



An Update on Blowing the Whistle Against Fraud & Abuse

Edwin Broecker, Quarles & Brady LLP

Katea Ravega, Quarles & Brady LLP



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Agenda

- Whistleblower Overview
- False Claims Act ("FCA")
- Recent False Claims Act *Qui Tam* Suits
- Policies and Procedures



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Overview of Whistleblowers

- What is a whistleblower?
 - Anyone making a good faith effort to disclose (orally or in writing) suspected fraudulent misconduct
 - Disclosure must be voluntary, not in response to a legal obligation.
 - Can be internal or external disclosure, to a person or entity that can investigate and respond to the issue if there is an issue (e.g., more intentional than gossip or confidentiality breach)

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Overview of Whistleblowers

- Disclosure must be of non-public, not previously disclosed information – often disputed in litigation
- Under the FCA, disclosure may be made by entities as well as individuals who are not employees, such as "contractors, agents or associated others." 31 U.S.C. §3730(h)(1).
- Executives, employees, potential business partners, competitors – all have been sources

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Overview of Whistleblowers

- What does a whistleblower have to gain if they become a *qui tam relator*?
 - Reinstatement if let go
 - Double back-pay
 - 15-30 percent of award recovered by DOJ – potentially lucrative

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Overview of Whistleblowers

- What do violators have to lose?
 - Intangibles: Reputation, employee morale, etc.
 - Civil Penalties: Treble damages, \$11,000+ per violation, costs/fees incurred by government.
 - Criminal Penalties: Imprisonment, criminal fines.
 - Exclusion and debarment
 - Licenses to practice or operate

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The Legal Landscape

- The Main Players

- Dept. of Justice
- Health & Human Services
- Securities & Exchange Commission
- CFTC

- The Supporting Roles

- FDA/CMS/DOL
- MACs/Part D Plans
- State Attorney General Offices
- State Licensing Boards
- Medicaid Fraud Control Units (MFCU)

There are also relevant state laws, varying by state.

- The Federal Enforcement Tools

- Criminal Statutes
 - Title 18 U.S.C. § 1514
 - Title 18 U.S.C. § 287
 - Anti-Kickback Statute – 42 U.S.C. § 1320
- Civil Authorities
 - False Claims Act (Medicare/Medicaid fraud - Goods/services paid for by government as a result of fraud)
 - Foreign Corrupt Practices Act (bribery)
 - Dodd-Frank & Sarbanes-Oxley Act (securities fraud)
 - OSHA (workplace safety/health)

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FCA Overview & Update on FCA Actions

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FCA – What is it?

- Federal statute allowing a whistleblower (known as a "Relator") with knowledge of fraud committed on the United States government to sue on behalf of the government (*qui tam*) to recover civil penalties and triple damages. (*U.S. Attorney General may also bring its own civil action.*)
 - Penalties:
 - Min. of \$11,181 and Max. of \$22,363 penalty per false claim.
 - Three times the damage sustained by the government.
 - Costs to reimburse for government prosecution.

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What Does the FCA Prohibit?

- The Scope of the FCA includes prohibitions of:
 - Making a false record or statement to have claim paid;
 - Conspiring to have a false claim paid;
 - Fraudulently withholding property from the government;
 - Buying government property from an unauthorized seller;
 - Making a false statement to avoid an obligation to pay money to the government.

31 U.S.C. § 3729

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More Than One Might Think

- "False claims" includes:

- The organization having violations of the anti-kickback statute
- Billing too much, too little, or any incorrect information in the claim submitted
- Submitting claims when the facility's license wasn't in force
- Claims submitted after certifying that annual CMS training was completed when it actually wasn't
- Submitting claims when people on staff are excluded or debarred
- What constitutes a 'false claim' evolves – recently government settled first FCA case related to HIPAA violations, involved fraudulent certifications on the part of an EHR vendor

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Qui Tam Action – How does it work?

For a FCA claim to succeed, the Relator and, if they participate, DOJ must demonstrate:

- (1) a false statement;
- (2) made with knowledge of its falsity;
- (3) that was material; and,
- (4) that involved a claim for money or property from the U.S. Government.

And the information disclosed has to have been something that was not previously disclosed.

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Qui Tam Action – How does it work?

- Relator Files Complaint:
 - Relators file a complaint under seal for a 60-day period during which the DOJ can investigate and move to have the case remain under seal.
 - Relators and the DOJ both have standing to bring a FCA claim.
 - Relators are represented by their own private counsel and they must cooperate with DOJ in its investigation and potential prosecution.

