

“SNAKE OIL” - NOW AVAILABLE IN CREAM FORM!!!

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In the 1800's snake oil salesmen made a living by selling drugs and potions with extravagant claims of healing effects that were patently untrue.

Medical con-men, like all con-men, trade in ignorance. The snake oil salesman trades in two varieties of this commodity: the individual's ignorance of medical science and the collective ignorance of community and business leaders to the snake oil salesman's fraudulent practices. Although the first commodity is unfortunately

abundant, medical fraud *can* be stopped when community and business leaders become wise to the tactics of the snake oil salesmen.

The snake oil for the 21st Century is currently being peddled by compounding pharmacies with claims of miraculous pain creams. This article explores the scope of this growing problem, examines the motivations of doctors and compounders, recommends industry action to coordinate and formulate strategies, and sets forth the arguments for why debunking compounded pain creams - a snake oil for modern times - is a task the entire insurance industry must embrace.

A CURE LIKE NO OTHER?

The fraud of compounded pain creams is relatively new. In fact, the public is still largely unfamiliar with compounding pharmacies and compounded drugs. This is unfortunately part of the problem.

Historically, compounding pharmacies were used for custom blended medications tailored to a specific patient due to allergies to certain ingredients, the need for unusual or special dosages, or to convert the medicine from pill to some other form due to a patient's inability to swallow. The small role played by compounding pharmacies led to a lack of oversight - compounding pharmacies are not required to register with the federal government, are not regulated by the FDA, and are generally not significantly regulated or inspected by state authorities.

Today, however, insurers are being barraged with bills for expensive compounded creams to treat pain following motor vehicle accidents, workers' compensation claims and premises related injuries. If these creams worked, and actually reduced patient reliance on oral narcotics, the high price might be warranted. The problem is that there is little evidence that the creams or many of their expensive ingredients actually work when rubbed into the skin. To the contrary, several

studies suggest that the topical application of the expensive ingredients in the creams provide nothing more than a placebo effect. More problematically, many patients who are prescribed compounded pain creams continue to also receive prescriptions for narcotic medications and oral drugs which duplicate ingredients found in the creams.

If there is indeed a paucity of medical evidence supporting the usage of compound pain creams – which there is – why has there been an enormous jump in prescriptions and dispensing? The obvious answer is money. There is a fortune to be made today in compounded pain creams, just as there was a fortune to be made on snake oil sales in the 1800's.

A MODERN DAY PROFIT FOR A MODERN DAY SWINDLER

Compound creams, in no uncertain terms, are costly. A single tube of this modern day “snake oil” can retail for up to \$10,000 and each new prescription – often offered as a “trial” of the cream – authorizes 10 refills. This means that one “trial prescription” for one patient can generate nearly \$100,000. Compounding pharmacies reach these incredible prices by including expensive and unproven ingredients in the compounded creams.

The pain creams with pharmaceutical ingredients come with dubious names such as CNA-8 or CNA-10 and can contain up to 8- or 10 individual drugs, such as Ketamine HCl, gabapentin, flurbiprofen, cyclobenzaprine, bupivacaine and baclofen to name a few of the more utilized components. The ingredients are powerful anti-inflammatories, muscle relaxants and analgesics. There is a dearth of information on effectiveness of using multiple ingredients in a topical application, but even more troubling is the complete lack of safety data. There are no studies concerning potential drug interactions, or even the stability of the drugs in this format. This is a very real danger to the public health. In fact, a child died in California after ingesting the “cream” from his mother's skin. These pharmaceutical “pain creams” are billed anywhere from \$3500 to \$10,000 per jar per month.

The compounders have so far been able get away with this because are no standards for what goes into compounded pain creams. The “recipes” are often pre-determined by the compounders and there is no regulation of the amount, if any, of active ingredients that go into the mix. The few ingredients of proven effectiveness in compounded pain creams are already available as vastly more affordable over the counter products. This includes menthol (Bengay), Lidocaine (Aspercreme), and capsaicin (Zostrix). Comparing the costs for these over the counter products – often in the range of \$10 to \$15 – to a compounded cream containing the same ingredients (such as a tube containing menthol and capsaicin but priced at \$2800) begins to reveal why the snake oil salesman gets up in the morning.

