

Life Science Webinar

December 15, 2010

K&L | GATES



Target on Pharma and Medical Devices: A New Enforcement Environment



Moderator



John S. Russell
Research Triangle Park
919.466.1117
john.russell@klgates.com

Presenters



Carol Elder Bruce
Washington, D.C.
202.778.9426
Carol.bruce@klgates.com



Michael R. Gordon
Research Triangle Park
919.466.1114
mike.gordon@klgates.com



Michael H. Hinckle
Research Triangle Park
919.466.1115
michael.hinckle@klgates.com



Steven M. Kowal
Chicago
312.807.4430
steven.kowal@klgates.com



Aggressive FDA Criminal Enforcement

Steven M. Kowal



I. FDA's Warnings of Aggressive Enforcement

- GAO Report released publicly – March 4, 2010
- Response letter from Commissioner Hamburg to Senator Grassley
 - The Commissioner promised to “hold responsible corporate officials accountable” by increasing “the appropriate use of misdemeanor prosecutions.”
- CDER Director of Compliance Congressional Testimony
 - “The agency is working to increase our enforcement on the criminal side and to connect carefully what we do on the criminal side with what we do on the civil side”



I. FDA's Warnings of Aggressive Enforcement

- DOJ Assistant Attorney General
 - Investigations of off-label promotion will be reviewed “with a view to charging responsible individuals.”
- FDA's Deputy Chief for Litigation
 - FDA “intends to look for cases in which to use the . . . strict liability doctrine.”
- FDA wants to increase deterrence
 - In off-label promotion, “the government has not imposed sufficient sanctions to counterbalance the profit motive and deter the conduct.”



II. FDA Misdemeanor Liability

- Section 333(a)(1) states:
 - “Any person who violates a provision of Section 301 of this title shall be imprisoned for not more than one year or fined not more than \$1,000 or both.”
- Section 301 defines the “prohibited acts” under the statute
- Commission of a “prohibited act” can support any level of FDA enforcement
- The statute does not define the level of participation necessary for a violation



II. FDA Misdemeanor Liability

- The extent of liability was addressed in *United States v. Dotterweich*:
 - “The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct – awareness of some wrongdoing. In the interest of the larger good, it puts the burden of acting at hazard upon a *person otherwise innocent but standing in responsible relation to a public danger*
 - The offense is committed . . . by all who have such a responsible share in the furtherance of the transaction which the statute outlaws Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting.”



II. FDA Misdemeanor Liability

- Misdemeanor liability was further explained in *United States v. Park*:
 - “Thus *Dotterweich* and the cases which have followed reveal that in providing sanctions which reach and touch the individuals who execute the corporate mission – and this by no means is necessarily confined to a single corporate agent or employee – *the Act imposes not only a positive duty to seek out and remedy violations when they occur, but also, and primarily, a duty to implement measures that will insure that violations will not occur.* The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them.”



II. FDA Misdemeanor Liability

- The statute creates a “strict liability” crime
- There is no requirement to prove personal knowledge or participation
- Liability is based on the failure to detect or prevent misconduct
 - Objective impossibility is recognized as a defense
- The statute provides the government with enormous discretion



III. FDA Felony Liability

- Section 333(a)(2) states:
 - “Notwithstanding the provisions of Paragraph (1), if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than \$10,000 or both.”
- Felony liability can be imposed in two ways
 - Second conviction for a misdemeanor offense
 - Commission of a “prohibited act” with intent to defraud or mislead
 - Intent will be inferred from circumstances



IV. Application of Strict Criminal Liability

- Who is potentially responsible?
 - *Dotterweich* – “. . . all who have a share in the furtherance of the transaction”
- The government will aim at high-level executives
 - A CEO insulated by numerous levels of management is “precisely the type of individual that the *Park* doctrine was designed to target.”
- Risk extends to all levels of responsible employees
 - “Unless the government shows more resolve to criminally charge individuals – at all levels of the corporate structure, not just the CEO . . . we cannot expect to make progress in deterring [violations].”



IV. Application of Strict Criminal Liability

- Will a warning precede prosecution?
 - Regulatory Procedures Manual states that with certain exceptions, a prosecution “recommendation should ordinarily contain proposed . . . charges that show a continuous or repetitive course of violative conduct Establishing a background of warning [will be important].”
- FDA litigation counsel states executives “have no legal entitlement to receive a Warning Letter before they can be held accountable”
- Purdue Pharma LP prosecution re: Oxycontin
 - President and CEO, Executive Vice President and Chief Legal Officer charged
 - The government acknowledged they were unaware of violations.



V. Enhanced Enforcement Weapons

- The Patient Protection and Affordable Care Act (PPACA) expands the definition of “Federal health care offense” in 18 U.S.C. §24(a)
 - Includes §301 of the FFDCA (21 U.S.C. §331)
 - Includes §1128B of the SSA (42 U.S.C. §1320a-7b) (AKS)
- FDA violations must “relate” to a health care benefit program
- Benefit program is defined broadly as “any public or private plan or contract . . . under which any medical benefit, item or service is provided to any individual . . .”



