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TECHNOLOGY MARATHON

**2023 Technology Marathon: Enforcement Update:
False Claims Act and International Trade**

Jennifer Wollenberg, Ryan McCarthy, Giovanna Cinelli, and Casey Weaver

June 29th, 2023 | 12:00-1:00 pm ET

Presenters



Jennifer Wollenberg



Ryan McCarthy



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The False Claims Act

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A Brief Introduction to the FCA

- The False Claims Act (31 U.S.C. §§ 3729-3733) is a Civil War era statute
- FCA amendments in 1943, 1986, 2009, and twice in 2010 expanded reach
- Majority of states have their own false claims statutes, patterned after the federal FCA
 - Some municipalities with false claims laws

FCA Liability

Principal bases for FCA liability:

- Making a false claim for payment to the government
- Making/using a false statement material to a false claim for payment (including “implied” certs)
- Avoiding an obligation to pay the government (known as a reverse false claim)
- Conspiring to violate the FCA

Collateral Estoppel:

- Upon guilty verdict (or plea), essentially cannot contest civil liability

Elements of an FCA Claim

- **“Claim” for payment or approval**
 - Or avoidance of an “obligation” to pay
- **That is “false or fraudulent” (or improperly avoided)**
- **“Knowingly” presented, made, or avoided**
 - Specific intent to defraud not required
 - Actual knowledge, deliberate ignorance, or reckless disregard
- **That is “material” to the Government’s payment decision**

FCA Damages, Penalties, Etc.

- **Statute of Limitations & Statute of Repose**
 - Generally six years, but up to ten years in certain circumstances
- **Treble Damages**
 - Damages sustained by the government “because of” the defendant’s act
- **Penalties**
 - Currently between \$13,508 and \$27,018
- **Related Concerns**
 - Suspension, debarment

FCA: Unique Qui Tam Provision

- 31 U.S.C. § 3730
- Authorizes private parties to sue
- Suits are filed under seal
- DOJ decides whether to intervene
- Relator receives a monetary bounty
- Plus attorneys' fees
- Spawned a qui tam plaintiffs' bar
- Relators come in all stripes
- Litigation funding now commonplace
- FCA's anti-retaliation provision

Gatekeeping Defenses

- **Public Disclosure Bar**
- **First to File Bar**
- **Government Action Bar**
- **Rule 9(b)**

FCA Recent Developments

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Recent Supreme Court Activity

- *United States ex rel. Schutte v. SuperValu Inc.*
 - Consolidated with *United States ex rel. Proctor v. Safeway, Inc.*
 - Subjective, rather than objective, scienter standard when ambiguous requirement
 - [In Key FCA Scienter Opinion, US Supreme Court Turns Focus on Subjective Intent](#)
- *United States ex rel. Polansky v. Executive Health Resources, Inc.*
 - DOJ has easily-met dismissal authority, even after initial declination decision
 - But three justices raised question of Constitutionality of qui tam provisions
 - [US Supreme Court Affirms Easy Government Dismissal Standard in Declined Qui Tam Cases, But Renews Constitutionality Debate](#)

Some Key Percolating Legal Issues

- **FCA/AKS Causation**: Whether improper remuneration must be “but-for” cause of a false claim for payment; relevance of independent medical judgment of HCPs.
- **AKS Scierer**: Whether an AKS violation requires “corrupt” intent.
- **FCA Materiality**: Relevance of government’s continued payment after knowing of allegations.
- **FCA Falsity**: Whether clinical/scientific opinions must be “objectively false” to trigger liability.

DOJ FCA Statistics – October 1986 to September 2022

NEW MATTERS ⁶		SETTLEMENTS AND JUDGMENTS ¹				RELATOR SHARE AWARDS ²			
NON QUI TAM	QUI TAM	NON ³ QUI TAM	QUI TAM			TOTAL QUI TAM AND NON QUI TAM	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL
		TOTAL	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL				
6,234	15,246	22,193,023,126	45,638,537,388	4,747,135,786	50,385,673,173	72,578,696,300	7,485,285,864	1,134,144,243	8,619,430,108

DOJ FCA Statistics – Health and Human Services

FY	NEW MATTERS ^o		SETTLEMENTS AND JUDGMENTS ¹					RELATOR SHARE AWARDS ²		
	NON QUI TAM	QUI TAM	NON ³ QUI TAM	QUI TAM			TOTAL QUI TAM AND NON QUI TAM	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL
				TOTAL	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED				
1987	12	3	11,361,826	0	0	0	11,361,826	0	0	0
1988	5	7	2,182,675	355,000	0	355,000	2,537,675	88,750	0	88,750
1989	19	16	350,460	5,099,661	0	5,099,661	5,450,121	50,000	0	50,000

