

DAMAGES & LIABILITY TO FEDERAL HEALTH PROGRAMS

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Agenda

- General Principles & Foundational Cases
- Theories of Liability and the Corresponding Measure of Damages
- Recent Developments
- Damages Analysis Techniques
 - Statistical Sampling
 - Health Care Examples
- Questions

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General Principles & Foundational Cases

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The False Claims Act

- A person who violates the FCA is liable for “3 times the amount of damages which the Government sustains because of the act of that person.” 31 U.S.C. § 3729(a)(1)
- The FCA also provides for a mandatory civil penalty for each false claim ranging from \$5,000 to \$10,000 (as adjusted for inflation). 31 U.S.C. § 3729(a)(1).
- The Government bears the burden of proving damages by a preponderance of the evidence. 31 U.S.C. § 3731(d).

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What’s the Purpose?

- Damages under the FCA should **make the government whole**.
 - U. S. ex rel. Marcus v. Hess, 317 U.S. 537, 551 (1943) (“We think the chief purpose of the statutes here was to provide for restitution to the government of money taken from it by fraud...”)
 - United States v. Sci. Applications Int’l Corp., 626 F.3d 1257, 1278 (D.C. Cir. 2010) (False Claims Act damages are meant to “put[] the government in the same position as it would have been if the defendant’s claims had not been false.”)
- Specific damage formulas must be determined case-by-case.

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No Single Rule

- While there is no single rule for calculating damages under the FCA, the following decisions established some foundational concepts.
- U.S. ex rel. Marcus v. Hess, 317 U.S. 537, 551 (1943)
 - Electrical contractors engaged in bid-rigging scheme in connection with federal projects.
 - Supreme Court held that damages were the difference between what the government paid under the contracts and what it would have paid had it known the true facts (i.e., that the bids were collusive).
- United States v. Bornstein, 423 U.S. 303, 317 n.13 (1976)
 - Contractor provided government with non-conforming electron tubes it received from a subcontractor.
 - Supreme Court held that the damages “are equal to the difference between the market value of the tubes it received and retained and the market value the tubes would have had” if they had met specifications, i.e. a benefit-of-the-bargain measure.

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Benefit of the Bargain

- U.S. ex. rel. Davis v. District of Columbia, 679 F.3d 832 (DC Cir. 2012)
 - Relator alleged that District of Columbia and its schools violated the FCA by submitting a Medicaid reimbursement claim without maintaining adequate documentation of the services, even though the services were admittedly provided.
 - Relator sought entire amount the government had paid, claiming it would not have paid anything had it known there was no documentation for the claim.
 - Court held that to establish damages under the FCA, "the government must show not only that the defendant's false claims caused the government to make payments that it would have otherwise withheld, but also that the performance the government received was worth less than what it believed it had purchased."
 - Applying this benefit-of-the-bargain analysis, the Court held that here "the government got what it paid for and there [were] no damages."

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No Consequential Damages, but...

- United States v. Aerodex, Inc., 469 F.2d 1003 (5th Cir. 1973)
 - Court rejected the government's demand for the cost of removing and replacing defective aircraft engine bearings.
 - Court held that "the language of the False Claims Act does not include consequential damages resulting from the delivery of defective goods."
- Commercial Contractors, Inc. v. U.S., 154 F.3d 1357 (Fed. Cir. 1998)
 - Government claimed contractor submitted false claims for payment for work on flood control project.
 - Court held that where Bornstein-type analysis is not possible, the government may use an "alternative basis" to compute damages (e.g., the cost of remedying the defects in the contractor's performance).

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No Consequential Damages, but...

- BMV-Combat Systems v. United States, 44 Fed. Cl. 141 (1998)
 - Government accused defense contractor of violating the FCA by failing to perform required particle tests on a key component of self-propelled howitzers.
 - While acknowledging that courts must be "careful not to award consequential damages" under the FCA, the Court cited the need to determine damages "in a flexible manner."
 - Court allowed the government to recover costs of inspection and repair; costs of manufacturing replacement components at government facilities; and interest on payments made prematurely due to fraudulent invoices.
 - However, the Court denied recovery of the government's administrative costs related to processing "requests for waivers" from product specifications.

