

## Trump needs to back bioscience to boost US drug making say experts

By Gareth MacDonald+, 11-May-2017

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**President Donald Trump should foster biotech investment if he wants more US-made pharmaceuticals say experts who argue that cutting regulations to attract small molecule drug manufacturers will only have a limited effect.**

In January, the ex-reality TV star turned statesman said he planned to encourage pharma firms to manufacture in the US, suggesting *"they are leaving left and right. They supply our drugs but they don't make them here, to a large extent."*

Trump's claim of a manufacturing exodus is not supported by US Government data.

According to a 2016 report by the US Department of Commerce (DoC), the US is the world's largest drug importer, buying around \$86bn (€79bn) worth of medicines from suppliers overseas in 2015.

However, the same report also states the majority of the \$333bn worth of drugs used in the US are made in the country.

### Regulations

Trump's statement may be wide of the mark, but there may be a kernel of truth in his contention production has moved overseas as a result of US laws governing drug manufacturing – or "job-killing regulations" as he put it.

Industry consultant James Bruno, managing director of Chemical and Pharmaceutical Solutions, agreed that *"some manufacturing was moved due to lower standards and less FDA oversight outside of the US."*

He added that: *"The FDA has improved the inspection of foreign plants and more plants are being inspected and the drug lines are a little better now but we are still at risk. Recent warning letters in India and China prove that there are issues that need to be addressed."*

Trump – who met with drug industry executives just days after his inauguration – issued an executive order giving Government agencies 60 days to identify rules that can be eliminated.

### Market access

But, while US regulations are a factor, access to international markets is also an important driver according to Bruno, who suggested manufacturers had relocated overseas to be closer to places in which they will generate revenue in the future.

*"China and India have much larger market potential than in the west"* he said, adding *"companies are interested in taking advantage of this and some of it has to do with production moving to these areas to improve and assist in market penetration."*

This was echoed by industry consultant Roger LaForce, who told us *"US big pharma companies have manufacturing plants all over the world, depending on logistical, cost and other factors."*

### Overseas APIs

The US does rely on active pharmaceutical ingredients (APIs) made elsewhere – 80% of the ingredients used in the country come from overseas according to US Food and Drug Administration (FDA).

However, this reliance has little to do with US regulations and is more to do with the European origins of the chemical industry and the emergence of lower cost suppliers in Asia according to LaForce.

He told us: *"The chemical industry first developed in Europe, mainly Germany,"* adding that *"this advantage of longstanding know-how and industrial location has further evolved"* and cited firms like Bayer, Lonza and DSM as examples.

More recently API manufacturers in Asia have replaced European companies as key suppliers to the US. However, this is changing again according to LaForce, who said: *"Some 20 years ago, the pharmaceutical industry started to move their outsourcing demand towards India and China, a trend that has at least halted, as a lot of outsourcing is now swinging back to Europe."*

### Biotech focus

If Donald Trump really wants to encourage US drug manufacturing, he should take the dynamics of the API sector and the growing importance of regional markets into account and focus his effort in specialized areas like biotech according to LaForce.

*"Should the US government or industry really want to build again manufacturing know-how in the US, this should be done for new technologies like biotechnology; new manufacturing concepts; and automation to drive innovation."*

He went on to say that: *"Therefore the government should first invest in science and innovation in order to help the industry and people"* adding that *"to me it looks as if the new government is going it the opposite way so far."*

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