



STRENGTHENING COMPLIANCE TO AVOID MANAGEMENT'S LIABILITY FOR OPIOID DIVERSION

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The Government's Announced Response to the Opioid and Fentanyl Crisis

- 9/21/16: USAO's must draft district-specific strategy aimed at addressing the opioid crisis (AG Lynch)
- 6/6/17: DEA fentanyl guidance (DAG Rosenstein)
 - 90 Americans a day die from opioid-related overdoses
 - DOJ's approach to crisis: "all hands on deck"; and "use all tools available"



The Government's Announced Response (cont'd)

- 10/17/17: Announcement of enforcement action to interdict illegal fentanyl and fentanyl analogues from entering the U.S. (DAG Rosenstein)
- 11/1/17: Fentanyl safety recommendations for first responders (AG Sessions)
- 11/9/17: Announcement of scheduling of fentanyl/fentanyl analogues as controlled substances (DOJ)



The Government's Announced Response (cont'd)

- 11/29/17: “Opioid coordinator” memo (AG Sessions)
 - USAOs must designate by 12/15/17
 - Coordinator responsibilities
 - Facilitate in-take of opioid/fentanyl cases
 - Convene task force of fed/state/local/tribal law enforcement to ID opioid cases for federal pros.
 - Provide legal advice/training on opioid pros.
 - “We must prevent unlawful prescribing and **illegal diversion** of highly addictive drugs”



If Past Is Prologue, Expect Continued Vigilance in Opioid Diversion Investigations/Prosecutions

- Historically, the government has prosecuted a number of opioid diversion cases
- Hospitals and health systems prosecutions
 - Wrongdoing by institutional health professionals
 - Physicians, nurses, pharmacists, surgical techs
- Individual prosecutions



The Government's Vigilance (cont'd)

- Dignity Health (2014)
 - Agreed to pay \$1.55 M
 - Compliance procedures/controls failed to detect/prevent diversion
 - More than 20,000 oxycodone pills diverted
 - Additional, significant shortages



The Government's Vigilance (cont'd)

- Mass. General (2015)



MASSACHUSETTS
GENERAL HOSPITAL

- Agreed to pay \$2.3 M
- 2 nurses stole approx. 16,000 oxycodone pills
- DEA audit: > 20,000 pills, missing/incomplete inventory, missing drug records
- Physician prescribed controlled substances without seeing patients
- Pediatric nurse with 12-year addiction
- Other medical staff stole medication

The Government's Vigilance (cont'd)

- Appalachian Regional Healthcare (2016)
 - Reached similar agreement with U.S.
 - Pharmacy improperly filled scripts for pills written by ER physician
 - Thousands of pills diverted



Appalachian Regional Healthcare

Individual Prosecutions Have Skyrocketed

- Nurse at Abbott Northwestern Hospital (11/8/17)
 - Accessed secured automatic dispensing machines
 - Used syringes to remove hydromorphone from vials intended for patients
 - Replaced missing drug by injecting vials with saline solution
 - If convicted:
 - 4 years imprisonment
 - \$250,000 fine



Individual Prosecutions (cont'd)

- Hospice nurse at Alliance Home Health Care (7/25/16)
 - Diverted 42,140 mg. oxycodone
 - Fraudulently ordered drugs for patients
 - Had courier service hold drugs so she could pick them up for illegal distribution
 - Got hospice to hire another nurse – defendant's co-conspirator
 - Faces 20 years imprisonment and over \$1 M in fines



The RCO – A Significant Weapon in DOJ's Arsenal

- Strict-liability theory of prosecution for violations of the FDCA
- Judicially created
- Allows govt to prosecute individuals in positions of authority for subordinates' violations of the FDCA
REGARDLESS OF KNOWLEDGE OR PARTICIPATION IN UNDERLYING CRIMINAL ACTIVITY



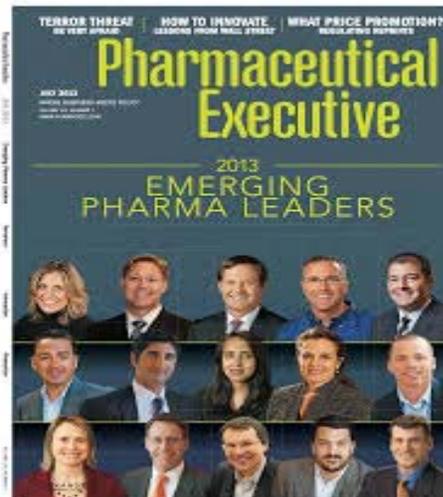
RCO – Seminal Cases

- U.S. v. Dotterweich, 320 U.S. 277 (1943)
 - FDCA “dispenses with conventional requirement for criminal conduct – awareness of some wrongdoing”
 - No one else is in a better position to act preventively to avoid problems with public health



RCO – Seminal Cases (cont'd)

- U.S. v. Park, 421 U.S. 658 (1975)
 - “The [FDCA] 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.”