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Qui Tam Action – How does it work?

- DOJ Investigates:
 - After its investigation, the DOJ may:
 - (1) intervene;
 - (2) decline to intervene; or
 - (3) move to dismiss the complaint (refer to January 10, 2018 Granston Memorandum for DOJ's list of factors used to determine merits of FCA claims).

If the statute of limitations expired, the complaint must be dismissed. The time period ranges from 3 years to 10 years after the event.

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Pre-Suit Tools Available Under the FCA

- Defending suspected allegations can have devastating costs before a claim is filed or company even knows
- Civil Investigative Demands (31 U.S.C. § 3733)
 - Allows U.S. AG to conduct pre-suit discovery to investigate false claims before ever commencing a civil proceeding.
 - Grants U.S. AG access to (31 U.S.C. § 3733(a)):
 - Documentary material
 - Written interrogatory answers
 - Oral testimony

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Where is DOJ's Focus: FCA Trends

- Since 1986, DOJ has recovered \$59 Billion from FCA Cases, with recoveries peaking in 2014. (Health & Human Services ("HHS"))
 - FY 2014 - \$6.1 billion recovered (\$2.4 billion for HHS cases)
 - FY 2015 - \$3.1 billion recovered (\$2.1 billion for HHS cases)
 - FY 2016 - \$4.9 billion recovered (\$2.7 billion for HHS cases)
 - FY 2017 - \$3.4 billion recovered (\$2.1 billion for HHS cases)
 - FY 2018 – \$2.8 billion recovered
 - \$2.5 billion in HHS cases

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Qui Tam Trends

Overview of All New Non-Qui Tam vs. Qui Tam Actions By Year		
Year	Non-Qui Tam	Qui Tam
2008	160	379
2009	131	433
2010	143	577
2011	125	634
2012	146	655
2013	101	757
2014	100	716
2015	114	640
2016	149	707
2017	145	680
2018	122	645

Health and Human Services New Non-Qui Tam vs. Qui Tam Actions By Year		
Year	Non-Qui Tam	Qui Tam
2008	60	231
2009	34	279
2010	42	386
2011	38	417
2012	26	417
2013	27	504
2014	32	470
2015	26	426
2016	70	503
2017	55	495
2018	60	446

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Qui Tam Cottage Industry

- Law firms specialize in representing *qui tam* relators
- Potential recovery is so lucrative, some have started businesses to facilitate research and filing of *qui tam* cases
- The FCA allows entities to be whistleblowers, though the similar laws governing IRS, SEC, and SFTC whistleblowing do not (must be a person)
- On June 24, 2019 DOJ announced dismissal of 30 meritless *qui tam* cases since Granston memo; uptick is significant – previously less than 1% cases

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Qui Tam Cottage Industry

- December 2018 DOJ requested dismissal of 11 *qui tam* cases brought by National Healthcare Analysis Group
- Complaints alleged patient support services were kickbacks
- The cases related to drug manufacturer support programs, which often align with federal healthcare programs' goals, and provided services agency guidance approved, such as toll free phone numbers

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Qui Tam Cottage Industry

- DOJ's motions to dismiss also cited that the relators used "false pretenses" to gain information
- Cases were filed by what the government called a "professional relator" who promised to pay people for information to put in a "research study" even though it was collected for *qui tam* complaints – unethical pretense
- Relator listed the employees it interviewed as "cooperating witnesses" alleging the companies violated AKS by white coat marketing & free support services

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Additional Recent Cases

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Recent cases of note

- General Counsel as a whistleblower
 - *Wadler v. Bio-Rad Laboratories*, No. 17-cv-16193 (9th Cir. Feb. 26, 2019)
- Director Personal Liability for compliance defects
 - *Marchand v. Barnhill*, No. 533 (Del. June 19, 2019)
- FCA - Criminal Fraud
 - *U.S. v. Walter Beich*, No. 1:15-cr-00282 (N.D. Ill. April 5, 2018)
- Anti-Kickback - Bribery
 - *United States et al v. Insys Therapeutic, Inc.*, No. CV 13-5861 JLS (C.D. Cal. 2018)
- FCA - Compounded Products
 - *United States v. Simsir et al.*, No. 1:16-cr-20399, (S.D. Fla. 2018)
- FCA – Inflated Medicare Claims
 - *U.S. ex rel. Swoben v. Secure Horizons, et al*, No. 09-5013 (C.D. Cal. 2018)
- FCA – Supreme Court
 - *Cochise Consultancy Inc. v. U.S., ex rel. Hunt* (5/13/19)