The marketing pitch for these moneymaking creams starts with physicians. Compounding pharmacies aggressively market their wares to doctors, especially those “pain management specialists” or surgeons who are closely allied with plaintiffs/claimants law firms. Compounding pharmacies offer to do everything possible to entice physicians to prescribe their creams including

writing the letter of medical necessity for the physician,¹ and attempting to collect from the insurers. In fact, in many cases, the prescriptions are pre-printed by the compounding pharmacy and sent to physicians to check a box next to the particular cream to be used. Another option offered to entice physicians in this pay-to-prescribe scheme is setting up a compounding pharmacy *in* the doctor's medical office; this allows physicians to offer point of service treatment to assist their bottom line.

Several investigations have uncovered online advertisements and job postings by companies linked to compounding pharmacies that were recruiting doctors to participate in studies and data collections related to compounded pain creams. Purportedly, the doctors could make \$5,000.00 to \$10,000.00 per month by screening and prescribing the compounded creams, even if the patients did not need them.

Physicians are not immune to the allure of these directed marketing tactics. In 2014, prosecutors in California indicted a business man, Kareem Ahmed, for paying a total of \$25 million in kickbacks to 14 doctors, chiropractors and pharmacists for overbilling the California workers' compensation system to the tune of more than \$100 million dollars for compounded pain creams.²

In September of 2015, a physician in Minnesota was indicted for allegedly receiving kickbacks via her own 501(c)(3) for writing fraudulent pain cream prescriptions.³

On December 23, 2015, the Attorney General for the Southern District of Georgia obtained almost \$10 million, the largest health care fraud recovery in that office's history, to resolve allegations that physicians had violated the False Claims Act by submitting claims to the Government in violation of the Stark Law (the federal anti-kickback law).

The U.S. Attorney General has warned that health care providers, large and small, should not be utilizing financial incentives for referrals when they are determining the best course of care for the nation's citizens.⁴

The nation's citizens are also a marketing target of the compounding pharmacies. Retired NFL quarterback Bret Favre has spoken on Sirius XM's NFL show to promote the benefits of RX Pro, a compounded cream. In the direct to patient model, patients take the prescription form to the physician to sign and fax to the pharmacy, and it is at this point that the pharmacy becomes impossible to contact. Thus, even when patients decide the creams do not work and try to stop the refills, they cannot get in touch with the compounder, the creams keep arriving by mail and bills sent to the carriers continue to accrue. The cost to insurers, government agencies and the public is enormous and growing, due to the remarkable profits that can be made on these preparations whether legal or illegal.

EVERY CON MAN NEEDS A VICTIM

So who is paying for these prescriptions? The first target of the compounded pain cream fraud was national health insurers. Ten years ago, compounding of pain creams was virtually unheard of. In 2010, Tricare, the health care program for active and retired service members and their families, was paying \$23 million for compounded drugs. By fiscal year 2014, costs had ballooned to \$513 million. A feeding frenzy in the first nine months of 2015 saw costs to Tricare for compounded drugs rise to \$1.7 billion.⁵

When Tricare balked at the costs of these “miracle” creams, and met with the pharmacies to set better pricing practices for compounded creams, the federal government got involved and began to look at the compounding pharmacies it had been authorized to oversee under the Federal Drug Quality & Security Act enacted in 2013.⁶ As a result, the federal government has begun prosecuting the fraudulent billing of compounded pain creams to governmental insurance carriers. In Florida, four pharmacies agreed to pay \$12.8 million to the government after an investigation into the billing practices for scar and pain creams.⁷ Several law firms are now advertising to provide a defense in the compounding pharmacy Tricare Fraud Investigation.