2020	122	459	402,745,794	1,295,390,759	180,079,049	1,475,469,808	1,878,215,602	230,136,355	48,094,625	278,230,979
2021	102	389	3,591,166,587	1,074,269,164	454,044,509	1,528,313,672	5,119,480,259	168,559,467	54,937,327	223,496,794
2022	93	371	106,369,498	641,697,050	1,013,116,617	1,654,813,666	1,761,183,164	115,525,911	296,535,477	412,061,388
TOTAL	1,469	9,306	11,594,083,366	35,132,871,824	3,711,760,235	38,844,632,059	50,438,715,425	5,788,750,879	885,764,744	6,674,515,623

DOJ FCA Statistics – Department of Defense

FY	NEW MATTERS ^o		SETTLEMENTS AND JUDGMENTS ¹					RELATOR SHARE AWARDS ²		
	NON QUI TAM	QUI TAM	NON ³ QUI TAM	QUI TAM			TOTAL QUI TAM AND NON QUI TAM	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL
			TOTAL	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL				
1987	236	21	27,897,128	0	0	0	27,897,128	0	0	0
1988	117	33	149,136,213	0	33,750	33,750	149,169,963	0	8,438	8,438
1989	115	36	154,588,297	10,002,058	0	10,002,058	164,590,355	1,394,770	0	1,394,770
2020	31	35	31,213,617	51,415,401	5,709,798	57,125,199	88,338,817	11,743,785	934,905	12,678,690
2021	26	27	21,778,471	98,491,421	35,000	98,526,421	120,304,892	20,062,097	10,150	20,072,247
2022	26	40	47,879,577	27,136,293	28,675,000	55,811,293	103,690,871	6,817,050	8,583,125	15,400,175
TOTAL	1,452	1,766	2,721,538,800	3,443,876,865	255,957,757	3,699,834,621	6,421,373,421	615,442,336	61,974,813	677,417,149

DOJ FCA Statistics – Other (Non-HHS & Non-DOD)

FY	NEW MATTERS ^o		SETTLEMENTS AND JUDGMENTS ¹					RELATOR SHARE AWARDS ²		
	NON QUI TAM	QUI TAM	NON ³ QUI TAM	QUI TAM			TOTAL QUI TAM AND NON QUI TAM	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL
				TOTAL	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED				
1987	92	7	47,220,995	0	0	0	47,220,995	0	0	0
1988	77	13	21,968,775	1,954,354	0	1,954,354	23,923,129	0	0	0
1989	81	42	42,263,423	10,000	1,681	11,681	42,275,104	2,000	200	2,200
2020	108	182	113,943,787	175,655,744	8,094,628	183,750,372	297,694,159	34,869,727	2,244,624	37,114,351
2021	84	182	380,433,763	65,056,279	26,574,764	91,631,041	472,064,805	12,753,493	7,540,921	20,294,414
2022	177	241	91,337,876	107,918,031	143,093,196	251,011,227	342,349,104	19,600,607	41,932,110	61,532,717
TOTAL	3,313	4,174	7,877,400,960	7,061,788,699	779,417,793	7,841,206,493	15,718,607,453	1,081,092,649	186,404,686	1,267,497,335

FCA Enforcement Trends

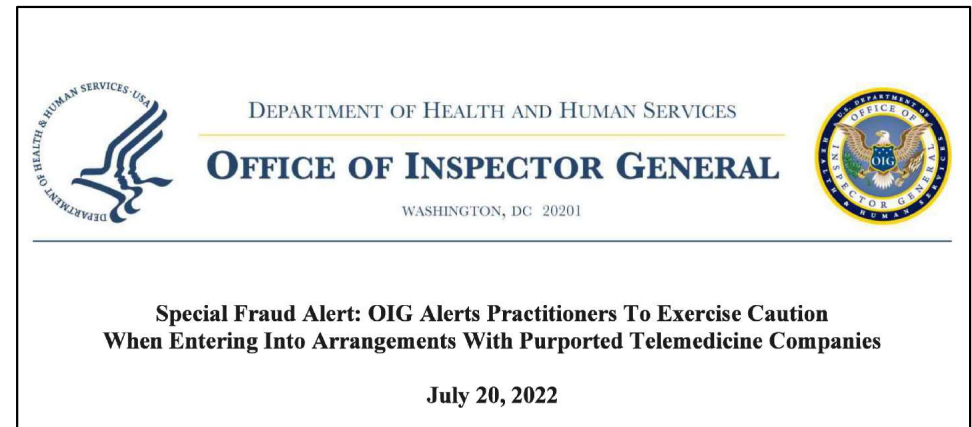
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FCA Enforcement Trend – Healthcare Companies

