

Compound Pharmacies: Civil and Criminal Enforcement

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Daniel Bernstein

- Since 2006, Assistant U.S. Attorney serving Southern District of Florida.
- From 2012 – 2017, served as Deputy Chief for Criminal Health Care Fraud
- Has tried a wide range of cases, including health care fraud related to compound pharmacies, mortgage fraud, and tax fraud
- State prosecutor from 1994 – 2006; tried over 100 cases

Sam Sheldon

- Current head of Quinn Emanuel Urquhart & Sullivan, LLP's Health Care Practice group
- Practice focuses on health care fraud (civil and criminal), including claims brought under False Claims Act and Stark Act
- Former Deputy Chief of the Criminal Fraud Division and Chief of the Health Care Fraud Unit of United States Department of Justice
- Former Assistant U.S. Attorney for Southern District of Texas

Compound Drugs

- **IN THEORY:** customized drugs for patients with specific health needs that cannot be met by commercially available drugs
- **REALITY:** ineffective and medically unnecessary drugs of dubious quality.
 - E.g., scar creams, pain creams, and wellness capsules

By The Numbers

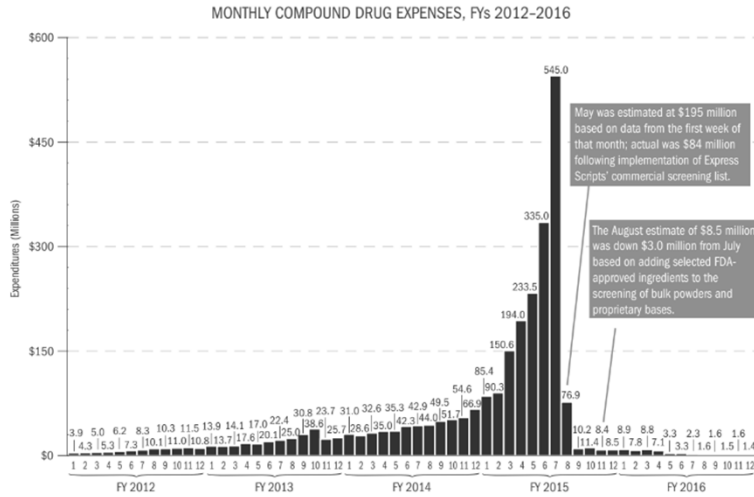
- From 2012 to 2015, the average cost for a compounded prescription increased from \$170 to \$2,135.
- Costs peaked in 2015: Tricare spent **\$1.6 billion** on compound drugs, a **threefold increase** from 2014
 - Nearly \$1 billion in first four months of 2015 alone
- Egregious price gouging
 - E.g., Pain cream that costs \$20 to make was billed at over \$3,000 tube
 - E.g., Diaper creams billed at over \$1,000 for a OTC pill that costs \$2.50

Source: Evaluation of the TRICARE Program: Fiscal Year 2017 Report to Congress

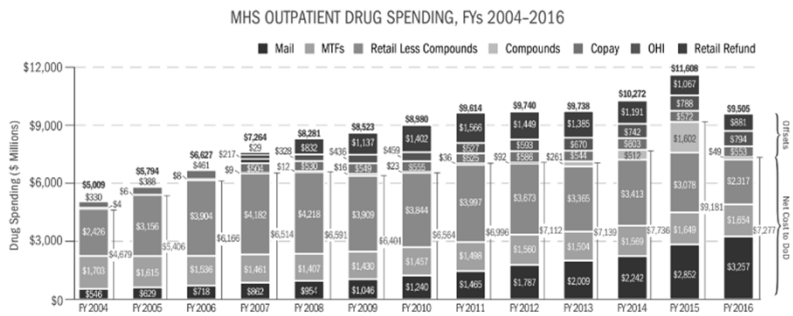
Reform in 2015

- May 2015: Tricare revised reimbursement policy to include only FDA-approved ingredients in compound drugs
- June 2015: compound claim spend decreased by almost 75%; number of filled prescriptions decreased from 105k to 42k.
- 2016: compound drug spend fell to \$49.1 million

Spend Over Time



Spend Over Time



Indicia of Compound Pharmacy Fraud . . .

