ON ENCRYPTION AND TELECOMMUNICATIONS CONTINUE TO EVOLVE AND AFFECT THE MEDTECH INDUSTRY.**

In May 2019, the U.S. Department of Commerce announced export controls restrictions against Chinese telecommunications equipment provider Huawei.

U.S. export controls limit the export of items, software and data, to include by electronic transmission outside of the U.S. and to non-U.S. persons within the U.S. (i.e., deemed exports).

Companies may need authorization from the U.S. Department of Commerce, Bureau of Industry and Security (BIS) prior to exporting items, such as electronic devices that use WiFi, Bluetooth and other telecommunications equipment.

In part, the new Huawei restrictions prohibit sending any U.S.-origin items, software or technology to Huawei without written authorization from Commerce.

This is having a major impact on U.S. technology companies, including companies in the medtech industry that, for example, may rely on Huawei smartphones or other equipment to deploy user applications.

After significant debate, Commerce started to issue licenses allowing some transactions with Huawei.

Additionally, in April 2020, Commerce issued additional rule changes that prohibit the export of many electronic items to military end-users or end-users in China and repealed two key licensing exceptions.

Some of the changes will be effective in June 2020 and others are already effective.

Once fully effective, this will be a significant expansion of prior rules. Commerce may issue additional rule changes and sanctions in the near future focused on China.

Medtech, telecommunications, semiconductor, and other companies are actively evaluating their compliance programs and impact.

Medtech companies who may be providing any items, software or technology to Huawei and/or whose own customers may

rely on using Huawei devices and/or any entity in China with a potential military connection need to carefully review their compliance protocols, supply chains and export licensing requirements.

In June 2019, Commerce also presented updates regarding their perspective on threats to national security, encryption controls and deemed export controls. In a session regarding encryption controls, Commerce noted various changes, including decontrols on “internet of things” items.

This includes changes to reduce controls on items that are connected for consumer applications, which could include some medtech devices designed for patient use and which have encryption to flow data between the patient’s device and other systems.

Additionally, in a session regarding deemed exports, Commerce specifically flagged that companies in the biotechnology and pharmaceuticals, acoustic communications and sensors, quantum computing, and communications and encryption technology are being targeted by foreign nations to use clandestine and illegal methods to collect those companies’ technologies.

Commerce also provided guidance on its concerns and how to successfully structure deemed export license applications. Those licenses can be critical to medtech companies who want to share controlled technology with non-U.S. employees.

In the coming year, medtech companies should carefully monitor what technology they have, how it is controlled under the export regulations, their internal access – and facility – control compliance programs and any licensing requirements.

### LIKELY DEVELOPMENTS – BOTH POSITIVE AND NEGATIVE – IN TRADE AGREEMENTS AND MARKET ACCESS.

The medtech industry can expect developments on international trade agreements and market access issues during the second half of 2020.

Trade agreements often include provisions related to tariffs as well as non-tariff issues, such as standard-setting, licensing, price controls and intellectual property rights.

For example, the recently finalized U.S.-Mexico-Canada Agreement (USMCA) will be going into effect on July 1.

The final amended USMCA removed the original provision on biologics, which provided 10-year data exclusivity protections for the class of drugs.<sup>10</sup>

USTR also has ongoing or upcoming bilateral negotiations with Japan, the European Union, Kenya, the United Kingdom and Brazil, all of which could affect the medtech industry.

Globally, several regional trade agreements may also be negotiated or concluded in 2020, including the 10-member Regional Comprehensive Economic Partnership (RCEP) and the expansion of the 11-member Comprehensive and Progressive Trans-Pacific Partnership (CPTPP).

### Notes

<sup>1</sup> See Notice of Modification of Section 301 Action: China’s Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation, 84 Fed. Reg. 45823 (Aug. 30, 2019).

<sup>2</sup> See Notice of Modification of Section 301 Action: China’s Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation, Office of the U.S. Trade Representative, available at <https://go.aws/3fUmyP5>.

<sup>3</sup> See Notice of Determination and Action Pursuant to Section 301: Enforcement of U.S. WTO Rights in Large Civil Aircraft Dispute, 84 Fed. Reg. 54245 (Oct. 9, 2019).

<sup>4</sup> See Office of the United States Trade Representative, Review of Action: Enforcement of the U.S. WTO Rights in the Civil Aircraft Dispute, USTR.gov (Dec. 6, 2019), <https://bit.ly/3bxiS1W>.

<sup>5</sup> See Sriram Lakshman, U.S. Will Consider ‘301 Probe’ on India, says Trade Official, The Hindu (July 12, 2019), <https://bit.ly/35ZifgB>.

<sup>6</sup> Venezuela General License 4C, U.S. DEPARTMENT OF TREASURY, <https://bit.ly/2Z1JbLb>.

<sup>7</sup> Treasury Sanctions Iran’s Central Bank and National Development Fund, U.S. DEPARTMENT OF TREASURY (Sep. 20, 2019), <https://bit.ly/3fQGMJa>.

<sup>8</sup> Financial Channels to Facilitate Humanitarian Trade with Iran and Related Due Diligence and Reporting Expectations, U.S. DEPARTMENT OF TREASURY (Oct. 25, 2019), <https://bit.ly/3fNRd0o>.

<sup>9</sup> OFAC, Fact Sheet: Provision of Humanitarian Assistance and Trade to Combat COVID-19 (Apr. 16, 2020), <https://bit.ly/2WVve15B>.

<sup>10</sup> See Adam Behsudi, Democrats get to Yes on USMCA, Politico (Dec. 10, 2019), <https://politi.co/3cyVH8V>. See also Grace Segers and Melissa Quinn, House Democrats Announce Deal on U.S. – Mexico – Canada Trade Agreement, CBS News (Dec. 10, 2019), <https://cbsn.ws/2WvwxB>.

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