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How Government Contractors Can Navigate Trade Agreements and False Claims

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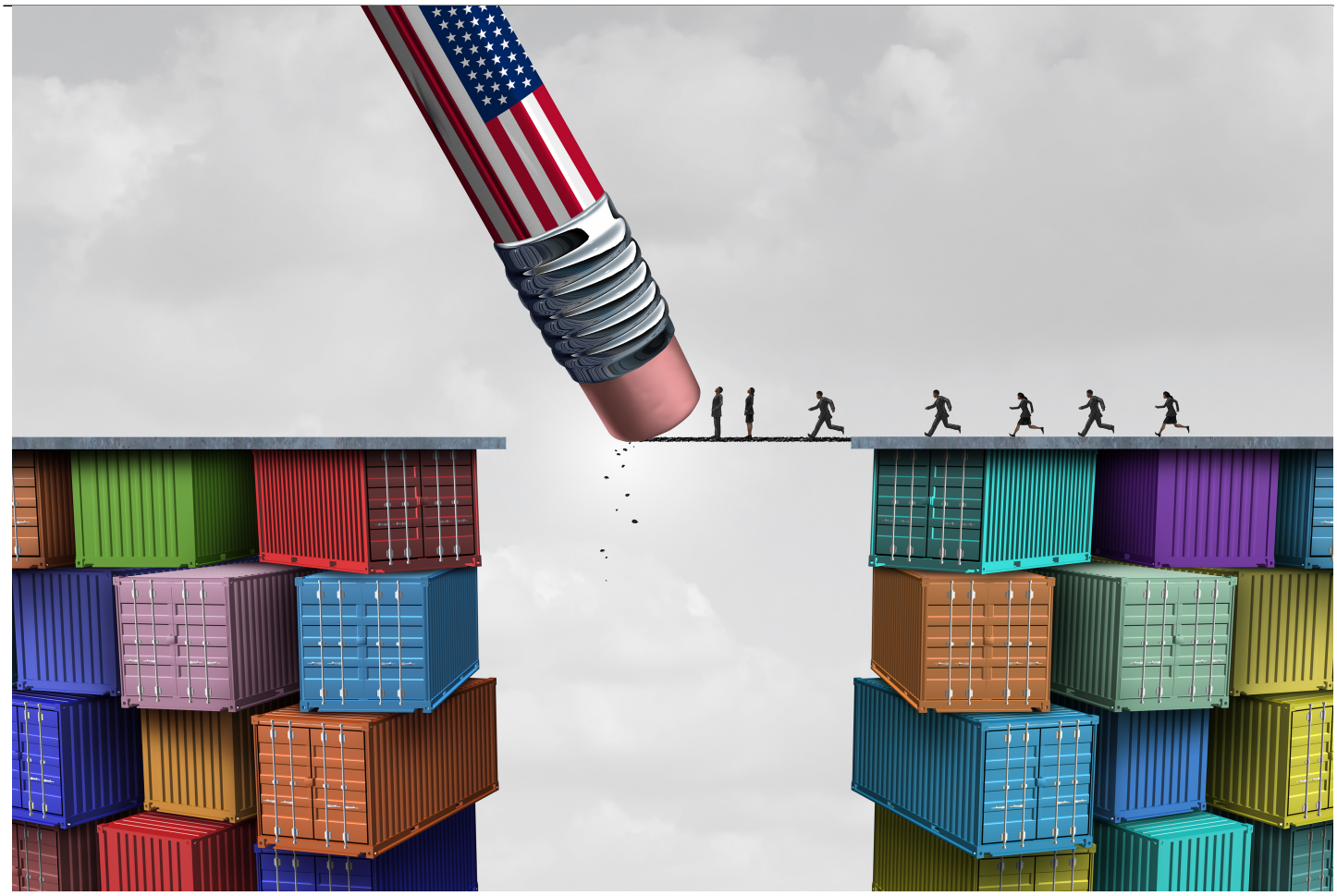

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Cheat Sheet

- **Criminal and civil risk.** Companies that engage in US federal procurement contracts are at risk of criminal and civil liability under the False Claims Act (FCA) if their products or services are not compliant with the Trade Agreements Act (TAA).
- **Supply chain challenges.** Compliance requires sufficient visibility and coordination across a company, particularly as sourcing strategies adjust in real time due to inflation, war, and other obstacles.
- **Clear violations are targets**. While recent case law has created some doubt as to the applicable standard for TAA compliance at the margins, clear-cut examples of violations are enticing targets for FCA prosecutions and/or *qui tam* actions.
- **If in doubt, seek help.** An outside opinion, for example from Customs and Border Protection, can be a key line of defense.

