

TAA Case Is Study On Contractors' FCA Vulnerability

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The U.S. Department of Veterans Affairs and Department of Defense are major buyers of medical devices and supplies. Companies wishing to sell in this multibillion dollar market, however, must be aware of an important federal procurement requirement regarding country of origin, which is inapplicable to nonfederal sales, and understand the risk of noncompliance.

Government contractors must agree that the products they sell to the U.S. government under contracts valued in excess of \$204,000 comply with the Trade Agreements Act, unless the TAA requirement is waived by a federal agency. Failure to comply with this requirement has provided grounds for whistleblower actions under the False Claims Act, particularly against companies that sell commercial items under Federal Supply Schedule contracts or through Distribution and Pricing Agreements, which require compliance with the TAA.

Recently, Smith & Nephew Inc., a medical device manufacturer, settled what may be the first such case involving allegations that a company knowingly sold medical devices manufactured in a country not compliant with the TAA to the company's government customers. See *United States ex rel. Cox v. Smith & Nephew Inc.*, No. 2:08-cv-02832 (W.D. Tenn., order of dismissal, Sept. 4, 2014).

Trade Agreements Act Requirements

The TAA is intended to remove barriers to government procurement of foreign-sourced items and to incentivize countries to become signatories to the World Trade Organization Government Procurement Agreement and other international trade agreements. When a contract is subject to the TAA, the Buy American Act and its preference for end items manufactured in the U.S. is waived, creating more opportunity for companies selling foreign-made products. At the same time, the TAA prohibits the U.S. government from acquiring end items other than those made in the U.S. or countries that have signed the WTO GPA (referred to as "designated country end products"), unless the agency determines that offers of eligible items are unavailable or insufficient to fill the agency's needs. If a contract is below the threshold amount, the agency may acquire an item made in a nondesignated country, such as India or China, under that contract. For contracts in which the quantity of items that may be ordered is indefinite, the estimated contract value is used in determining whether the applicable threshold has



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been exceeded. As a policy matter, the TAA applies to all FSS contracts, including those covering medical supplies and devices administered by the VA.

The TAA is implemented through mandatory contract clauses in government contracts over the threshold amount and country of origin representations and certifications made by companies responding to a federal contract solicitation, as prescribed by the Federal Acquisition Regulation Part 25.4 and FAR 52.225-3 through 52.225-6. A product's country of origin must be disclosed when it is manufactured in a nondesignated country. If the TAA applies, the contracting agency, in its discretion, may make a nonavailability determination or may request a categorical waiver of the TAA from the Office of the U.S. Trade Representative. The agency also may order small amounts of the product under individual contracts below \$204,000 in value without regard to the TAA. Unless the TAA has been waived or is, by law, inapplicable to a transaction, the acquisition of end items from a nondesignated country violates the TAA. Accurate representations by the contractor are thus necessary for a federal customer to adhere to procurement law and regulations.

The test the government uses for determining country of origin under the TAA is the "substantial transformation" test applied by U.S. Customs and Border Protection when assessing import duties under Section 304 of the Tariff Act of 1930, and implementing regulations. Customs' regulations define "country of origin" as "the country of manufacture, production or growth of any article of foreign origin entering the United States" and also provide that "[f]urther work or material added to an article in another country must effect a substantial transformation in order to render such other country the 'country of origin' within the meaning of this part." 19 C.F.R. 134.1(b). In general, a substantial transformation occurs when an article emerges from a process with a new name, character or use different from that possessed by the article prior to processing, but will not result from minor manufacturing or combining process that leaves the identity of the article intact. Determining where a product has been substantially transformed into the end item acquired by the government often requires a fact-intensive analysis of the manufacturing process.

For example, in a July 2014 decision regarding the country of origin of a medical device that interfaces with a breath monitor, Customs considered the country of origin of the item's components, the extent of the processing that occurred within a country and whether such processing rendered a product with a new name, character and use. The device consisted primarily of tubing from Israel, cut to length in China and combined there with various connectors, filters and adaptors sourced from several countries. The decision noted that the "key issue is the extent of operations performed and whether the parts lose their identity and become an integral part of the new article," that "factors such as the resources expended on product design and development, extent and nature of postassembly inspection and testing procedures and the degree of skill required during the actual manufacturing process may be relevant," and that "assembly operations that are minimal or simple, as opposed to complex or meaningful, will generally not result in a substantial transformation." Holding that the tubing imparted the essential character to the end product and that this tubing was not substantially transformed by the cutting and assembly operations in China, Customs, in this case, held that the country of origin of the finished product was Israel.