Recognizing the outrageous costs at issue, the lack of demonstrated efficacy, and the ongoing fraud prosecutions, most health insurers have removed compounded pain creams from their formularies. Unfortunately, this has not stopped the fraud. In 2015, the federal government obtained pleas from a compounding pharmacist in New Jersey - Vladimir Kleyman, the owner of Prescriptions R US - for payments to another individual in the tens of thousands of dollars (\$50,000.00) to bribe physicians for referring prescriptions for the compounded creams to his pharmacy. The defendant knew that certain health insurance carriers, including the federal health care benefit programs, did not cover compounded pain cream, but he dispensed them and billed them as a covered item. The defendant was sentenced to 20 months in prison for defrauding health care benefits programs of hundreds of thousands of dollars.⁸

As it has become more difficult to sell this particular snake oil to national health insurance carriers, the new target of the compounded pain cream fraud is state workers' compensation carriers and auto insurers. Due to regulation, workers' compensation and other liability carriers often have limited options in denial of payment.

As a result, some states have begun to review the practices of these compounding pharmacies. In 2013, the Texas Attorney General (AG) began investigating compounding pharmacies which were soliciting physician investors in Texas and other states for potentially lucrative deals in which the doctors would refer patients to a pharmacy and share in resultant profits.⁹ By 2014, the Texas legislature was questioned about its oversight of compounding pharmacies and the lucrative deals involving doctors being solicited to write prescriptions for custom drugs.¹⁰ In January 2015, the Texas AG issued Civil Investigative Demands (CIDs) to a compounding pharmacy and several affiliates seeking information under the Texas Deceptive Trade Practices Act, which focused on

physician ownership and financial relationships, and which imply greater oversight and enforcement will be forthcoming.¹¹

In California, legislation has been passed attempting to control the high cost of compounded drugs by preventing the compounder from using only the highest ingredient price, and allowing each ingredient to be individually billed and paid.

This legislative amendment, not surprisingly, resulted in the opposite of its intended effect. Following the California amendment, additional ingredients were added to each prescribed cream based upon the highest ingredient costs, which resulted in the fastest growing pharmaceutical cost to California's workers' compensation system. Following the price control legislation, the costs of these compounded creams rose from \$10 million in 2006 to \$145 million in 2013.¹²

Last year, federal investigators seized assets and bank accounts of Frank V. Monte, president of Centurion Holdings, a marketing firm. This civil action was put on hold due to a pending criminal investigation by the U.S. Attorney's Office. The defendants allegedly made payments to patients and used an active duty Air-Force member to recruit others to obtain prescriptions for compounded prescription creams - each selling for up to \$17,000 for a tooth-paste sized tube. The U.S. Attorney General, Lee Bentley noted that "the vast majority of these compound creams - some of which costs in excess of \$40,000 - are nothing more than elaborate shams to steal from the Tricare program and military personnel." ¹³

WHAT IS THE REAL CURE FOR THIS EPIDEMIC?

As should now be evident, the snake oil salesmen of the compounded pain cream industry, having exhausted the trust of national health insurance carriers, have moved on to the deep pockets of liability and workers' compensation insurance carriers. Once aware of the problem, insurers and self-insurers alike must act. Fraud trades on ignorance and snake oil salesmen can be stopped when leaders become wise to their tactics by:

1. Identifying the players (compounding pharmacists, physicians and others);
2. Determining the methodology of and relationships between the players (pay to prescribe, ownership and direct sales);
3. Quantifying the costs utilizing components, coding, and available caps; and
4. Developing responsive strategies including, but not limited to: legislative involvement, data mining from insurers and TPAs, use of existing state remedies, and RICO/fraud investigations & litigation.

To stop the compounded pain cream fraud there must be a concerted effect between carriers, attorneys and even some physicians. If you come across these creams or encounter these snake oil salesmen, you should contact your legal representative immediately.

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¹ The compounding pharmacy will send a "Letter of Medical Necessity" for the prescribing physician to sign when the bills are sent which vary little between patients and prescribers. These letters make the claim that the oral medications can produce bothersome adverse effects which have created the need for topical analgesic formulations. The citations to studies have no relationship to the drugs being mixed together and usually cite to a study of a single ingredient topical application.