Companies that engage in US federal procurement contracts must comply with applicable country-of-origin laws, including most notably the Buy American Act of 1933 (BAA) or the Trade Agreements Act of 1979 (TAA). The TAA prohibits supplying products and services from non-designated (i.e., ineligible) countries, including major manufacturing countries like China and India. In recent years, individuals and corporations that violated these laws have been held liable under the False Claims Act (FCA). While there may be some gray areas at the margins of compliance, FCA liability for non-compliance usually follows a common pattern.

First, a corporation manufactures products in or acquires them from an ineligible country or countries, which becomes increasingly likely when products consist of multiple parts from various nations. The company then sells the products to a US government agency, in violation of the law. In parallel, the company submits an invoice for payment to the government agency, which certifies that the products are compliant. This submission, which is false, then triggers FCA liability.

> ... inadequate flow of information and coordination can lead to violations.

Although this pattern is common, varying company compliance and operational processes as well as case examples highlight the spectrum of actions (or inactions) that can ultimately lead to liability under the FCA. Indeed, a different department within an organization may be responsible for sourcing products or components than those making product design or manufacturing site decisions, or relevant certifications to the US government. Thus, inadequate flow of information and coordination can lead to violations. In this article, we outline the intersection between the TAA and the FCA, recent legal developments and enforcement trends, and practical compliance strategies for companies that can also offer a competitive edge.

Understanding the Trade Agreements Act

Effectively, the TAA harmonizes the United States' international free trade agreements with its domestic preference laws. A number of domestic preference laws (most notably the BAA) provide price or other preferences for US-origin products. Given that the TAA typically applies to larger contracts (US$200,000 or more), we have chosen to focus on this statute rather than the BAA.

Where applicable, the TAA works alongside relevant free trade agreements by guaranteeing there will be no discrimination against eligible foreign products and services while prohibiting the purchase of ineligible products and services (in other words, those from non-TAA designated countries). The list of TAA-designated countries is readily available online and changes with some major manufacturing countries, such as China and India.

A number of potentially relevant exemptions and exceptions to TAA compliance requirements exist, such as for small businesses. Discretionary agency waivers can be granted as well, especially if sourcing from TAA-designated countries is difficult or impossible.

Importantly, where the TAA applies — usually, only to US federal procurement contracts for goods and services or construction procurements that meet certain threshold dollar amounts, which are adjusted every two years — there is an outright prohibition against countries that are not TAA-designated.

For services, the country-of-origin is where the company providing the services is "established," meaning the country of its headquarters or incorporation. However, the test for products is more complicated:

> An article is a product of a country or instrumentality only if (1) it is wholly the growth, product, or manufacture of that country or instrumentality, or (2) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

To the degree an end product contains any components from non-TAA-eligible countries, recent case law suggests that meeting the definition of mined, produced, or manufactured *in the United States* under the Federal Acquisition Regulation's definition is also sufficient for compliance. Thus, for end products manufactured in the US, meeting the substantial transformation test may not be necessary even if there are components from non-TAA-eligible countries. However, end products manufactured outside the US with components from ineligible countries must pass the test.

The substantial transformation test is fact-specific and based on the totality of the circumstances, focusing on the final stage of the process and determining whether, at that stage, the product is transformed into "a new and different article." Some factors that have been considered are the complexity and required skill level of the processes involved, and whether there is a new name, character, and use.

Intersection of the False Claims Act and the TAA

The FCA, 31 U.S.C. §§ 3729-3733, makes it unlawful for an individual or entity to submit, or cause to be submitted, false or fraudulent claims for payment to the US government. A FCA violation requires three elements:

1. Knowledge (including deliberate ignorance or reckless disregard);
2. Falsity; and
3. Materiality (i.e., the falsity must be material to the government's decision to pay or be paid).

