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Chinese Device Exports, Supply Chains Holding Up In The Face Of Coronavirus – For Now

by Shawn M. Schmitt

Exports of components and finished medical devices coming from coronavirus-stricken China will continue to flow to the US and other countries for now, but there could be trouble soon if government quarantines and international travel bans remain in place, an industry expert in Shanghai tells *Medtech Insight*.

Exports of components and finished medical devices coming from coronavirus-stricken China will continue to flow to the US and other countries for now, but there could be trouble soon if government quarantines and international travel bans remain in place.

That's the upshot from Stephen Sunderland, a partner in the Shanghai office of L.E.K. Consulting, and an expert on medtech and health care in China. He says many device makers there probably stockpiled inventory before the weeks-long Chinese New Year festivities began, alleviating short-term shortage fears.

"The timing of the outbreak and the ramp-up in the outbreak relative to the New Year is a double-edged sword, for sure," Sunderland told *Medtech Insight* in a 4 February interview.

The first case of coronavirus 2019-nCoV was reported on 31 December in Wuhan, the capital city of Hubei province in central China.

"The pre-Chinese New Year season is a very busy season for production schedules – typically that's when inventories are run up," Sunderland said. "If it's an export or export-driven business, then they'll have loaded up their lorries over the last couple of weeks" before the New Year began on 25 January.

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There are more than 11,000 manufacturers of class II and III devices in China, according to data provided by L.E.K. Consulting. (See the interactive map below.)

Of those firms, about half are located in the provinces of Jiangsu and Guangdong, and the cities of Tianjin and Shanghai – all on coastal land that is some distance from the landlocked Hubei, the epicenter of the 2019-nCoV outbreak. Nevertheless, those four areas have seen incidents of the virus, too.

Medtech Manufacturing In China

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Source: JSMPA; NMPA; Tianjin Municipal Commission of Industry and Information Technology; Guangdong MPA; L.E.K. Consulting analysis

"I would expect that most of those 11,000-plus firms will be affected because their staff will be effectively on leave" because of quarantines, Sunderland said. "They're not allowed to produce any output. They're not allowed to congregate. They're not allowed to come to the office. They're not allowed to do any of that."

Complicating matters, he said, is that many device makers – even if their manufacturing facilities are located outside Hubei – will have some staff and/or key personnel who have traveled recently to Wuhan or, more broadly, Hubei.

"That could have some impacts on the firms' ongoing operations or some part of their supply chains," Sunderland said. "The impact should be effectively severe and relatively broad as we get toward the end of February, assuming that there aren't further extensions of the current holiday mode."

"The US flow to China is a lot of finished product - relatively highvalue product - while a lot of the flow from China to the US is either intermediate manufactured product or lower-value finished product." - Stephen Sunderland

Sunderland pointed out, however, that only a fraction of Chinese device manufacturers – "hundreds of firms," he says – export product.

Those exports are typically what the US International Trade Administration (ITA) calls "low-end consumables," including false teeth, hearing aids and wheelchairs, just a to name a few. But when it comes to "high-end consumables" – diagnostic imaging and endoscopy devices, for example – the <u>ITA said in a 2018 report</u> that China is more of an importer.

In fact, industry advocacy group AdvaMed confirmed with *Medtech Insight* on 6 February that devices and diagnostics imported from China account for less than 3% of the \$170bn US medtech market.

"The trade-flow balance around medtech from the US to China and China to the US in dollar-value terms is relatively balanced," Sunderland said. "But the US flow to China is a lot of finished product – relatively high-value product – while a lot of the flow from China to the US is either intermediate manufactured product or lower-value finished product."

The good news is that many of those lower-end products can be bought from manufacturers outside of China – undoubtedly a relief for health care providers who are worried about device shortages.

"Consider a low-value surgical instrument coming out of China that's used in US hospitals. If those hospitals need to find an alternate source for them, they can do that, because there are manufacturing sources south of the border in Mexico, and other places around the world," Sunderland said.

"And ultimately, if that supply [of products from outside China] dries up, there are alternatives that are maybe more costly, but are unlikely to lead to full stock-outs – or at least it will allow caregivers to use their inventory in a more controlled way," he added.