² Foshay, Karen, The Price of Pain: Indictments allege a massive compound cream scam, www.scpa.org/news/2014/09/11/46622/the-price-of-pain-indictments-allege-a-massive-compound-cream-scam, SEP 11, 2014.

³ Federal Bureau of Investigation. District of Minnesota. September 23, 2015. <https://www.fbi.gov/minneapolis/press-releases/2015/bloomington-pain-management-doctor-indicted-for-accepting-kickbacks-as-part-of-large-scale-health-care-fraud-scheme>

⁴ Department of Justice, The United States Attorney's Office, Southern District of Georgia, December 23, 2015. www.justice.gov/usao-sdga/pr/government-settles-alleged-false-claims-act-violations-Memorial-Health.

⁵ Tom Philpott, Stars and Stripes, July 30, 2015. <http://www.stripes.com/news/us/compound-drugs-fleece-tricare-create-deep-budget-hole-1.360510>

⁶ The bill (H.B. 3204, signed into law on November 27, 2013 by President Obama) would modify the Federal Food, Drug, and Cosmetic Act to grant the Food and Drug Administration (FDA) more authority to regulate and monitor the manufacturing of compounded drugs. The bill would exempt compounded drugs from new drug requirements, labeling requirements, and track and trace requirements if the drug is compounded by or under the direct supervision of a licensed pharmacist in a registered outsourcing facility and meets applicable requirements.

The bill would establish annual registration requirement for any outsourcing facility. The bill would require a facility to report biannually to the United States Secretary of Health and Human Services (Secretary) on what drugs are compounded in the facility and to submit adverse event reports. The bill would subject such facilities to a risk-based inspection schedule.

However, to date, there is no information of compliance for these newly created "outsourcing facilities." There are no safety studies, no stability studies and no assurance that the compounded creams actually contain the dosage and ingredients stated on the prescription form. Patients are not informed how to use the cream other than to apply it several times per day to the area that hurts. The physicians are not doing their due diligence to assure that a product with multiple ingredients that overlap medications do not have adverse reactions. There is almost no regulation of the pain related compounding pharmacies. In fact, this federal law, which was enacted following the deaths of 70 people from a purportedly "sterile" steroid for injection contained a deadly fungus, only made it voluntary to register as a non-manufacturing facility that makes individualized products for a particular patient. If sales are too good, then the compounding pharmacy would fall under the FDA purview as a manufacturer. They get around this by simply opening another compounding pharmacy right next door to get around the full review by the FDA.

⁷ Walker, Joseph, WSJ, 11/8/15, <http://www.wsj.com/articles/u-s-targets-pharmacies-over-soaring-claims-to-military-health-program-1447032619>

⁸ Department of Justice, The United States Attorney's Office, District of New Jersey, November 4, 2015. <http://www.justice.gov/usao-nj/pr/compounding-pharmacist-sentenced-20-months-prison-paying-kickbacks-referrals-health-care>.

⁹ Roser, Mary Ann, [American-Statesman](#), 11/9/2013.

¹⁰ Rose, Mary Ann, [American-Statesman](#), 4/14/2014.

¹¹ McKenna, Sean, Woodruff, Kenya S., Kreick, Jennifer S., [Physician Investment un Compounding Pharmacies – Under Fire from Texas AG?](#), 3/18/2015, www.haynesboon.com/news-and-events/news/alerts/2015/03/18/physician-investment.

¹² Foshay, Karen, [The Price of Pain: High Costs Spur Questions about Compound Creams](#), www.scpr.org/news/2014/09/10/46553/the-price-of-pain-questionable-marketing-loose-oversight, SEP 9, 2014.

¹³ Elaine Silberstein, ['Wolf of Wesley Chapel' under fraud investigation by feds](#). [Http://www.tbo.com/news/crime.wolf-of-wesley-chapel-under-fraud-investigation-by-feds-20160124](http://www.tbo.com/news/crime.wolf-of-wesley-chapel-under-fraud-investigation-by-feds-20160124).