V. Enhanced Enforcement Weapons

- The definition of a violation of §301 as a “Federal health care offense” has numerous ramifications
- Such a conviction can trigger a criminal forfeiture under 18 U.S.C. §982(a)(7)
- The definition creates a basis for conviction for “laundering of monetary instruments” under 18 U.S.C. §1956(3)
- The definition creates a basis for conviction for obstruction of criminal investigations of health care offenses under 18 U.S.C. §1518
- Authorizes DOJ to use administrative subpoenas to investigate under 18 U.S.C. §3486(a)(i)
- Increases potential sentences



VI. Practical Implications

- Redirection of government focus to personal accountability
 - Reflected in extensive certification requirements in recent CIAs
- Problematic areas
 - Off-label promotion
 - Product safety concerns
 - Conduct of clinical trials
 - GMP compliance
- Will require more direct high-level corporate oversight
 - Compliance and risk assessment must become part of every aspect of the business
 - Compliance with legal and regulatory requirements must be viewed as a component of business success



For more information, contact:

Steven Kowal
K&L Gates LLP
70 West Madison Street
Suite 3100
Chicago, IL 60602
312.807.4430
steven.kowal@klgates.com



Expanded Use by DOJ of Traditional and New Statutes to Prosecute Corporations and Individuals

Carol Elder Bruce



Criminal Cases Here and on the Horizon

- Most significant recent case is *U.S. v. Lauren Stevens*, pending in federal court in U.S. District Court in Maryland. It is scheduled for trial in February 2011.
- Stevens was an in-house counsel for GlaxoSmithKline who was charged with obstructing an official proceeding (an FDA investigation), concealing and falsifying documents, and four counts of making a false statement to the FDA



Criminal Cases Here and on the Horizon



- Indictment in Stevens case alleges that Stevens did not produce documents that would have exposed GSK's promotion of off-label uses of a prescription drug.
- The indictment alleges that Stevens requested a "Pros and Cons" Memo regarding the production – pros were "responds to FDA's request," and "potentially garners credibility with FDA," and a con was "provides incriminating evidence about potential off-label promotion."
- Shows that FDA/DOJ is willing to prosecute individuals who deal with them in investigations, including counsel.

I. Traditional obstruction of justice statutes – 18 USC 1503 and 1505

A stack of three petri dishes containing bacterial cultures. The top dish has a red agar medium with small white colonies. The middle dish has a yellow agar medium with small white colonies. The bottom dish has a yellow agar medium with small white colonies.

A. Section 1503 has general “omnibus clause,” criminalizing actions corruptly influencing, obstructing, or impeding the due course of justice in the context of a pending judicial or grand jury proceeding.” Need a “nexus” between the charged conduct and the proceeding. *US v. Aguilar* (S. Ct. 1995) (10 years; \$250,000 max fine unless alternative fine act applies – 2X defendant’s gain or loss to a person)

B. Section 1505, uses similar language and makes it illegal to corruptly . . . obstruct . . . a pending US proceeding (i.e. department or agency proceeding) or congressional inquiry (5 years; \$250,000 fine or 2X gain or loss; 8 years if offense involved terrorism)

C. Both statutes require that there be a pending federal investigation or judicial proceeding and that defendant acted “corruptly.”

II. New DOJ use of post-Enron obstruction of justice statute – 18 USC 1519

A vertical stack of three petri dishes containing bacterial cultures. The top dish has a red agar medium with small white colonies. The middle dish has a yellow agar medium with small white colonies. The bottom dish has a yellow agar medium with small white colonies.

A. Section 1519 enacted as part of SOX in 2002. Anticipatory Obstruction of Justice. (20 years; \$250,000 max fine). Entitled “Destruction, Alteration, or Falsification of Records in Federal Investigations,” including conduct in “contemplation of any federal investigation.” Potentially very broad. Statute not used much at first.

B. *US. v. Ray*, 08-CR-1443 (C.D. Cal 2008) Back-dating stock options case. Defendant made false statements to his company’s general counsel during internal investigation intended to thwart any SEC investigation.

C. *US v. Hong “Rose” Carson*, 09-CR-0077 (C.D. Cal 2009). FCPA case. Defendant, former sales director of CCI, flushed bad documents down toilet when she learned of internal corporate investigation. Withheld evidence from outside counsel.

II. New DOJ use of post-Enron obstruction of justice statute – 18 USC 1519 - continued

D. *US v. Wolff*, 08-CR-417 (E.D.Ill. Aug 2010).
Food fraud, anti-dumping indictment.

- Government’s position is: Obstructive conduct need not be “corrupt” and need not be tied by intent to any pending or imminent proceeding. Big cover up intended to avoid detection with respect to a matter “within the jurisdiction” of a US agency; defendants acted in “relation to” or “in contemplation” of such a matter; but no particular pending federal investigation is necessary. In sum, defendants concealed and destroyed evidence that some day might have revealed their crime to a federal agency with jurisdiction.



