

American Health Lawyer's Association 2011 Annual Meeting

The Era of Individual Accountability – Is a Liability Hailstorm on the Way?

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Government Enforcement Update

- Criminal and Civil Corporate Prosecutions and Settlements
- Individual Liability
- Responsible Corporate Officer Doctrine
- Individual Administrative Permissive Exclusion or Debarment from Federal Healthcare Programs



Government Prosecutions

- **U.S. v. GlaxoSmithKline-SB Pharmco, Puerto Rico.** Cidra manufacturing plant operated by GSK subsidiary. Criminal and Civil resolution originating from False Claims Act Qui Tam. GMP violations. Criminal fine \$140 million. Civil damages under FCA \$600 million. No OIG or FDA CIA.
 - Management and staff turnovers.
 - Untimely or failure to report product deficiencies.
 - Failure to implement internal compliance recommendations.

Government and Qui Tam Relator Cases

- **U.S. v. Stryker Biotech (Boston USAO).** Individual and corporate indictment for misbranding violations associated with bone-growth implants, putty, and filler. Senior management ignored warnings, off-label promotion incentives for sales force, manipulation of HDE.
- **U.S. ex rel. Steury v. Cardinal Health. (5th Cir. 2010).** Defective infusion pumps sales to VA in violation of FAR.
- **U.S. ex rel. Cox v. Smith & Nephew (WD Tenn. 2010).** Misrepresentation of country of origin and false labeling for items sold to GSA and VA.



Individual Liability

- Criminal liability may be direct or indirect.
- Conduct-based liability: FDCA, false statements, obstruction, anti-kickback, or conspiracy allegations.
- Indirect or strict liability based on corporate responsible officer doctrine (ROCD), otherwise known as Park doctrine.
- Civil liability-False Claims Act for causing submission of false claim.
- Administrative-mandatory exclusion or debarment based on conviction of specified offenses. Permissive exclusion based on agency exercise of discretion of certain offenses, including RCOD.



Direct Individual Liability

- **U.S. v. Stevens.** Obstruction of agency investigation of off-label allegations in connection with response to request for documents. Assistant general counsel indicted. Trial. Rule 29 acquittal. Advice of counsel defense on document production.
- CEOs, senior management, general counsels, compliance officers, outside counsel and consultants have been pursued for criminal, civil, and administrative sanctions.



Direct Individual Liability (*cont.*)

- Augustine Medical Supply: CEO, GC, national sales manager, reimbursement consultant.
- Synthes: President and COO, SVP, regulatory affairs.
- Purdue: CEO, Chief Medical Officer, and GC.
- AbTox: CEO, director of marketing and clinical.
- Caputo: CEO and compliance officer.
- Intermune: CEO.
- Stryker: SVP and senior management.
- Tenet: GC and compliance officer



Responsible Corporate Officer Doctrine

- First recognized in 1943 in **U.S. v. Dotterweich** - permits criminal liability for any corporate employee responsible for legal violations that impact public welfare for life and health if:
 - statute intended to improve common good; and
 - no culpable intent requirement (strict liability).
- More recently, used in FDA-focused prosecutions. Concept has broadly morphed to denote government perspective on individual accountability.

Responsible Corporate Officer Doctrine (*cont.*)

- 1975 - **U.S. v. Park** (Park Doctrine) affirms that individuals may be criminally liable for misdemeanor violations if in a position of corporate responsibility and failed to act to prevent violation that impacts public health. Park: CEO misdemeanor violations of FDCA for exposing food to rodent-infested warehouse. Repeated warnings.
- Purdue Pharma prosecution. 2007. RCOD applied to senior managers and general counsel.
- KV Pharma prosecution. 2011. RCOD applied to CEO.
- No constitutional issue for strict liability public-welfare offenses if no *mens reas* requirement, penalties small, and no grave injury to individual's reputation. Is this true today?

FDA's Agency Position On Responsible Corporate Officer Doctrine

- FDA policy on application of the Park Doctrine. Special procedures for referral and recommendation. Misdemeanor prosecutions are valuable enforcement tool.
- Applies to corporate officials without proof of intent to deceive or defraud or proof of negligence.
- Primary consideration is person's position in company and relationship to violation and whether person had authority to correct or prevent violation.
- Other factors include actual or potential harm to public, violation is obvious, pattern of violations or unheeded warnings, violation is serious, and prudent use of agency resources.
- FDA Commissioner Hamburg enforcement position on Park and FDA debarment.




HHS OIG Exclusion

- 20 statutory bases for exclusion in section 1128 of SSA
- 4 bases for mandatory exclusion – 1128(a)
 - Convictions for specified types of crimes
- 16 bases for permissive exclusion
 - Derivative (e.g., conviction, loss of license)
 - Affirmative (initiated by OIG)
- Convictions = Exclusion (almost always)
- Civil = CIA (sometimes exclusion)



Holding Individuals Accountable

- OIG investigates individuals for criminal, civil, and administrative prosecution
- Exclusion of individuals - civil cases
 - False Claims -- 1128(b)(7)
 - Poor quality care – 1128(b)(6)(B)
- Corporate Integrity Agreements
 - Certifications by members of management and board
 - Reviewed area of responsibility
 - In compliance OR non-compliance being addressed



Section 1128 (b)(15) of SSA

- Individual owners who knew or should have known of the conduct that led to the sanction
- Officers and managing employees
- of a “sanctioned entity.”



OIG Guidance on Exclusion of Officers/Managers under 1128(b)(15)

- Circumstances/Seriousness of the Offense
- Individual's Role in the Sanctioned Entity
- Individual's Actions in Response to Misconduct
- Information about the Entity









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