Although required to certify TAA compliance, a reseller of an item acquired from its manufacturer may be unable to validate country of origin independently. Recently, however, the D.C. Circuit affirmed in another whistleblower case that resellers may reasonably rely on their suppliers' country of origin representations, and, absent evidence that would make such reliance unreasonable, need not conduct independent evaluations before they provide their own certifications in order to shield themselves from FCA liability. See *United States ex rel. Folliard v. Gov't Acquisitions Inc.*, No. 13-7049 (D.C. Cir. Aug. 29,

2014).

This was an important decision for wholesalers and distributors that contract directly with agencies like the DOD and VA to supply medical devices that they purchase from device manufacturers. In such cases, the contractor may not be liable if the product is a nondesignated country end item, but misrepresentation concerning country of origin by the manufacturer supplying the contractor could still be potentially actionable against the manufacturer.

Once a company represents that an item is a U.S. or designated country end product and it is placed on the company's FSS contract, the company must ensure that units manufactured in nondesignated countries are not delivered to government customers ordering under the FSS. If a manufacturer of medical supplies sources a product in a nondesignated country for sale to commercial customers, because it is more economical to do so, it must have a second, designated-country source before it sells the product to the federal government under its FSS contracts and must have inventory controls designed to ensure that shipments to government customers conform to the representations and certification of TAA compliance. The VA has explicitly advised manufacturers sourcing from nondesignated countries of the need to implement such inventory controls. See Dear Manufacturer Letter [here](#).

Smith & Nephew Settlement

In the Smith & Nephew case, the company allegedly imported items from Malaysia, a nondesignated country, repackaged them in the U.S. and failed to segregate them from products sourced in designated countries that could be sold to the government. Thus, the company could not ascertain whether units shipped to customers that ordered under its medical/surgical FSS contract or the GSA Advantage website were TAA compliant. The company voluntarily disclosed to the DOD Office of Inspector General and VA National Acquisition Center that it may have violated procurement law and the terms of its contracts and took corrective action. However, three months later, a former employee filed a whistleblower action against the company for knowingly violating the TAA, and the court declined to dismiss the case on the grounds that the FCA public disclosure bar applied to the voluntary disclosure.

Reducing the Risk of Liability in TAA Whistleblower Suits

The Smith & Nephew case highlights the vulnerability of device manufacturers that source products from nondesignated countries to potential FCA liability and the need not only for diligence in ascertaining country of origin, but also for controls to prevent products manufactured in nondesignated countries from being supplied to the government when such sales are not permitted.

Reasonable controls could include: (1) a system that identifies country of origin, and segregates and tracks inventory from import to shipment if items are purchased from both designated and nondesignated countries; (2) a system that monitors sourcing decisions before changes are made to ensure the item continues to be substantially transformed in the U.S. or a designated country; (3) a policy requiring country of origin representations of vendors if the components are not later substantially transformed into the delivered end item; and (4) a procedure for obtaining legal opinions when the country of origin is unclear or, in some cases, an opinion from Customs.

Purchasing items made in nondesignated countries may substantially reduce production costs and make economic sense, and a company's sales to the federal government may be very small compared to its commercial business. However, the risk of exposure to a whistleblower suit and the consequences for

failing to implement measures to avoid violating the TAA are likely considerably greater than the cost of compliance.

In the Smith & Nephew case, the company was forced to defend an action that settled for millions of dollars even though it disclosed the situation to the VA, and the department neither referred the matter to the U.S. Department of Justice nor intervened in the whistleblower case after it was unsealed.

Judicial precedent is currently divided over the application of the public disclosure bar to such voluntary disclosures. In the Smith & Nephew decision, it is unclear whether the company's disclosure to the VA affected the settlement negotiations in which the VA participated, or the department's decision not to intervene, but it is also noteworthy that the VA's policy has been to encourage self-disclosure. Thus, although the company's actions did not shield it from a whistleblower suit, they may have protected the company from greater harm.

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