III. Significant DOJ and SEC Focus on FCPA

- A. FCPA – Elements and Background
- B. DOJ targeting pharma industry sector – Nov 2009
- C. UK's Serious Fraud Office (SFO) targeting pharma industry with new UK Bribery Act – effective April 2011
- D. D. Practical implications for the regulated industry



For more information, contact:

Carol Elder Bruce
K&L Gates LLP
1601 K Street, NW,
Washington, D.C., 20006-1600
202.778.9426
carol.bruce@klgates.com



False Claims Act Enforcement

Michael R. Gordon



I. FCA Is A Powerful Tool

- Civil Penalty of \$5,500 - \$11,000 per violation
- Treble damages
- Designed to combat procurement fraud in Civil War
- Not intended for cases with high volume of claims like health care fraud cases
- Recent quote on FCA from Tony West – Head of Civil Division



Head of Civil Division

A stack of three petri dishes containing bacterial cultures. The top dish has a red agar medium with small white colonies. The middle dish has a yellow agar medium with small white colonies. The bottom dish has a yellow agar medium with small white colonies.

And since January 2009, we have recovered nearly \$4 billion under the False Claims Act – an unprecedented amount in such a relatively short period of time.

So we intend to use this important tool to its fullest potential in the Civil Division, to investigate, pursue and deter fraud in three primary areas: health care fraud; financial fraud, particularly mortgage fraud; and procurement fraud.

Tony West - Assistant Attorney General - ABA 8th Annual National Institute on the Civil False Claims Act and Qui Tam Enforcement - Washington, DC - June 3, 2010

II. False Claims Act Has Fostered Whistleblower Culture

- James Wetta, Sales Representative and double whistleblower
 - 2010: \$520M AstraZeneca whistleblower
 - 2009: \$1.3B Eli Lilly whistleblower
- Cheryl Eckard
 - 10/28/10 \$96M payment
 - Largest payment to an individual relator
 - Takeaways from this case



III. PPACA's Pro-Government/Relator Changes to FCA

- Violation of Anti-Kickback Statute is a false claim
- Relator can rely on public disclosure of state proceedings, reports, hearings, audits or investigations
- Original source exception is loosened.
- Retention of overpayment >60 days = FCA violation
- Issuance of Civil Investigative Demand at local level and use on FCA cases



IV. North Carolina Initiatives

- North Carolina Medicaid Fraud Control Unit
 - Expanded budget
 - Several additional attorneys and investigators hired within last few months
- Recent North Carolina legislation mirroring PPACA
 - Should increase local relator bar



For more information, contact:

Michael R. Gordon
K&L Gates LLP
430 Davis Drive, Suite 400
Morrisville, NC 27560
919.466.1114
mike.gordon@klgates.com



FDA Non-Criminal Enforcement

Michael H. Hinckle



FDA Has Numerous Enforcement Options

- FDA primarily uses non-criminal approaches to encourage compliance
 - Warning Letters
 - Significant business impact—used by competitors
 - Press Release
 - FDA can destroy demand for product (e.g., zinc nasal spray and propoxyphene)
 - Import Detention
 - Only requires “appearance” of misbranding/adulteration
 - Approval/Clearance Restrictions
 - Potential to hold up business objectives indefinitely



Potential Problem Areas

- cGMP/QSR compliance
- Advertising and Promotion
 - Off-label, Fair balance, Implied superiority claims
- GCPs—clinical trials
- GLPs—non-clinical studies
- Adverse Event Reporting
- Post-approval safety/efficacy challenges (e.g., Avandia, Menaflex)



What does it mean?

- FDA need not resort to criminal prosecutions, seizures, injunctions or civil penalties to achieve its objectives.
- Regulated companies should proactively head off potential compliance issues to avoid significant adverse business impact.
- Manufacturers may not get the opportunity to fully explain their actions before FDA takes action.



For more information, contact:

Michael Hinckle
K&L Gates LLP
430 Davis Drive, Suite 400
Research Triangle Park, NC 27709
919.466.1115
michael.hinckle@klgates.com



Q&A

- You may submit questions via the Webex chat feature or by emailing brittany.erwin@klgates.com



Moderator



John S. Russell
Research Triangle Park
919.466.1117
john.russell@klgates.com

Presenters



Carol Elder Bruce
Washington, D.C.
202.778.9426
Carol.bruce@klgates.com



Michael R. Gordon
Research Triangle Park
919.466.1114
mike.gordon@klgates.com



Michael H. Hinckle
Research Triangle Park
919.466.1115
michael.hinckle@klgates.com



Steven M. Kowal
Chicago
312.807.4430
steven.kowal@klgates.com