- **Key areas of recent and likely continued focus for DOJ and whistleblower bar**
 - Telehealth and other technology-aided provider services
 - Patient support programs, including copayment assistance
 - Involvement of HCPs in promoting products or services
 - Data security/privacy

FCA Enforcement Trend – Telehealth and Technology

- **Rapid growth of remote care during COVID-19**
- **Focus on distinct areas:**
 - Quality of remote patient encounters
 - Compensation and credentialing for remote providers
 - Prescriptions for drugs/DME resulting from remote patient encounters
- **Emerging issues implicating both the AKS and FCA**



- The Practitioner does not have sufficient contact with or information from the purported patient to meaningfully assess the medical necessity of the items or services ordered or prescribed.¹¹
- The Telemedicine Company compensates the Practitioner based on the volume of items or services ordered or prescribed, which may be characterized to the Practitioner as compensation based on the number of purported medical records that the Practitioner reviewed.

FCA Enforcement Trend – Patient Support

- **Services or support provided for patients can present FCA/AKS issues**
 - Patient assistance programs
 - Contributions to co-pay assistance foundations
 - Nurse educators
 - Transportation services
 - Assistance to clinics and non-profits (i.e., technology, equipment, etc. for storage and administration of drug)
 - Genetic testing programs
- **Government theory: All resulting claims are tainted by AKS violation → treble damages**

“Kickbacks in the healthcare industry are pernicious because of their potential to subvert medical decision-making and to increase healthcare costs.”

DOJ Press Release
(Feb. 1, 2022)

FCA Enforcement Trend – HCPs and Promotion

- **Focus on involvement of non-employee HCPs in promoting products and services that may be government-reimbursed**
 - Pharmaceutical promotional speaker programs/dinners/events; resumption of in-person activities with loosening of COVID-19 restrictions
 - HCP consultancies/boards
 - “White coat” marketing
- **Government theory: All resulting prescriptions/services are tainted → treble damages**



- Attendees include individuals who don't have a legitimate business reason to attend the program, including, for example, friends, significant others, or family members of the speaker or HCP attendee; employees or medical professionals who are members of the speaker's own medical practice; staff of facilities for which the speaker is a medical director; and other individuals with no use for the information;
- The company's sales or marketing business units influence the selection of speakers or the company selects HCP speakers or attendees based on past or expected revenue that the speakers or attendees have or will generate by prescribing or ordering the company's product(s) (e.g., a return on investment analysis is considered in identifying participants);

FCA Enforcement Trend – Government Contractors

- Procurement Collusion
 - Strike force established to “lead a coordinated national response to combat antitrust crimes and related schemes in government procurement, grant, and program funding at all levels of government”
- Technology and Cybersecurity Requirements
 - Host of requirements being incorporated into contracts
 - Federal Information Security Modernization Act
 - FAR and DFARS
 - National Institute of Standards and Technology Special Publication
 - Cybersecurity Maturity Model Certification
 - Often ambiguous requirements and changing technology landscapes
 - In October 2021, DOJ announced its Civil Cyber-Fraud Initiative

Enforcement Trend – State Laws & Non-Government Contractors

- In recent years, banks and other companies targeted for their unclaimed property / escheatment practices
 - Last year, Colorado passed a second expansive act to target this as first was limited to Medicaid fraud
- Tax avoidance has been a hot topic unique to certain state and municipal laws
 - NY just expanded law to include failure to file return

State	Qui Tam	Title of Statute
Alaska	No	State Procurement Code
Arizona	No	Arizona Health Care Cost Containment System*
Arkansas	No	Medicaid Fraud False Claims Act*
California	Yes	California False Claims Act
Colorado	Yes	Colorado False Claims Act
	Yes	Colorado Medicaid False Claims Act*
Connecticut	Yes	Connecticut False Claims Act*
Delaware	Yes	Delaware False Claims and Reporting Act
District of Columbia	Yes	District of Columbia False Claims Act
Florida	Yes	Florida False Claims Act
Georgia	Yes	Taxpayer Protection False Claims Act
	Yes	False Medicaid Claims*
Hawaii	Yes	Hawaii False Claims Act
Illinois	Yes	Illinois False Claims Act
Indiana	Yes	False Claims and Whistleblower Protection
	Yes	Medicaid False Claims and Whistleblower Protection*
Iowa	Yes	Iowa False Claims Act
Kansas	No	Kansas False Claims Act
Kentucky	No	Control of Fraud and Abuse*
Louisiana	Yes	Medical Assistance Programs Integrity Law*
Maine	No	Civil Liability of Persons Making False Claims*
Maryland	Yes	Maryland False Claims Act
	Yes	Maryland False Health Claims Act*
Massachusetts	Yes	Massachusetts False Claims Act
Michigan	Yes	The Medicaid False Claim Act*
Minnesota	Yes	False Claims Against the State
Mississippi	No	Medicaid Fraud Control Act*
Missouri	No	Health Care Payment Fraud and Abuse*
Montana	Yes	Montana False Claims Act

