

## Compound Pharmacy Prosecutions: Past Lessons and Future Trends

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## The Compound Drug Scheme

- Compounded Medicine: Allegedly Custom -Tailored to Unique Health Needs of Individual Patients
- Targeted TRICARE and Government Retirement Programs
- In the first 9 months of 2015, Tricare paid \$1.7 billion, or 20% of their total prescription drug budget, on compounded drugs.
- Compared to just \$23 million in 2010, a 7,291% increase
- In two years, TRICARE's average cost for a compound drug jumped from \$192 to \$2,595



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## The Compound Drug Scheme

- Pain creams, scar creams, wound creams, hormone replacement
- Some egregious cases have involved compounded drugs ranging from \$5,000 to \$40,000 per script
- Defense Health Agency had to Seek Additional Funding to Cover \$2 Billion Budget Hole
- Intense Media Scrutiny - CBS Nightly News and Wall Street Journal
- DOJ, DOD, OPM dedicate substantial resources to "clean up"



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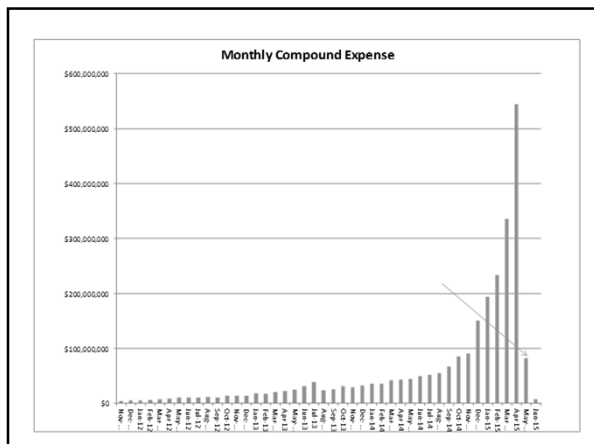
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### Compounding Pharmacy Fraud: Fact Patterns & Trends

- **Physician Kickback Schemes:**
  - Research Studies
  - Medical Director Positions
  - Providing High Salary Jobs to Spouses, Family Members
  - “Evaluation” or “Encounter” Fees for TeleMed Docs
- **Marketer Kickback Schemes**
  - % Based Compensation to Marketer; Commissions as High as \$8,000 per script
  - Concealed as Hourly Fees for Lead Generation, Consulting, Patient Screening, Patient Verification




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### Compounding Pharmacy Fraud: Fact Patterns & Trends

- **Patient Kickback Schemes:**
  - Co-Pay Assistance
  - Research Participation Fees
  - % Payments and Untraceable Gift Cards
- **Other Schemes**
  - Identity Theft: Unsolicited Deliveries to TRICARE Beneficiaries
  - Targeted Phone Solicitations, Phishing Schemes
  - Doctors and Patients in Different States; No Physician Evaluation = No Bona Fide Patient-Physician Relationship
  - Changing Formulas to Maximize Reimbursement




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### Data Mining & Target Selection

- Historically, civil enforcement actions generated by whistleblowers
- Now, TRICARE Data Mining is Used to Identify Targets
- Data Doesn't Lie; Signs of Trouble:
  - Rapid billing spikes for compounds drugs from 2013 to May 2015
  - Claims Attributable to a Small Number of High Volume Prescribing Physicians
  - Doctors and Patients in Different States
  - Multiple Compounds for Each Patient
  - Identical Compounds for Each Patient



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### Government Enforcement Tools

- **Civil Enforcement Proceedings:** False Claims Act
- **Criminal Enforcements:** Indictment in Florida, Texas, California
  - Prosecutors using traditional tools including search warrants, phone recordings, body recorders and surveillance.
- **Administrative Sanctions**
  - Exclusion Proceedings
  - Recoupment of Overpayment
  - Corporate Integrity Agreements
- **Other Remedies**



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### Other Consequences

- State Licensure & Disciplinary Issues for Medical and Pharmacy Professionals
- Loss of Privileges at Hospitals
- Adverse Employment Actions
- Loss of Professional Opportunities
- Termination of Payor Contracts
- On-Site Inspections and Audits
- Public Shaming

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**TRICARE Rules:  
What You May Not Know**

- Reimbursements Come from Private PBMs: Express Scripts and CVS Caremark.
  - Don't be fooled; it is still government money
- Stark Law Not Applicable
- 60 Day Report and Refund Not Applicable
- Administrative Definitions (32 CFR 199.9)




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**Advice of Counsel Defense**

- Very common in compounding pharmacy cases
- Many pharmacies sought legal advice regarding physician relationships and marketing relationships
- Gut-Wrenching Decisions for the Defense
  - Waiving Privilege
  - Exposing Advice, Good and Bad, to the Government
  - Exposing Attorneys to Interviews
  - Did your client tell attorney *everything*?
  - Did the client *really* follow the advice?
- Possible malpractice claims against Attorneys

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**The Yates Memo:  
A Check May Not Solve the Problem**

- To be eligible for any cooperation credit, corporations must provide to the Department all relevant facts about the **individuals** involved in corporate misconduct.
- Both criminal and civil corporate investigations should **focus on individuals** from the inception of the investigation.
- Criminal and civil attorneys handling corporate investigations should be in routine communication with one another. Every whistleblower case is evaluated by criminal.
- Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals.
- Corporate cases should not be resolved without a clear plan to resolve related individual cases before the statute of limitations expires.
- Civil attorneys should **consistently focus on individuals** as well as the company. Focus is on accountability and deterrence, not just money




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**Compliance for Compound Pharmacies  
& Lessons Learned**

- Hire a Compliance Officer
- Develop and Implement an Effective Compliance Program
- Conduct internal and coordinate external billing audits
- Develop and implement corrective action plans
- Train staff and providers to address compliance issues

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**What's Next?  
Future Enforcement Trends**

- Continued prosecutions – both civilly and criminally
- Expanded focus nationally
- Focus on pharmacies, doctors, marketers and others
- Other agencies getting involved
- Emerging growth of Department of Defense fraud investigators

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**Questions?**

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