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General Counsel as Whistleblower

- Hopefully everyone remembers in 2017 the news about Bio-Rad Laboratories being sued by its general counsel for retaliation
 - The GC sent a memo to the audit committee about FCPA violations
 - Some unique facts including using attorney-client privileged information at trial
 - Jury awarded \$11M for the retaliation claim
 - In February 2019, the 9th Circuit Court of Appeals affirmed but cut the award to \$8+M but did not decide the use of privileged evidence
 - Because he only reported internally, Wadler was not covered by the federal Dodd-Frank protections after the 2018 *Digital Realty Trust* Supreme Court case
- Takeaways
 - Gatekeepers (in-house counsel, compliance professionals, etc.) can be whistleblowers
 - Need to appropriately respond and address concerns raised internally
 - Need to assume that issues raised internally are also raised to regulators



Director Personal Liability for Compliance

- In 2015 Blue Bell Creameries had a bad listeria outbreak and three people died and company shut down production for a while
- Shareholders sued claiming directors breached fiduciary duties, including the duty of loyalty
 - Claim that Board failed to adopt or implement any reporting and compliance systems was a breach of their duty of oversight. The utter failure of which is a breach of the duty of loyalty
 - There was no reports regarding food safety issues to the board and no process in place to alert Board on food safety issues
- Takeaways
 - Breach of Duty of Loyalty means no insurance
 - Board needs to have process in place for monitoring events and escalating issues
 - Boards need to be routinely updated on and monitor high-risk areas

Criminal Fraud - *U.S. v. Walter Beich, No. 1:15-cr-00282 (N.D. Ill. April 5, 2018)*

- Relief Sought:
 - Defendant accused of insurance fraud for submitting false claims to private insurers and filling prescriptions with counterfeit drugs.
- Facts and Procedural History:
 - Defendant operating Corwin Pharmacy was also the owner and pharmacist. Used real patient information to submit insurance claims for prescriptions he either filled with counterfeit drugs, or did not fill at all.
 - Defendant billed insurers for expensive over-the-counter drugs but actually dispensed things like fish oil, vitamins, or cheaper alternatives to patients. In some cases, Corwin Pharmacy patients received non-FDA-approved, foreign-made drugs instead of the drugs they were prescribed.

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Criminal Fraud - *U.S. v. Walter Beich, No. 1:15-cr-00282 (N.D. Ill. April 5, 2018)*

- Facts and Procedural History:
 - Defendant also led his employees to unknowingly create fraudulent pharmacy records by falsely telling them that he had received phone-in prescription orders from patients' physicians. Between 2010 and 2013, Defendant used patient information to submit or cause the submission of nearly 200 fraudulent claims for reimbursement.
 - Defendant ultimately pled guilty to defrauding Medicare, Medicaid, and several other private insurance companies out of \$2.4 million.
- Sentencing
 - Sentenced to 4 years and ordered to repay nearly \$2.3 million in restitution.
 - Judge gave 4 years instead of 70-80 months due to age and health of defendant.

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Bribery – *United States et al v. Insys Therapeutic, Inc., No. CV 13-5861 JLS (C.D. Cal. 2018)*

- Relief Sought:
 - DOJ charged drug manufacturer and executives for violation of the federal Anti-Kickback Statute, False Claims Act, and racketeering and fraud.
- Facts and Procedural History:
 - On May 15, 2018, the DOJ announced that it had intervened in five *qui tam* lawsuits against Insys Therapeutics, Inc. (“Insys”) stemming from the pharmaceutical maker’s marketing of its opioid painkiller, Subsys.
 - Two of the relators were employees of a payor conducting an audit of Subsys reimbursement claims.