State	Qui Tam	Title of Statute
Nebraska	No	False Medicaid Claims Act*
Nevada	Yes	Nevada False Claims Act
New Hampshire	Yes	Medicaid Fraud and False Claims*
New Jersey	Yes	New Jersey False Claims Act
New Mexico	Yes	Fraud Against Taxpayers Act
	Yes	Medicaid False Claims Act*
New York	Yes	New York False Claims Act
North Carolina	Yes	North Carolina False Claims Act
	No	Medical Assistance Provider False Claims Act*
Oklahoma	Yes	Oklahoma Medicaid False Claims Act*
Oregon	No	Oregon False Claims Act
Puerto Rico	Yes	False Claims to Government of Puerto Rico Programs, Contracts, and Services Act (official law in Spanish)
Rhode Island	Yes	Rhode Island False Claims Act
Tennessee	Yes	Tennessee False Claims Act
	Yes	Tennessee Medicaid False Claims Act*
Texas	Yes	Texas Medicaid Fraud Prevention Act*
Utah	No	Utah False Claims Act*
US Virgin Islands	Yes	Virgin Islands False Claims Act
Vermont	Yes	Vermont False Claims Act
Virginia	Yes	Virginia Fraud Against Taxpayers Act
Washington	Yes	Medicaid Fraud False Claims Act*
Wisconsin	[Yes]	Wisconsin False Claims for Medical Assistance Act*
Wyoming	No	Wyoming Medicaid False Claims Act*

* Healthcare Only

FCA Enforcement Trend – Non-Government Contractors / Importers as FCA Defendants

- No government contract required / purely commercial businesses are at risk
- Discuss first the rules and enforcement mechanisms in the International Trade space and then circle back to the crossroads of FCA and Trade

Export Controls

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Overview of U.S. Export Jurisdiction

U.S. Department of State's Directorate of Defense Trade Controls ("DDTC")

- Exercises jurisdiction over manufacture, export, temporary import and brokering of defense articles, defense services, and technical data (including software related to defense articles)
- Items subject to DDTC jurisdiction are listed on the US Munitions List ("USML") in the International Traffic in Arms Regulations ("ITAR")
- An export license is almost always required
- Importers, exporters, manufacturers, and brokers of ITAR items are required to register with DDTC

U.S. Department of Commerce's Bureau of Industry & Security ("BIS")

- Exercises jurisdiction over exports of "dual-use" or military/commercial items (hardware, software, and technology)
- Items subject to BIS jurisdiction are listed on the Commerce Control List ("CCL") in the Export Administration Regulations ("EAR")
- An export license may be required, depending on the classification of the product, destination for the export, and/or end user
- BIS does not impose registration requirements

Overview of U.S. Export Jurisdiction

ITAR's U.S. Munitions List (USML)

- Contains 21 categories of defense items, technical data, and defense services (*e.g.*, ammunition, launch vehicles, military electronics, aircraft, spacecraft, military training equipment, engines)
- Controls apply to all countries
- Format in Roman Numerals with subcategories, *e.g.*, Category X(a)(1)

EAR's Commerce Control List (CCL)

- Contains ten (10) categories of commercial/military hardware, test equipment, material, software, and technology
- Very detailed technical specifications
- (Relatively) new 600 series and 9X515 ECCNs for transfer of items from USML to CCL
- Controls apply to selected countries
- Format in five (5) alpha-numeric characters with subcategories, *e.g.*, 1A613.d

What is an “export”?

