Damages & Liability to Federal Health Programs

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Agenda

- General Legal Principles
- Practical Reality – Damages Analysis in DOJ Conference Rooms
- Damages Analysis Techniques
  - General Concepts
  - Statistical Sampling Considerations
  - Specific Examples
- Questions

General Legal Principles

No Statutory Definition of "Damages"

The False Claims Act, 31 U.S.C. § 3729

- A person who violates the FCA is liable for:
  - Treble Damages: "3 times the amount of damages which the Government sustains because of the act of that person"

  plus
  - Civil Penalties: $5,000 to $10,000 per claim, adjusted for inflation to roughly $11,000 to $22,000 per claim for violations after 2017

Constitution Limits Apply, But Not Yet Tested

- 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 found 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.

First Principle – Benefit of the Bargain

- FCA damage awards should **make the government whole**.
  - "[T]he chief purpose [of the statute] was to provide for restitution to the government of money taken from it by fraud…"

    U. S. *ex rel.* Marcus v. Hess, 317 U.S. 537, 551 (1943)
  - FCA 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."

    United States v. SAIC, 626 F.3d 1257, 1278 (D.C. Cir. 2010)
- "**Benefit of the Bargain**" Formulation is the Touchstone
  - Damages are the difference between what the government received and what the government paid for.

    United States v. Bornstein, 423 U.S. 303, 317 n.13 (1976)

Second Principle – No Consequential Damages

- As a general rule, the FCA "does not include consequential damages resulting from the delivery of defective goods."

  United States v. Aerodex, Inc., 469 F.2d 1003 (5th Cir. 1973)

- But, where benefit of the bargain doesn't seem to fit, the government has been allowed to use an "alternative basis" to compute damages (e.g., the cost of remedying the defects).

  Commercial Contractors, Inc. v. U.S., 154 F.3d 1357 (Fed. Cir. 1998)

- Example: Failure to perform required tests on a key component of self-propelled howitzers.
  - While acknowledging need to be "careful not to award consequential damages" under the FCA, 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; but denied recovery of the government's administrative costs related to processing "requests for waivers" from product specifications.

  BMY-Combat Systems v. United States, 44 Fed. Cl. 141 (1998)

Third Principle - Materiality

- U.S. *ex. rel.* Davis v. District of Columbia, 679 F.3d 832 (DC Cir. 2012)
  - DCPS submitted claim to Medicaid without maintaining adequate documentation of the services.
  - Relator sought all dollars paid on the claim, arguing Medicaid would not have paid anything had it known there was no documentation for the claim.
  - Court rejected the argument, holding "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."
  - Here "the government got what it paid for and there [were] no damages."
  - Penalty could still be imposed if material to payment nonetheless

Materiality – Developing Law

- 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."

Escobar Materiality and Damages

- U.S. *ex rel.* Harman v. Trinity Industries, Inc., 2017 WL 4325279 (5th Cir. 2017)
  - Relator alleged that undisclosed design changes rendered roadside guardrail end terminals ineligible for Federal reimbursement.
    - Relator asserted that 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 to defendant, citing Escobar.
    - "[T]hough 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."
    - Continued payment at the same rate after notice of design changes "strongly suggest[ed] that the government … considers the value of the [changed] units … to be identical to the value of the previous … units."
    - "If 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."

Continuing Hot Topic – False Statements and Certifications

- Damages can be full amount paid based on false statements
  - U.S. *ex rel.* Feldman v. Van Gorp, 697 F.3d 78 (2d Cir. 2012)
    - Grantee found to have made material false statements in renewal applications, allegedly performed research unrelated to purpose of grant.
    - "[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."
- But not just because the government says so . . .
  - U.S. *ex rel.* Wall v. Circle C. Construction, 813 F.3d 616 (6th Cir. 2016)
    - Government alleged construction contractor falsely certified to compliance with federal law requiring that electrical workers receive certain wage rates and claimed the entire construction project was "tainted" as a result; sought to recover full amount paid for the electrical work.
    - Court rejected the government's argument, "**actual damages by definition are damages grounded in reality**" and are to be determined under a benefit of the bargain analysis.

But Healthcare Kickbacks Are Different

Damages held to be dollars paid for goods or services resulting from illegal referrals

- U.S. v. Rogan, 517 F.3d 449 (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."
- U.S. *ex rel.* Drakeford v. Tuomey Healthcare System, Inc., 792 F.3d 364 (4th Cir. 2015)
  - Stark Law "prohibits the government from paying any amount of money for claims submitted in violation of the law."
  - "Compliance 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."

Trebling and Offsets

- United States v. Anchor Mortgage, 711F.3d 745 (7th Cir. 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").

Practical Reality – Damages Analysis in DOJ Conference Rooms

Key Resolution Considerations

- Cooperation with the investigation and the production of information
- Once trust is developed, opportunity to take the lead in analysis
- Not strictly bound by legal principles – room for "equity" arguments
- Specific substantive/legal arguments vs. "litigation risk"
- Application of multiplier
- No ultimate need for both sides to agree on the methodology for arriving at the settlement amount
- Providing sufficient means to support "the memo"

Damages Analysis Techniques

General Damages Analysis Techniques

- Qualitative Assessment
  - Assess the industry and regulatory backdrop
    - Clarity of regulations
    - Consistency of industry practice
  - Assess completeness of the record
- Quantitative Analysis
  - Sampling
    - Statistical sampling
    - Non-statistical sampling
  - Data Analysis
  - Recalculation
  - Offsets (including lower level of care as well as prior settlements and repayments)

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 scienter

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."

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
  - While often handled through chart review, can also be addressed through data analysis

Health Care Examples (cont'd)

- **Coding Cases**
  - Potential issues:
    - Coding of Major Complications and Co-Morbidities (MCCs) was appropriate
    - Coding of Patient Assessments in home health and SNF settings
    - Coding of diagnoses impacting Managed Care risk adjustments
    - Use of modifiers
  - Coding requirements – ambiguities; requirements versus "lore"
  - New, non-intervened qui tams based on data analysis

Health Care Examples (cont'd)

- **Kickback Cases**
  - Many different types of potential issues
  - Key distinction between Stark and kickback analysis
  - Many avenues for possible data analysis:
    - Initial identification of claims at issue
    - Filtering of claims based on time periods; physician roles; etc.
    - Correlation of inducements and referral patterns
    - Other factors which might explain patient decision to use a particular facility (past relationship, proximity, etc.)

Health Care Examples (cont'd)

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

Health Care Examples (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 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.

Questions?

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