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There are Limits

- Vermont Agency of Natural Resources v. U.S. ex rel. Stevens, 529 U.S. 765 (2000)
 - In ruling that States are not subject to *qui tam* liability, the Court observed that the post-1986 version of the FCA "imposes damages that are essentially punitive in nature... ."
- United States v. Mackby, 261 F.3d 821 (9th Cir. 2001)
 - Court held that **both** the civil penalty and treble damages provisions of the FCA are punitive in nature, not solely remedial, and therefore are subject to Constitutional limitations under Excessive Fines Clause of Eighth Amendment.

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Treble What?

- United States v. Anchor Mortgage, Nos. 10-3122, 10-3342 & 10-3423, 2013 U.S. App. LEXIS 5552 (7th Cir. March 21, 2013)
 - Government alleged that mortgage broker violated FCA by paying kickbacks to realtors who referred borrowers for FHA-guaranteed loans.
 - Government sought as damages three times the total amount it had paid to lenders under the guarantees ("gross trebling").
 - Court held instead that damages should be trebled only after reducing the guarantee payments by the value of the collateral securing the loans to calculate a net loss ("net trebling").

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Theories of Liability and the Corresponding Measure of Damages

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Delivery of Defective/Non-Conforming Goods or Services

- Damages = Value of what government was promised – Value of what it actually received
- U.S. v. Bornstein, 423 U.S. 303 (1976)
 - Contractor provided government with non-conforming electron tubes it received from subcontractor.
 - Supreme Court held that the damages “are equal to the difference between the market value of the tubes it received and retained and the market value the tubes would have had” if they had met specifications.

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Misrepresentation of Cost Resulting in Overcharges

- Damages = Amount charged to government as a result of the misrepresentation
- U.S. v. Ehrlich, 643 F.2d 634 (9th Cir. 1981)
 - Contractor overstated costs of constructing low income housing on form required to be submitted to HUD for the project sponsor to obtain an insured mortgage and subsidized interest payments
 - Court held that “[t]he damage calculation begins ... with a determination of the amount by which [defendant] falsely overstated those costs.”

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Government Grant Obtained by Fraud

- Damages = Full amount of grants awarded to defendant based on false statements
- U.S. ex rel. Feldman v. Van Gorp, et al., 697 F.3d 78 (2d Cir. 2012)
 - NIH research grantee made material false statements on its grant renewal applications and performed research unrelated to purpose of grant program.
 - Court held that the benefit-of-the-bargain measure of damages does not apply when the government received nothing of tangible value from the defendant; rather, the government is entitled to the full amount that it paid.
 - “[T]he government did not receive less than it bargained for; it did not get the ‘neuropsychology with a strong emphasis upon research training with HIV/AIDS’ program it bargained for at all.”

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Retention of Overpayment (Reverse False Claim)

- Damages = Amount of overpayment not returned to government
- U.S. v. Bourseau, 531 F.3d 1159 (9th Cir. 2008)
 - In case involving alleged misrepresentations on Medicare costs reports, Court stated that “[d]amages for a reverse false claim consist of the difference between what the defendant should have paid the government and what the defendant actually paid the government.”
- NOTE: To avoid liability, the overpayment must be returned w/in 60 days
 - Clock starts to run when provider is put on notice of a potential overpayment, not when it's determined that an overpayment was actually made. U.S. ex rel. Kane v. Continuum Health Partners, Inc. et al., No 1:11-cv-02325 (S.D.N.Y. Aug. 3, 2015).