- “Export” includes all of the following:
 - An actual shipment or transmission out of the United States, including the sending or taking of an item out of the United States in any manner
 - Performing a “defense service” on behalf of, or for the benefit of, a foreign person, whether in the United States or abroad
 - “Releasing” or otherwise transferring EAR-controlled “technology” or source code (but not object code), or ITAR-controlled “technical data” to a foreign person in the United States (a “deemed export”)
 - Release can be oral, visual, or written

Deemed Exports

- Under the ITAR
 - Foreign person = anyone who is **not** a U.S. citizen, green card holder, or protected individual; also any business entity or group that is not incorporated or organized to do business in the U.S.
 - Any export of ITAR-controlled technical data to a foreign person is deemed to be an export to **all** countries in which the foreign person has held or holds citizenship or holds permanent residency.
- Under the EAR
 - Foreign person = anyone who is **not** a U.S. citizen, green card holder, or protected individual; also any business entity or group that is not incorporated or organized to do business in the U.S.
 - Any export of EAR-controlled technology or source code to a foreign person is deemed to be an export to the foreign person's **most recent** country of citizenship or permanent residency.

Controlled Items

Under the ITAR

- Defense articles
- Defense services
- Technical data (including software)

Under the EAR

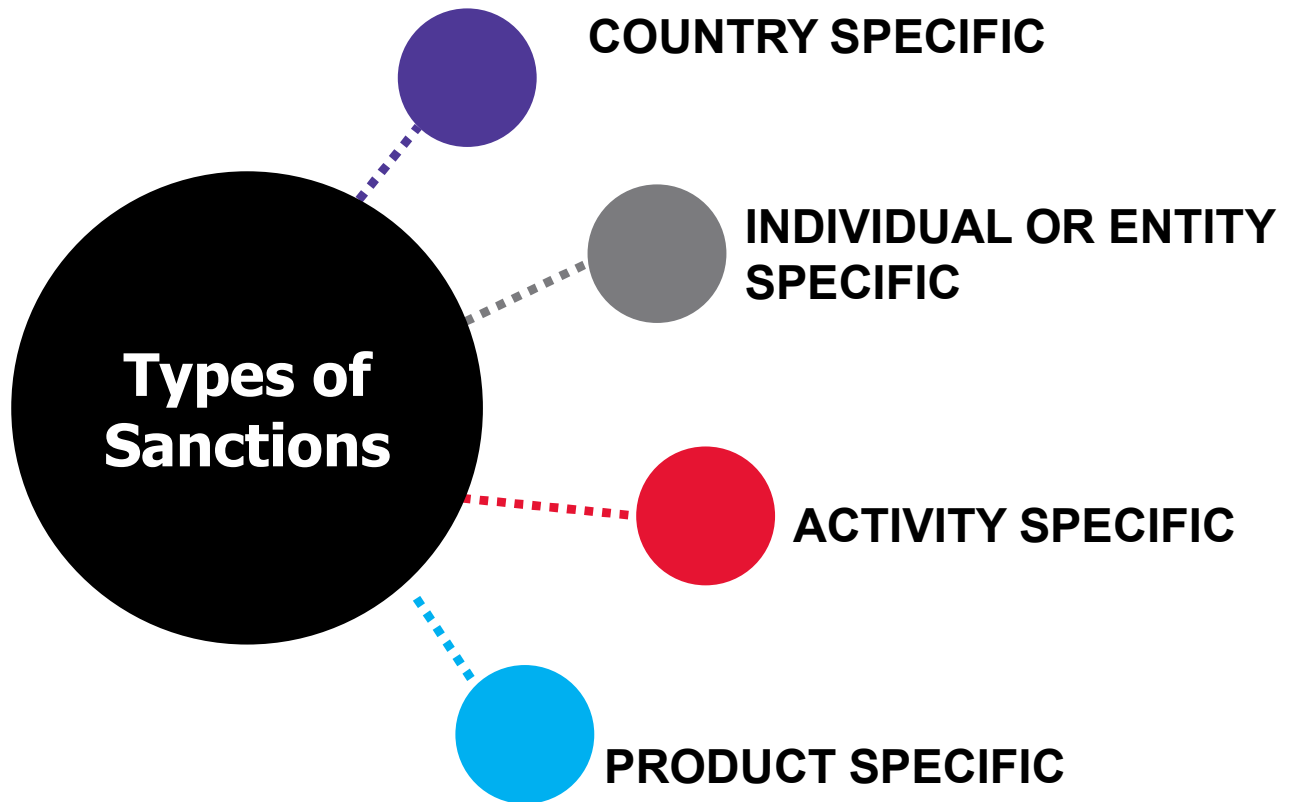
- Dual use items and software
- Services are not controlled
- Technology

Sanctions

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THE OFFICE OF FOREIGN ASSETS CONTROL

OFAC, within the U.S. Department of the Treasury administers and enforces economic and trade sanctions.