Hypo # 1 – Traditional Scheme

- Compound pharmacy partners with marketing co to promote compound drugs
- Marketer identifies Tricare beneficiaries, oftentimes through cold calling and by pretending to be affiliated with Tricare, and promotes pain creams, scar creams, and wellness capsules
- Marketer refers beneficiary to a doc employed by (or that contracts w/) the marketing co
- Doc authorizes prescriptions (over phone), sometimes without any prior relationship w/ patient and without regard for the medical necessity of the prescription
- Doc sends prescription back to compound pharmacy directly (eliminates risk of beneficiary selecting a different compound pharmacy)
- CP fills prescription at a very high cost; Tricare reimburses
- CP pays marketers a fixed amount per prescription, or a percentage of the reimbursements the CP receives

Hypo # 2 – Traditional Scheme

- CP selects formulas for compound drugs that are designed to maximize Tricare reimbursement (formulas not based on scientific effectiveness), aka “High-Yield Compound Meds”
- CP contracts with marketers and solicit docs to prescribe the High-Yield Compound Meds
- CP designs pre-printed prescription forms encouraging docs to prescribe High-Yield Compound Meds
- Kickbacks from CPs to marketers from CPs, and also from marketers to docs
- Marketers even give kickbacks to beneficiaries, and also waived co-payments (illegal)

Hypo # 3– Sham Studies

- Marketer pays Tricare beneficiaries a fixed monthly payment for filling prescriptions at partner compound pharmacy
- Marketer disguises payments as “grants” for participating in sham medical study; marketer falsely presents study as approved by TRICARE
- Marketer creates bogus 501c to funnel “grants” through charity and even calls the grants “donations” in check memos
- Marketer also pays prescribing doctor for each prescription filled at a partner CP
 - Some of these payments were paid through the charity, disguised as “consulting fees” in connection with sham “study” noted above

Hypo # 4– Gift cards for Specimens

- Lab owner offers low-income Tricare beneficiaries gift cards in exchange for giving specimens for testing billed to Tricare
- At peak, lab owner collects 200 specimens - *per day* - from Tricare beneficiaries
- Lab owner pay docs flat monthly fee to sign orders authorizing the testing; docs never saw the patients and had no prior relationship with them
- The testing is almost always unnecessary, but labs put false diagnosis codes on the submission to justify testing
- Beneficiaries not even get test results

Hypo # 5– Telemedicine Sites

- Telemedicine site operator contracts with doctors; sends the doctors blank compound drug prescription forms
- Telemedicine site operator encourages doctor to prescribe the compound drugs on these forms
 - In some instances, telemedicine site even refused to pay prescribing doc unless s/he prescribed the compound drugs
- Telemedicine site operator faxes prescription directly to CP (prescription is not given to patient)
- In exchange, telemedicine site operator receives payment from CPs for advertising/pushing the compound drugs

Hypo # 6– Overflow Prescriptions

- CP A has so many prescriptions that it refers prescriptions to another CP, i.e., CP B. AKA “Overflow Prescriptions”
- CP B receives over 200 Overflow Prescriptions in a three week period
- CP B pays CP A referral fees for the Overflow Prescriptions
- To avoid detection, CP A disguises the aggregated referral fee as an “advance” for another business

Hypo # 7– Co-pay Waiver and Auto Refills

- Compound pharmacy reduces or waives co-pays (prevents patients from asking questions about expense of the drugs and from canceling prescriptions)
- Compound pharmacy encourages docs to sign “auto refill” authorization forms so that CP can continue to charge patients for refills
- As is typical, CP pays docs kickbacks (either flat fee per prescription, or a % of total reimbursement)

Hypo # 8– Valid Contract?

- CP wants to enter into contract with marketer. CP will pay marketer a % for each referred prescription that Tricare subsequently reimburses.
- CP wants to enter into contract with marketer. CP will pay marketer to cold call prospective patients; pay is not tied to number or size of referred prescriptions that Tricare subsequently reimburses
- CP enters into contract with marketer. CP agreed to pay marketer for general marketing services, and as an extra incentive promises to pay marketer a “performance-based” bonus.
 - Questions to consider: Are fees tied to the number of patients involved? Are fees tied to whether patient is Tricare beneficiary?