RCO Resurfaces Over Past 10 Yrs

- Purdue Frederick Co. (2007) – Pres./CEO/CLO/CMO: 3 years prob./400 hrs. community service/d disgorged \$34 M/debarred from fed. health programs for 12 yrs
- Synthes (2009) – COO/Pres. of Div./VP of Ops: 5 – 9 mos. imprisonment/\$100K fine
- KV Pharmaceutical (2011) – Chair and CEO: 30 days imprisonment/\$1 M fine
- Acclarent (2015) – CEO/VP of Sales: convicted at trial/pending sentencing



U.S. V. Decoster

- Owner and COO pleaded guilty to introducing adulterated eggs into I/C
- Over 50,000 cases of salmonella poisoning
- Claimed imprisonment unconstitutional b/c had no knowledge of contamination at time of shipment
- Sentenced to 3 mos. imprisonment/\$100K fine
- 8TH Cir. aff'd convictions
- 5/22/17 – S. Ct. denied cert. which would have addressed RCO
- Industry watchers hopeful S. Ct. would have rejected doctrine
- Takeaway – **RCO Doctrine Is Here To Stay**

Opioid Crisis: RCO As An Effective Weapon

- Opioid units now being established – D.N.J.; ED. Pa. for example
- Initially targeting was to interdict opioids manufactured in clandestine labs overseas
- Recent announcements indicate targeting of “everyone making a living off these dangerous and addictive drugs”



Who Is At Risk

- Pharma
- Pharmacies/pharmacists
- Hospitals/health systems
- Manufacturers
- Distributers
- Wholesalers
- Doctors



Healthcare Management Faces Genuine Catch 22 If Government Uses RCO

- If management uncovers sig. diversion or government commences diversion investigation, management must provide DOJ all relevant facts relating to individuals responsible to qualify for “cooperation credit” under the Yates memo
- In doing so management may unwittingly point the finger at themselves given RCO tenants



Resolution: Evaluating/Strengthening Compliance Program

- DOJ Fraud Section's February 2017 Evaluation of Corporate Compliance Programs
 - Not a rigid checklist or formula
 - But does summarize topics prosecutors typically consider when evaluating compliance programs and IDs questions prosecutors ask themselves in making those evaluations



Evaluating/Strengthening Compliance Program (cont'd)

- By evaluating/strengthening compliance program, management may be able to show that they were powerless to prevent/correct the violation by subordinates (e.g., the employee who despite enhanced compliance “goes rogue”)
- Only real defense to RCO. Park, 421 U.S. at 673; Decoster, 828 F.3d at 632.



DOJ Fraud Section's February 2017 Evaluation of Corporate Compliance Programs

- Analysis and remediation of underlying misconduct
 - Has company undertaken “root-cause” analysis of the underlying misconduct; what has analysis shown?
 - Were there prior opportunities to ferret out the misconduct?
 - Why were those opportunities missed?
 - Has company implemented changes to reduce risk of reoccurrence?
- Senior and middle management
 - Is there truly a culture of compliance throughout the org?
 - Do senior leaders and management message/model strong, ethical behavior?



Evaluation of Corporate Compliance Programs (cont'd)

- Autonomy and Resources

- Does compliance function act independently within org?
- Is the compliance function properly resourced?
 - Funding
 - Personnel

- Policies and Procedures

- Who is involved in designing/implementing policies and procedures?
- Are policies/procedures effectively implemented?
- How accessible/how are policies communicated?
- Are policies/procedures operationally integrated?

*Policies &
Procedures*



Evaluation of Corporate Compliance Programs (cont'd)

- Risk Assessment

- What methodology has company used to ID and analyze risk?
- Did info and metrics detect or miss underlying misconduct?
- If missed, what steps has company taken to mitigate risks?

- Training and Communications

- What compliance training have employees received, particularly high-risk employees?
- Has senior management made company's position on misconduct clear?
- What resources are available to employees to consult for guidance on compliance policies?



Evaluation of Corporate Compliance Programs (cont'd)

- Confidential Reporting and Investigation
 - Did the company collect, analyze, and use info from its reporting mechanisms?
 - What is the company's assessment of the seriousness of the allegations?
 - Was ensuing investigation conducted independently and objectively by qualified personnel with full access to the reporting function?
 - How high within org is reporting and investigation elevated?
- Incentives and Disciplinary Measures
 - What discipline did company impose and when was it imposed?
 - Were managers held accountable for failure in oversight?
 - Who participated in the disciplinary decisions?
 - Is discipline imposed fairly and consistently across the org?



Evaluation of Corporate Compliance Programs (cont'd)

- Continuous Improvement, Periodic Testing, and Review

- Has company learned from its mistakes?
- Has company periodically tested its vulnerabilities, reviewed results, and made systemic improvements in its controls?



- Third Party Management

- Has company appropriately managed its third parties to mitigate risk as part of its compliance program?

- Mergers and Acquisitions

- Was misconduct/risk of misconduct ID'd during due diligence process?
- Was compliance function consolidated into the merger, acquisition, and integration process?

Practical Tips To Avoid Management's Liability For Opioid Diversion – Strengthen Compliance

- Conduct comprehensive background checks and investigations of employee candidates
- Concomitantly, report individual's obvious wrongful conduct to state and local law enforcement and to employee's future employer
 - Prevents diverters from taking advantage of industry that naturally resists disclosure given HIPAA and privacy environment
 - Concealing diversion from authorities invariably will result in far-worse consequences
- Drug-testing pre-employment and random, periodic drug testing for all employees
 - Test for specific substances in addition to common street drugs
 - Prosecutor applying DOJ's Evaluation of Compliance Programs will distinguish between company that tests to mitigate specific risk from company that skimps in an effort to save a few extra \$\$



Practical Tips (cont'd)

- Regularly audit opioid/fentanyl dispensing mechanisms/storage facilities
 - Address head-on the findings from the audit
 - Conduct root-cause analysis of why dosage/units counts are off and how they went missing
 - Test vials/ampules of liquid opioids/fentanyl to see if they have been surreptitiously replaced with saline/water
- Consider placement of opioid/fentanyl dispensing dispensers/machines
 - Avoid isolated rooms, out of public view, or near bathrooms
 - Instead, place them near other health care professionals who can report diversion



Practical Tips (cont'd)

- Install security cameras near opioid dispensaries
- Train employees and third parties about diversion and prevention
- Senior leaders should instill zero-tolerance culture against diversion
- If misconduct uncovered, permit independent, objective investigation by qualified personnel



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QUESTIONS???

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