Primary & Secondary Sanctions

- Primary Sanctions
 - U.S. citizens and permanent residents
 - Entities organized under the laws of the United States and their foreign branches
 - Persons physically located in the United States
 - In some cases, entities owned or controlled by U.S. persons
 - U.S. dollars
- Secondary Sanctions
 - Target activities by non-U.S. persons where the transaction has no U.S. nexus.
- Blocking Statutes, Foreign Sanctions Laws and Countermeasures
 - European Union
 - United Kingdom
 - China
 - Russia



Sanctions Lists – Restricted Parties

The U.S. Government maintains several lists of entities, individuals, governments, and countries who are subject to restrictions or sanctions and with whom dealings are prohibited or restricted:

OFAC

- ❖ Specially Designated Nationals and Blocked Persons List (SDN)
- ❖ Sectoral Sanctions Identification List (Russia) (SSI)
- ❖ Non-SDN Chinese Military-Industrial Complex Companies List (NS-CMIC)
- ❖ Foreign Sanctions Evaders List (FSE)

Commerce

- ❖ Entity List
- ❖ Unverified List
- ❖ Denied Persons List

State

- ❖ Cuba Restricted List

OFAC's 50% Rule



Entities directly or indirectly owned, 50% or more, by one or more SDNs are blocked, regardless of whether such entities are specifically named.

Applies to the Russian sectoral sanction identification list.

Does not apply to CMIC List or Entity List

Requires diligence on a customer's ownership and the owner's/owners' blocked party status.

OFAC Framework for Compliance

- OFAC administers and enforces U.S. economic and trade sanctions programs against targeted foreign governments, individuals, groups, and entities in accordance with national security and foreign policy goals and objectives.
- OFAC encourages organizations to employ a risk-based approach to sanctions compliance by developing, implementing and routinely updating a sanctions compliance program (SCP).
- Each program should incorporate at least 5 essential components of compliance
 1. Management Commitment
 2. Risk Assessment
 3. Internal Controls
 4. Testing and Auditing
 5. Training

Managing Sanctions Compliance

- Sanctions Change Quickly
 - “live” sanctions clauses in all agreements
- Conflicting Obligations: Anti-Foreign Sanctions Laws and Blocking Statutes
 - Where the company’s business partner is prohibited from complying with certain U.S. sanctions
 - Agreement drafting
 - Dispute resolution
 - Ethical wall
- Differing Rules Amongst Jurisdictions
 - U.S. v. E.U. v. UK

Imports

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Customs Modernization



Informed Compliance - CBP must take steps to inform importers what is required prior to initiating punitive measures for import activity.



Shared Responsibility - Importers are responsible for declaring accurate and complete data elements to CBP; CBP is responsible for ensuring entry is made correctly and determining the amount of duties due.



Obligation to Exercise Reasonable Care - Even if an importer has retained the services of a customs broker, the importer must still exercise reasonable care and must furnish the broker with the best information available.

Key Customs Issues

Correct **CLASSIFICATION** of goods

- Impacts customs duties owed
- Impacts free trade agreement benefits
- Antidumping, countervailing duties, Section 232 duties, Section 301 duties, Section 201 duties

Correct **VALUATION** of goods

- Amount of duties is derived from the value of goods
- Some things may be deducted from invoice value and others must be added into the invoice value
- Related parties have additional parameters regarding what valuation may be used

Correct **ORIGIN** of goods

- Impacts free trade agreement benefits
- Antidumping, countervailing duties, Section 232 duties, Section 301 duties, Section 201 duties
- May be relevant for government sales through domestic preference requirements (e.g., Buy America laws and Trade Agreements Act)

The Harmonized Tariff System

Classification is the primary factor in determining duties owed on imported merchandise.

For imports into the US, proper classification is determined according to the Harmonized Tariff System of the United States (HTSUS).

HTSUS is based on the international Harmonized Tariff System.

Classification appears in the format **1234.56.7890**, broken down by headings, subheadings, and statistical breakouts.

Customs Valuation Methods

- Appraised value serves as the basis for assessment of applicable duties, fees, and taxes on the imported merchandise.
- All methods are designed to determine “commercial reality”
 - Transaction Value
 - Transaction Value of Identical or Similar Merchandise
 - Deductive Value
 - Computed Value
- Transaction value can be applied if the buyer and seller are not related, or the buyer and seller are related but the transaction value is acceptable under one of two tests: circumstances of sale or test values.

