

## Medical device contractor settles FCA allegations based on TAA violations

13 August 2019

On Thursday, 8 August 2019 the U.S. Department of Justice (DOJ) [announced](#) that Danish medical device company, Ambu Inc. (Ambu), will pay US\$3.3 million to settle False Claims Act (FCA) allegations that it violated the Trade Agreements Act (TAA) (19 U.S.C. § 2518) by selling products to the Defense Logistics Agency (DLA) and the Department of Veterans Affairs (VA) that were made in China and Malaysia. The TAA restricts the federal government's purchase of "end products" to only those (1) manufactured in the United States or wholly manufactured in a "designated country," or (2) "substantially transformed" in the United States or a designated country. China and Malaysia are not designated countries.

According to the DOJ press release, Ambu executives certified that its products came from TAA-compliant countries despite allegedly knowing that most of the products were manufactured in noncompliant locations. Between December 2011 and March 2015, more than 80 percent of the products sold by Ambu to the federal government came from noncompliant countries.

FCA settlements are not new to the health care industry. Nearly 90 percent of recoveries during 2017 and 2018 under the FCA came from the health care industry, according to an [analysis by Bloomberg Law](#). The TAA focus of the allegations, however, is notable.

In recent years, there have been policy changes that have arguably increased the ability of the government to purchase products that do not meet the TAA standard. In 2016, the VA adopted a blanket non-availability determination for its Federal Supply Schedule contract that applies to innovator pharmaceutical products that are considered "covered drugs" under the Veterans Health Care Act of 1992. In addition, a 2018 decision by the Court of Federal Claims broadened the definition of "U.S.-made end product," under the Federal Acquisition Regulation TAA clause to include products subject to partial manufacture in the United States that do not otherwise meet the TAA "substantial transformation" test. See *Acetris Health, LLC v. United States*, No. 18-433C (Fed. Cl. 10 July 2018). However, this interpretation is pending appeal and may not survive.

Despite these changes, the Ambu settlement demonstrates that the government is still focused on and enforcing TAA compliance. In addition, private whistleblowers can initiate FCA complaints. (It is unclear whether or not a whistleblower was involved in the Ambu case.) To avoid FCA liability, it is important for companies to understand the evolving landscape and ensure that all certifications under federal contracts are current and accurate.

Should you have any questions about this alert or otherwise, please do not hesitate to contact our federal contracts team.

## Contacts



**Joy E. Sturm**  
Partner, Washington, D.C.  
T +1 202 637 5990  
[joy.sturm@hoganlovells.com](mailto:joy.sturm@hoganlovells.com)



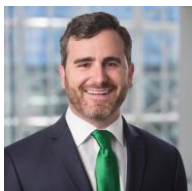
**Allison D. Pugsley**  
Partner, Washington, D.C.  
T +1 202 637 6817  
[allison.pugsley@hoganlovells.com](mailto:allison.pugsley@hoganlovells.com)



**David (Dave) W. Burgett**  
Senior Counsel, Washington, D.C.  
T +1 202 637 6597  
[david.burgett@hoganlovells.com](mailto:david.burgett@hoganlovells.com)



**Annie D. Vanselow**  
Senior Associate, Washington, D.C.  
T +1 202 637 5592  
[annie.vanselow@hoganlovells.com](mailto:annie.vanselow@hoganlovells.com)



**Ryan M. Harrigan**  
Associate, Washington, D.C.  
T +1 202 637 3586  
[ryan.harrigan@hoganlovells.com](mailto:ryan.harrigan@hoganlovells.com)

## [www.hoganlovells.com](http://www.hoganlovells.com)

"Hogan Lovells" or the "firm" is an international legal practice that includes Hogan Lovells International LLP, Hogan Lovells US LLP and their affiliated businesses. The word "partner" is used to describe a partner or member of Hogan Lovells International LLP, Hogan Lovells US LLP or any of their affiliated entities or any employee or consultant with equivalent standing. Certain individuals, who are designated as partners, but who are not members of Hogan Lovells International LLP, do not hold qualifications equivalent to members. For more information about Hogan Lovells, the partners and their qualifications, see [www.hoganlovells.com](http://www.hoganlovells.com). Where case studies are included, results achieved do not guarantee similar outcomes for other clients. Attorney advertising. Images of people may feature current or former lawyers and employees at Hogan Lovells or models not connected with the firm.  
© Hogan Lovells 2019. All rights reserved.