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False Certification

- Damages = Value of what government was promised – Value of what it actually received
- U.S. ex rel. Wall v. Circle C. Construction, 813 F.3d 616 (6th Cir. 2016)
 - Government alleged that contractor, hired to build warehouses on Army base, failed to comply with federal law requiring that electrical workers receive particular wages, and falsely certified that it had complied with law.
 - Government claimed the entire construction project was “tainted” by this payroll failure and the false certification of compliance and sought to recover as damages all payments made to the contractor for the electrical work done.
 - Court rejected the government’s damages calculation, explaining that “actual damages by definition are damages grounded in reality” and are to be determined under a benefit of the bargain analysis.

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Kickbacks

- Damages = Total amount government paid for goods or services that resulted from illegal referrals
- U.S. v. Rogan, 517 F.3d 449, 452 (7th Cir. 2008)
 - Government alleged that hospital administrator paid doctors for referrals in violation of Stark and AKS and billed Medicare and Medicaid for related services.
 - Court found that provision of care did not affect damages analysis and that defendant was liable for entire amount of paid claims.
 - “Nor do we think it important that most of the patients for which claims were submitted received some medical care... The government offers a subsidy (from the patients’ perspective, a form of insurance) with conditions. When the conditions are not satisfied, nothing is due.”

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Fraudulent Inducement

- Damages = Total amount of payments made by government under the fraudulently induced agreement
- U.S. ex rel. Longhi v. Lithium Power Tech., 575 F.3d 458 (5th Cir. 2009)
 - Government alleged that technology company misrepresented itself on grant proposals to induce government to award it research grants.
 - Court affirmed damages award equal to the total amount of grants paid out to the defendant, trebled, even though there was no allegation that the invoices submitted in support of the payments were false (i.e., the research was done).
 - "In cases such as this, where there is no tangible benefit to the government and the intangible benefit is impossible to calculate, it is appropriate to value damages in the amount the government actually paid to [defendant]."

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Recent Developments

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Recent Developments

- U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc., Case No. 3:05-cv-02858 (D.S.C.), settled 10/16/15
 - Government agreed to accept \$72.4 million to settle \$237 million jury verdict against Tuomey, a nonprofit hospital in a rural community.
 - Government alleged that Tuomey entered into compensation agreements with physicians that violated the Stark Law and sought damages equal to the sum of all related claims paid by Medicare, claiming they were "tainted".
 - Tuomey argued that damages should be limited to the difference (if any) between the true value of the services provided and what the government paid.
 - A trial, the jury found that Tuomey had submitted 21,370 false claims to Medicare with a total value of \$39,313,065. The Court trebled this amount and assessed penalties, resulting in a judgement of \$237 million.

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Recent Developments (Cont'd)

- U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc., Case No. 3:05-cv-02858 (D.S.C.), settled 10/16/15
 - Tuomey appealed, but the Fourth Circuit agreed with the government's damages analysis and affirmed the jury's verdict, despite the absence of proof of any actual damages. See Tuomey, 792 F.3d 364 (4th Cir. 2015)
 - Court noted that the Stark Law "prohibits the government from paying any amount of money for claims submitted in violation of the law."
 - Explaining further, the Court stated that "[c]ompliance with the Stark Law is a condition precedent to reimbursement of claims submitted to Medicare. When Tuomey failed to satisfy that condition, the government owed it nothing. ...By reimbursing Tuomey for services that it was legally prohibited from paying, the government has suffered injury equivalent to the full amount of the payments."

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Recent Developments (Cont'd)

- Universal Health Services, Inc. v. U.S. ex rel. Escobar, 136 S. Ct. 1989 (2016)
 - Relators alleged that mental health clinic defrauded Medicaid by submitting reimbursement claims that made representations about services provided but failed to disclose various regulatory violations (staff qualifications, etc.).
 - Court held that the implied false certification theory can be a basis for FCA liability but that misrepresentations will be evaluated under the FCA's "demanding" materiality standard.
 - "A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual condition as a condition of payment."

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Recent Developments (Cont'd)

- Universal Health Services, Inc. v. U.S. ex rel. Escobar, 136 S. Ct. 1989 (2016)
 - "Proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement."
 - "Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material."
 - Court emphasized that the FCA "is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations."