Country of Origin Determination and Marking



Importers are required to make accurate declarations in the entry documents as to the country of origin of the imported goods



Importers are also required to mark every imported item of foreign origin (or its container) with the English name of the country of origin of the item, unless an exception from marking is provided for in the law



Country of origin marking must be conspicuous, legible, indelible and permanent

Country of Origin



The country of manufacture, production, or growth of an article

Determines goods' eligibility for trade programs and treaties

Takes into consideration "substantial transformation" of an article

Is not necessarily the country from which the goods are shipped

Special Marking Rules

- If a product is determined to be of US origin, it is not required to be marked.
- Special rules apply if, in addition to the country of origin, "U.S.A." "American," etc. or the name of a U.S. city, also appear on an article or its container – can't mislead consumer
- Marking exceptions - e.g., J list articles, articles for use by the importer that won't be resold (but containers must be marked)
- Other agencies have additional rules and requirements (FDA, FCC, etc.)

Domestic Preferences

- Government procurements often include a domestic preference requirement.
- The requirements appear in the prime contract, subcontracts (including master purchase agreements and purchase orders), published regulations, and terms and conditions.
- It is important to understand the applicable standard to ensure compliance with any domestic preference obligations – there is not a single standard.
- Common domestic preferences include the Trade Agreements Act and the Buy American Act.

Trade Remedies: Antidumping & Countervailing Duties

- Antidumping: duties imposed to combat foreign manufacturers and exporters selling goods at a lower price than what is sold in the exporting country.
- Countervailing: duties imposed to combat subsidies provided by the exporting country's government.
- Application is typically based on the country of origin or country of export, and the narrative description of subject merchandise – not simply the HTSUS classification.

Communication with CBP

- CF-28 – Request for Information
- CF-29 – Notice of Action
- A **protest** is an administrative contest of a CBP decision relating to imported goods.
- A **petition for relief** is an administrative request for relief from a forfeiture, a penalty, or a claim for liquidated damages.

Liability for Customs Violations (19 U.S.C. 1592)

- Importers may violate Customs laws and regulations by:
 - Misclassifying imported goods
 - Undervaluing imported goods
 - Inaccurately declaring and/or marking country of origin
- CBP imposes penalties under section 592 according to whether the violation was fraudulent, grossly negligent, or negligent

Prior Disclosure

- If potential violations are discovered, address them proactively.
- Prior disclosures are voluntary.
- Must be filed by disclosing party prior to knowledge that CBP has initiated a formal investigation.
- To receive protection, disclosure must be complete, and duties owed must be paid.

The Intersection of Trade and the FCA

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Trade: Fertile Ground for FCA Enforcement

- Enforcement Trend: Importation Violations as “Reverse False Claims”
 - Misclassification of goods
 - Undervaluation
 - Inaccurate country of origin marking
- Other Alleged Trade Violations as FCA Claims

Key Outstanding Questions re Trade and the FCA

- Prior disclosure eliminate/mitigate FCA claims?
- Overlapping/duplicative damages and penalties?
- Jurisdictional question
 - [Ninth Circuit Revisits Jurisdiction Over FCA Claims Based on Alleged Customs Violations](#)

Biography



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Jennifer M. Wollenberg has extensive experience handling complex civil litigation with an emphasis on civil fraud enforcement matters, particularly those brought under the federal False Claims Act (FCA), state false claims statutes, and the civil fraud enforcement provision of the Financial Institutions Reform, Recovery, and Enforcement Act (FIRREA). Her practice ranges from compliance and counseling to internal investigations, litigation, and appellate engagement and spans across industries, including the defense and traditional government contracting space, insurance, banking and other financial services, technology, and healthcare and pharmaceuticals.

Jenny writes and lectures extensively on various aspects of the FCA. She is co-author of *Civil False Claims and Qui Tam Actions* (Wolters Kluwer, 5th Ed.), the comprehensive, two-volume treatise that frequently is cited by federal and state courts. She also co-authors a chapter in the Government Investigations & Civil Litigation Institute's *General Counsel's Guide to Government Investigations*.

Biography



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Ryan McCarthy defends clients in high-stakes litigation and sensitive government investigations across a range of industries, including life sciences, healthcare, financial services, technology, and digital assets. Ryan frequently defends companies in enforcement actions and whistleblower litigation alleging violations of federal law, including the Anti-Kickback Statute and False Claims Act, and in complex civil litigation following government investigations. Drawing on deep industry knowledge from a career as a defense-side litigator, Ryan collaborates with clients to assure that their business objectives drive the legal strategy at every turn.

Biography



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Giovanna M. Cinelli is the Firm's global leader of the International Trade and National Security practice. As a practitioner for more than 35 years, she counsels clients in the defense and high-technology sectors on a broad range of issues affecting national security and export controls, including complex export compliance matters, audits, cross-border due diligence, and export enforcement, both classified and unclassified.