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Bribery – *United States et al v. Insys Therapeutic [sic], Inc., No. CV 13-5861 JLS (C.D. Cal. 2018)*

- Facts and Procedural History:
 - The five cases, which have been consolidated in the Central District of California, allege that Insys bribed doctors and nurse practitioners with exorbitant speaking fees and lavish dinners and entertainment in order to boost the sales of Subsys. Prior to the DOJ's intervention, bribery allegations led to criminal charges against seven Insys executives, including its billionaire founder and chairman John Kapoor, in October of 2017.
 - Insys executives allegedly identified a relatively small number of practitioners who wrote the greatest number of prescriptions for Transmucosal Immediate-Release Fentanyl (“TIRF”) drugs like Subsys.
 - Insys allegedly made these practitioners the key targets of their sales efforts. This was initially done through traditional sales pitches over the phone or face-to-face at the doctor’s office. However, when initial sales were underwhelming, the complaints allege that Insys executives conspired to induce the practitioners to prescribe—and in many cases over-prescribe—Subsys through a system of illegal kickbacks.

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Bribery – *United States et al v. Insys Therapeutic, Inc., No. CV 13-5861 JLS (C.D. Cal. 2018)*

- Facts and Procedural History:
 - Executives took prescribers out for expensive meals and entertainment and created a speaker program in order to directly funnel money to practitioners in return for prescribing Subsys to their patients.
 - The ten highest compensated prescribers allegedly received over \$200,000 from Insys in exchange for delivering talks that were often nothing more than dinners with the practitioner, the practitioner's staff, Insys sales representatives, and friends and relatives.
 - In addition to prescribing Subsys for cancer patients with breakthrough pain, the complaint alleges that Insys used bribes to induce practitioners to prescribe Subsys for off-label use. By September 2016, only 4 percent of all Subsys prescriptions were written by oncologists.
 - In addition to the bribery allegations, Insys and its executives are also alleged to have defrauded insurers by devising a scheme in which Insys employees would file false or misleading claims on behalf of the prescriber in order to ensure that the patient's Subsys treatment would be covered.

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Bribery – *United States et al v. Insys Therapeutic, Inc., No. CV 13-5861 JLS (C.D. Cal. 2018)*

- Status:
 - Practitioners involved in the alleged bribery are also being prosecuted for their roles in current opioid crisis. Insys has reportedly already paid close to \$10 million to settle investigations in several states.
 - DOJ reported in June 2019 that Insys has agreed pay the federal government \$225 million dollars in liability related to these charges.
 - Specifically, Insys has agreed to enter into a deferred prosecution agreement and has agreed to plead guilty to five counts of mail fraud, paying a \$2 million fine and \$28 million forfeiture. The company will pay \$195 million to settle allegations it violated the FCA.
 - This settlement comes in the wake of a Massachusetts jury recently convicting 5 former Insys executives of racketeering charges. A total of 8 company executives have been convicted or pled guilty in Massachusetts federal court.

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FCA - Compounding - *United States v. Simsir et al.*, No. 1:16-cr-20399, (S.D. Fla. 2018)

- Relief Sought:
 - US Government alleged that pharmacy owner and employee submitted false claims to TRICARE and defrauded the government of more than \$30 million.
- Facts and Procedural History:
 - Owner of Atlantic Pharmacy and Compounding ("Atlantic"), Serge Francois, and his employee Patrick Tonge allegedly entered into a "vast conspiracy" to pay a number of marketers who then paid doctors to write prescriptions for expensive topical medications. These prescriptions were eventually compounded at Atlantic and charged for prices up to \$17,000 a bottle.
 - Doctors involved in the conspiracy wrote the prescriptions based only on patient notes, without seeing the actual patient. The pharmacists then set prescriptions to refill automatically. This caused refills to be sent without co-payments to patients who had neither requested nor needed the refills.
 - The scheme targeted Tricare and the Federal Employee Health Benefits Program, which resulted in Tricare paying more than \$30 million in false claims. Francois used the money to fund a lavish lifestyle, including the purchase of a \$3.6 million mansion once owned by celebrity, Dwayne "The Rock" Johnson, as well as purchasing Ferraris, Rolls-Royces and other luxury vehicles.

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FCA - Compounding - *United States v. Simsir et al.*, No. 1:16-cr-20399, (S.D. Fla. 2018)

- Verdict and Sentencing:
 - On September 5, 2017, Francois and Tonge were both found guilty by a federal jury of multiple health care fraud, conspiracy, kickback, and money laundering offenses. Francois was also found guilty of charges of misbranding drugs and making false statements.
 - On March 9, Judge Gayles sentenced Francois to 204 months (17 years) in prison followed by three years of probation. Tonge was sentenced to 188 months (15 years) in prison and three years of probation. The judge also ordered the pair to pay \$31,259,252 in restitution.
 - In total, 17 people have either pled guilty or have been convicted for their involvement in similar fraudulent billing schemes or for receiving kickbacks related to the conspiracy.