While the TAA itself contemplates criminal penalties for false statements to the government under 18 US Code § 1001, the FCA has become an integral tool in combatting fraud in government contracts, including for TAA violations. If an individual or entity falsely represents that its products or services comply with the TAA, then the individual or entity may be liable for violating the FCA.

Repercussions for violating the FCA can be enormous: Violators can be liable for treble (triple) damages plus penalties ranging from US$12,537 to US$25,076 per violation plus attorney's fees and other costs. This gives financial incentive for private citizen whistleblowers ("relators") to assist in combatting fraud by filing *qui tam* suits on behalf of the government.

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Recent case law highlights such risk from both the government and individuals. For example, in August of 2022, a global healthcare company paid US$6.3 million to resolve FCA allegations that arose from selling needles that were manufactured in non-TAA-designated countries. Furthermore, the GSA's most recent Inspector General's semiannual report to Congress highlights deficiencies in TAA enforcement, suggesting that the agency "should address these weaknesses in order to support recent federal initiatives and ensure future compliance with federal regulations." In addition, comply with the TAA negatively impact reputation, it can also limit a company's ability to win contracts since

it can either rejecting an offer or for a bid protest. As an aside, FCA liability can also follow from other country-of-origin laws where the TAA does not apply, such as with contracts subject to the BAA.

Finally, while the government can uncover violations on its own, it is often employees, contractors, or even competitors who become the relators that bring potential FCA liability. For example, a 2018 case involved a relator that was a competitor of the defendant and accused the company of selling non-TAA compliant products to the government. Although the court dismissed the case, the suit serves as a reminder that TAA compliance can be a sword and a shield.

Compliance measures that can provide a competitive edge

Proper information flow

TAA compliance can resemble a fast shell game — with multiple shells and balls of different colors. In some industries, relevant products may be more likely to have the country-of-origin change regularly because of where parts come from and shifting design, manufacturing, or supply strategies.

For instance, smart devices that digitally connect with other hardware and software, such as sophisticated medical equipment, can consist of electronics, resins, and numerous other materials.

Business success depends on keeping an eye on the enterprise's moving parts.
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Some components may be more readily available and/or cost-effective from certain countries, with geopolitics, natural disasters, pandemics, and inflationary pressures compounding the picture. Continuously iterating functionality and/or safety improvements can further alter required components, where they are sourced, manufacturing processes, and/or where various stages of production occur.

At a minimum, therefore, companies with more complicated and evolving sourcing and manufacturing operations need to break silos and ensure enterprise visibility of information necessary for analyzing country-of-origin. This includes implementing policies and procedures — outlining the "why" behind the framework, what the relevant pieces of the puzzle are, who stewards them, where such data should go, when that should happen, and who has overall compliance accountability — as well as accounting for employee transition and onboarding that may affect the integrity of this information flow.

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Indeed, while knowledge is an essential element of TAA claims under the FCA, and enforcement often involves clear-cut fraud where a company knowingly provides products from a non-TAA eligible country and falsely represents these same products are TAA compliant, companies that possess requisite facts to verify TAA compliance but fail to do so have also been held liable for violating the FCA. In 2021, the US Department of Justice (DOJ) settled with Brighton Cromwell LLC on this failure to verify theory. Despite the fact that it knowingly engaged in a contract that required TAA compliance, Brighton Cromwell did not ascertain and verify that its products were not end products of a non-TAA eligible country. Numerous other examples exist of companies having to pay large amounts for violations of country-of-origin laws, with approximately 10 relevant settlements since 2014.

Beyond mitigating risk, proper visibility to information can guide strategy and accelerate speed to market. For example, managers, engineers, and others benefit from timely intel on proposed supply chain adjustments that are meant to address price and/or availability of materials needed for existing or future product releases.

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If contemplated sourcing changes could render particular configurations non-TAA compliant, or design alterations will entail components from non-TAA eligible countries, then a company that accounts for these considerations upfront can make better decisions on how to produce their goods (and for what markets). Clear overall accountability by a specific individual or individuals, such as someone who oversees all aspects of a particular product, thus facilitates both compliance and business optimization.