She handles complex civil and criminal export-related investigations and advises on transactional due diligence for regulatory requirements involving government contracts, export policy, and compliance, as well as settlement of export enforcement actions. She advises clients on matters before the Committee on Foreign Investment in the United States (CFIUS), and addresses mitigation requirements that may apply as part of CFIUS clearances for cross-border transactions.

Biography



Casey Weaver

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Casey Weaver focuses her practice on regulatory compliance matters, government and internal investigations, and government contracts. Her regulatory practice involves US laws and regulations affecting international trade, including import and export controls, economic and trade sanctions, and anti-corruption. Casey counsels clients regarding compliance with federal, state, and local government contracting, including domestic preference obligations. Her experience and knowledge of a breadth of compliance obligations allow her to help clients efficiently navigate a complex regulatory landscape.

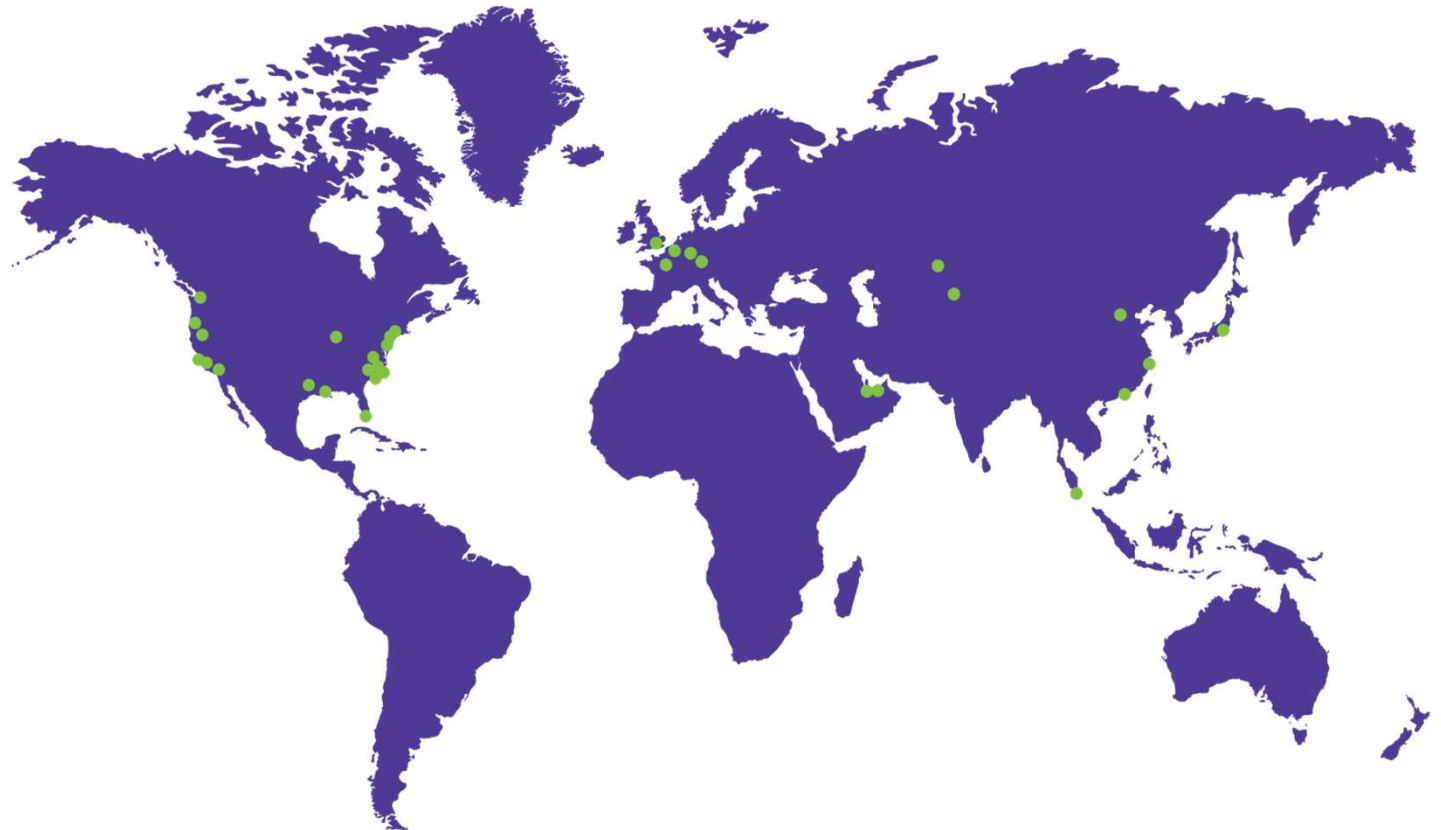
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