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Recent Developments (Cont'd)

- U.S. ex rel. Harman v. Trinity Industries, Inc., 2017 WL 4325279 (5th Cir. 2017)
 - Relator alleged that Trinity falsely certified that its roadside guardrail end terminals were eligible for reimbursement by the Federal Highway Authority (FHWA) despite undisclosed design changes.
 - Relator claimed the measure of damages was the difference between the guardrail component as scrap and the value of the component the government had bargained for. Jury agreed and awarded \$663 million in damages.
 - Fifth Circuit reversed and entered judgment as a matter of law as to Trinity based on its application of the test for materiality approved by the Supreme Court in Escobar.

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Recent Developments (Cont'd)

- U.S. ex rel. Harman v. Trinity Industries, Inc., 2017 WL 4325279 (5th Cir. 2017)
 - Court explained that “though not dispositive, continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality.”
 - Court found that FHWA’s continued reimbursement for the guardrails with the design changes at the same rate as the unchanged guardrails “strongly suggest[ed] that the government ... considers the value of the [changed] units ... to be identical to the value of the previous ... units.”
 - Court held that “[i]f the government received units of equivalent value, and thus has already enjoyed the benefit of its bargain, then the proper measure of actual damages should be zero.”

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Recent Developments (Cont'd)

- U.S. ex rel. Delaney v. eClinicalWorks, LLC, Case No. 2015-cv-00095-WKS (D. Vt.), settled 5/31/17
 - eClinicalWorks (eCW), a leading electronic health records (EHR) vendor, agreed to pay \$155 million to settle FCA claims.
 - Case involved the EHR Incentive Program, which pays incentives to Medicare and Medicaid providers who “meaningfully use” certified EHR technology.
 - Government claimed eCW caused providers who used its software to submit false claims for incentive payments (i.e., by falsely attesting to their meaningful use of certified EHR software).
 - Government also claimed that payments eCW made to current customers for referring new customers were illegal kickbacks.

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Recent Developments (Cont'd)

- U.S. ex rel. Delaney v. eClinicalWorks, LLC, Case No. 2015-cv-00095-WKS (D. Vt.), settled 5/31/17
 - Government initially contended that eCW's software merely failed to satisfy all of the functionality requirements for certified EHR software. As the investigation continued, it claimed that eCW had falsely obtained certification for its software by concealing defects from the testing body.
 - As the government's theory of liability shifted from delivery of defective/non-conforming goods to fraudulent inducement, so did its damages calculations.
 - Government ultimately claimed it was entitled to recover from eCW all of the MU incentives paid to every provider who used eCW's software, totaling in excess of \$1 billion, even though none of that money was paid to eCW and the software was in fact used to treat patients as intended by the Program.

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Damages Analysis Techniques

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General Damages Analysis Techniques

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|---|---|
| <ul style="list-style-type: none"> • Qualitative Assessment <ul style="list-style-type: none"> ◦ Assess the industry and regulatory backdrop <ul style="list-style-type: none"> ▪ Clarity of regulations ▪ Consistency of industry practice ◦ Assess completeness of the record ◦ Consider offsets and alternatives | <ul style="list-style-type: none"> • Quantitative Analysis <ul style="list-style-type: none"> ◦ Sampling <ul style="list-style-type: none"> ▪ Statistical sampling ▪ Non-statistical sampling ◦ Data Analysis ◦ Recalculation |
|---|---|

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General Damages Analysis Techniques (Cont'd)

- Consider whether credits for amounts already paid to the government or counterclaims reduce the amount of damages owed
 - Credits for amounts already paid to the government are deducted from *total* damages (after actual damages have been trebled), not from actual damages. See U.S. v. Bornstein.
- Some jurisdiction specific issues may affect the damages calculation, such as whether:
 - The government is entitled to recover consequential damages;
 - Pre-judgment interest is available (it usually is not); or
 - Investigative costs are recoverable.