Automation

Comprehensive, practical policies, procedures, and associated training may still not suffice when facing dynamic and challenging factors such as those confronting companies in 2022-2023: COVID-19, war between Russia and Ukraine, economic sanctions, and soaring prices. Shifts in prevailing conditions may occur so rapidly that human efforts cannot keep pace.

Global enterprises might therefore invest in automated tools that can help keep up real-time or near real-time with these variables (with the ability to flag potential concerns) — including a company's own responses thereto, e.g., manufacturing and supplier locations — and how they impact country-of-origin

for one or more products. A single platform or paired technology could even routinely review contracts to identify ones that fall under the TAA, as the dollar threshold for TAA application are refreshed every two years.

Efficiency gains from such a solution would free precious bandwidth to focus on more complex, higher value tasks. Instead of manually checking updates to eligible countries and price thresholds for example, in-house counsel can stay abreast of more fundamental legal developments in this space, advise on less clear-cut substantial transformation determinations, and even help the business take advantage of any relaxed TAA requirements.

Documentation

Consistent with general best practices, companies should have a document retention policy that covers TAA-related content. When implementing an automated tracking mechanism, it is important to avoid inadvertent loss of records. Failure to archive has led to adverse inferences — that is, an unfortunate conclusion that the claims are false. Such an adverse inference was granted where the defendants first kept a manual spreadsheet, updated it a few times per year (i.e., it would be inaccurate at times until the updates) and then switched to an automated system that ultimately overwrote the prior country of origin information — without record of it being retained — until finally adopting a system that both had timely updates and preservation of historical data.

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Finally, companies should also integrate TAA compliance into their broader contracting framework. Since the TAA is not a mandatory flow down for subcontracts (and the prime contractor remains responsible for compliance), companies should ensure that relevant subcontracts with suppliers or other third parties have relevant assurances (for instance, resellers should obtain some level of certification from the manufacturer). Since the obligation ultimately sits with the prime contractor, subcontractors and foreign suppliers / manufacturers have far less incentive to address this area.

Get help when needed

Even with contracting management that accounts for the TAA, whether the latter applies is not always apparent from reviewing the certifications and clauses contained in agreements and solicitations to which a company is or seeks to become a party. Where there is some doubt, a contractor can seek clarity from counsel, who can assist in inquiring or other discussions with the procuring agency or the prime contractor as well. In addition to assessing whether other domestic preference laws could govern in the absence of a TAA requirement, counsel can potentially help companies by obtaining waivers.

Similarly, determining if actions are in fact compliant can also prove tricky. Where there is a close call, companies might seek an opinion from Customs and Border Protection as to country-of-origin in the form of either an advisory ruling or final determination. For instance, the “substantial transformation” prong of the TAA has led to potential liability under the FCA where a company and the government disagree as to whether the product underwent significant change.

In the recent case of *U.S. ex rel. Medina v. Stryker Orthopaedics*, the relator alleged that Stryker manufactured implantable medical devices in non-TAA-designated countries, shipped the products to

TAA-designated countries, and simply relabeled the products as a kit in the latter locations. Stryker claimed that changes essential to the end product's purpose or function occurred in a TAA-designated country because the end product was an entire surgical kit rather than the individual components. This case was ongoing as of August 2022. Having an outside opinion to back up a company's decisions can therefore provide a key line of defense.

Finally, when issues arise, companies have had some success defending FCA cases involving the TAA. To the degree a TAA violation forms the basis of an FCA proceeding, all the elements of a false claim must still be met, including materiality and knowledge. These can be difficult to prove. Materiality has become an area where defendants in FCA cases have found success in defending claims, particularly in light of the Supreme Court's 2016 decision in *Universal Health Services v. United States ex rel. Escobar*. Under the *Escobar* decision, continued payments by the government despite being aware of non-compliance are "very strong evidence" that violations are not material under the FCA. However, in with continued government payments, the court still refused to opine, holding that the issue was better left to a jury when the government sends "mixed signals."

Thus, having experienced counsel ready can potentially help companies mitigate or eliminate the harm from potential violations.

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