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FCA – Medicare - *U.S. ex rel. Swoben v. Secure Horizons, et al*, No. 09-5013 (C.D. Cal. 2018).

- This case stems from DOJ's broader investigation of "risk adjustment" payments under Medicare Advantage.
- HealthCare Partners *self-reported* its historical use of inaccurate information that caused Medicare Advantage Organizations (MAOs) to receive inflated Medicare payments.
 - However, the claims were related to a pending *qui tam* action originally filed in 2009.
- DOJ alleged the company ignored inaccurate diagnosis codes that, if deleted, would have decreased Medicare reimbursement.
- Without admitting wrongdoing, the company settled for \$270 million.

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SCOTUS - Expanding Whistleblower suits

- *Cochise Consultancy Inc. v. U.S., ex rel. Hunt* (5/13/19)
 - In 2010, Relator informed government officials that a defense contractor submitted false claims in 2006 & 2007.
 - Relator filed *qui tam* suit in 2010 and government declined to intervene.
 - Circuits were split as to whether relators are entitled to the FCA's three years statute of limitations where DOJ declines to intervene.
 - FCA's three-year statute of limitations tolls until a government official learns of alleged fraud, but extends no more than 10 years from the date of the false claim.
 - *Holding*: Tolling period applies to a relator's claim even where DOJ declines to intervene. Moreover, the time of the *relator's* discovery of the conduct does not trigger the start of the statute of limitations.

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Indiana FCA Decision

- *U.S. v. ImmediaDent of Indiana LLC*, No. 3:13-cv-222-CRS (W.D. Ky.)
 - In 2013, a Relator filed a qui tam action against a dental care firm with nine Indiana clinics.
 - Alleged, under the Indiana FCA, that it submitted false claims by up-coding dental procedures, billing for medically unnecessary procedures, and that it allegedly violated state law prohibiting rewarding, disciplining, or directing personnel in a manner that compromised clinical judgment.
 - In October 2018, Indiana and the United States intervened.
 - By the end of October 2018, the firm settled with the government.
 - The firm settled by paying \$3.4 million to the United States and \$1.8 million to the State of Indiana.
 - The firm refused to enter into CIA—thus, government now flags firm as "continuing high risk."
 - CIA's are increasingly being seen as a tool used to strong arm defendants.

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Role of the Compliance Program

Institutional strategies and policies and procedures

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A Culture of Compliance & Transparency

- Encourage employees to raise concerns – address issues before they escalate
- Create multiple avenues for reporting.
 - Include an anonymous reporting mechanism.
- Follow through on reported allegations.
 - Update the reporting employee on status of investigation and the outcome, when possible.
- Communicate to workforce how policies have worked effectively and, when appropriate, relay changes and improvements to enhance policies.

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Have Policies Prohibiting Retaliation

- Anti-retaliation policies cover employees and contractors if they allege FCA violations.
 - The FCA protects employees, contractors, and agents who engage in protected activity from retaliation in the form of their being “discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment.” 31 U.S.C. § 3730(h)(1). FCA retaliation protection has been interpreted to extend not only to employees and contractors, but also to partners. *See U.S. ex rel. Kraemer v. United Dairies, L.L.P.*, 2019 WL 2233053 (D. Minn. May 23, 2019).
- Anti-retaliation protection should be broad.
 - An employee’s refusal to sign fraudulent reimbursement documentation can be viewed as protected behavior. Courts have noted that “[t]here is, at best, a hair’s-breadth distinction between complaining internally that a practice is illegal under the FCA and advising a supervisor of one’s refusal to engage in that illegal practice.” *Fabula v. American Medical Response, Inc.*, 865 F.3d 71 (2d Cir. 2017).
- Communicate policies and procedures regularly, including the anti-retaliation policies.

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Additional Compliance Program Considerations

- Relevant Compliance Program Components include:
 - Annual training, including training on policies and procedures
 - Clear reporting mechanisms – having in place an internal process for reporting concerns can reduce government likelihood to intervene if those policies weren't followed first
 - Respond to reports in a timely manner
 - Limiting personnel data and systems access to only the information people actually need to carry out their role in the organization
 - Board awareness of compliance issues and processes
 - Review compliance program periodically against current government guidance and laws to ensure it stays up to date – NEW guidance this year on program effectiveness
 - Seek legal counsel for operational and investigation support as needed

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Questions?

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