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Statistical Sampling

- The FCA is silent with respect to the use and appropriateness of statistical sampling
- Plaintiffs are increasingly pushing to use statistical sampling, not only to prove damages, but also to prove liability under the FCA
- Potential benefits of statistical sampling:
 - Cost and time efficient
 - Conservation of judicial resources
- Potential problems with statistical sampling:
 - Reliability
 - Applicability to scientist

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Statistical Sampling (Cont'd)

- District Courts differ on whether the use of statistical sampling is allowed
- U.S. ex rel. Martin v. Life Care Centers of America, Inc., No. 1:08-cv-251 (E.D. Tenn. Sept. 29, 2014)
 - Government alleged that Life Care engaged in nationwide scheme that caused Skilled Nursing Facilities to submit claims to Medicare for unnecessary services.
 - Court approved use of statistical sampling to prove both damages and liability.
 - Life Care settled for \$145 million on ability to pay basis.
- U.S. ex rel. Michaels v. Agape Senior Cmty., Inc., No. 0:12-3466-JFA, 2015 WL 3903675 (D.S.C. June 25, 2015)
 - Relators alleged that Agape submitted claims to Medicare and Medicaid for services not provided to patients or provided to patients that did not qualify for them.
 - Court rejected statistical sampling on the grounds that every claim submitted required a "highly fact-intensive inquiry."

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Statistical Sampling (Cont'd)

- Permissibility of statistical sampling turns on **reliability**.
- Tyson Foods, Inc. v. Bouaphakeo, 136 S. Ct. 1036 (2016).
 - In this Fair Labor Standards Act case, the Supreme Court rejected the petitioner's argument for a "categorical exclusion" of statistical sampling evidence.
 - Court held instead that whether statistical sampling is permissible turns on its reliability.
- U.S. v. Vista Hospice Care, Inc., 2016 WL 3449833 (D.D.C. 2017)
 - Relator alleged that Vista submitted Medicare Hospice Benefit claims for ineligible patients and falsely certified compliance with the Anti-Kickback Statute.
 - Court refused to permit the use of statistical sampling evidence to establish liability or damages, finding the evidence unreliable because the "nature of the claim require[d] an individualized determination" of liability, the data related to the "subjective clinical judgment of a number of certifying physicians at multiple locations," and the expert's methodology was flawed as he did not use a random sample from the entire pool of patients or control for relevant variables."

Health Care Examples

- **Medical Necessity Cases**
 - Potential issues:
 - Whether setting of treatment was proper
 - Inpatient vs. outpatient services
 - Whether the procedure was appropriate
 - Whether the level of therapy provided was reasonable
 - Clinical judgment required
 - Differences of opinion vs. "falsity"
 - Offsets

Health Care Examples (Cont'd)

- **Retained Overpayment Cases**
 - Amount of the overpayment or time value of money?
 - Nature of the underlying payment
 - If the result of an FCA violation, then remedy under the FCA
 - If the result of mere negligence, honest mistake or just inadvertence, then single damages and pre-judgment interest under unjust enrichment or payment by mistake common law theories of liability?

Health Care Examples (Cont'd)

• Kickback Cases

- o In Rogan, the Court ruled that the government was entitled to the full amount it had paid for the illegally referred services
- o In United States ex rel. Singh v. Bradford Regional Medical Center, U.S. Dist. LEXIS 119355 (W.D. Pa. Nov. 10, 2010), the Court followed the same analysis in a case that involved both AKS and Stark violations
- o These decisions are inconsistent with purpose of damages under FCA, which is to make the government whole, not provide windfalls
 - Damages might include overutilization, unnecessary services, services not rendered, etc.
 - Penalties would still apply
- o Key distinction between Stark and kickback analysis

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Health Care Examples (Cont'd)

• Marketing off-label use of drugs/devices

- o How many drugs/devices would not have been used absent the inappropriate marketing?
- o What factors influence usage patterns?
- o Possible offsets
 - Would another drug/device have been used anyway?
 - Were more expensive alternatives avoided?
- o Measures of damages = profits, total drug/device cost, reimbursement impact, etc.

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Questions?

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