FDA, AHA Address Potential Shortages

In a 3 February email to *Medtech Insight*, US Food and Drug Administration spokesperson Megan McSeveney said manufacturers "have not reported impacts on the supply chain that are creating the potential for shortages of critical medical products in the US," but she acknowledged that "this remains an evolving situation."

McSeveney went on: "If there is a potential disruption reported, we will

FDA Responds To Coronavirus By Getting Out First Emergency-Use Novel Coronavirus Diagnostic

By Sue Darcey

04 Feb 2020

The US agency on 4 February issued its first Emergency Use Authorization of a 2019-novel coronavirus test by enabling emergency use of the Centers for Disease Control and

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utilize all tools we have available, such as working with manufacturers and expediting review of alternate supply, to prevent shortages."

She noted that the FDA has been in contact with manufacturers to remind them that they should notify the agency if they experience supply disruptions.

Prevention's 2019-nCoV Real-Time RT-PCR Diagnostic Panel. The move will allow use of the test at any CDC-qualified lab across the US.

Read the full article here

"If a potential shortage of a critical medical product is reported, the FDA will take steps to quickly share that information with the public," McSeveney said.

"Our members have expressed concern that the already fragile supply chain will break with the worsening conditions in China." – Tom Nickels

Meanwhile, the American Hospital Association (AHA) also says it's not aware of any shortages to date – but it's worried that things could get out of hand quickly should the virus continue to spread.

"Because China produces such a large proportion of the US's drugs and medical supplies – especially personal protective equipment (like masks, gowns and gloves) that are used by hospital caregivers to protect themselves and their patients from infection – our members have expressed concern that the already fragile supply chain will break with the worsening conditions in China," AHA executive VP Tom Nickels said in a 4 February email.

He pointed out that the AHA is working with the US Department of Health and Human Services (HHS) – the overseer of the FDA – to keep it abreast of potential shortages.

"Hospitals and health systems are also working with their supply chain partners and local public-health authorities to ensure that they have adequate supplies of medications and personal protective equipment to get them through this public-health emergency," Nickels said.

US/China Trade War Forced Manufacturers To Reevaluate Supply Chains

One of the more immediate concerns for supply chains is the availability of Chinese upstream

componentry, consultant Sunderland said.

Such components can be "difficult to track because a lot of that from a trade-flow perspective can look like just other industrial goods," he said.

"So, for example, cable assemblies coming out of Guangdong – it doesn't really matter whether Varian [Medical Systems] is using them to plug into high-end radiotherapy devices, or Philips is using them to plug into a blender or one of its high-end medical diagnostic imaging units. It's pretty difficult from a trade flow to be able to tell which of those it is," Sunderland explained.

Boston Scientific Expects Up To \$40M Impact In Q1 From Coronavirus Outbreak; 10%-12% Revenue Increase For 2020

By Marion Webb

05 Feb 2020

Boston Scientific said in an earnings call it expects the coronavirus outbreak may lead to a \$10m to \$40m loss in first-quarter sales as a result of lower procedures volumes and disrupted supply chains in China. For the fourth quarter, Boston Scientific reported \$2.9bn in sales.

Read the full article here

He noted that most large US device companies have some level of Chinese componentry exposure.

"Some of that might just be cable assemblies, and maybe they can get that rerouted and sourced elsewhere in the same way that they could with a surgical knife – just buy it in Mexico," Sunderland said.

But switching to a new supplier can be quite disruptive for device makers, especially for firms that have had contracts with particular vendors for years. And things can become extra tricky if a firm buys components from a sole-source supplier.

If there is a (surprising) silver lining to all of this, it's that the ongoing trade war between the US and China forced device firms to reevaluate their supply chains long before the coronavirus popped up.

"Because of the trade war, companies have been questioning how much of their business is exposed to cross-border trade flows, particularly on the US/China route," Sunderland said.

"It was just assumed by firms that they could buy from suppliers halfway around the world without having much in the way of business risk or long-term economic consequence, but I think a lot of that type of complacent thinking has been unwound over the past 24 months."

Medtech Insight senior reporter <u>Ferdous Al-Faruque</u> contributed to this report.