From:

Sent: To: Subject: Paonessa, Albert </O=MAIL/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AL.PAONESSA3> Sunday, June 10, 2012 7:46 PM Cochrane, Patrick; Cochrane, Michael Fwd: Oxy & Harvard



Great article. Don't forward to anyone. Thanks

Albert Paonessa III President Anda, Inc.l

Begin forwarded message:

From: Terry Haas <<u>thaas@harvarddruggroup.com</u>> Date: June 10, 2012 12:53:05 PM CDT To: Albert Paonessa <<u>Al.Paonessa3@Andanet.com</u>> Subject: Fwd: Oxy & Harvard

Sent from my iPad

Begin forwarded message:

From: David Liming <<u>dliming@harvarddruggroup.com</u><<u>mailto:dliming@harvarddruggroup.com</u>>> Date: June 7, 2012 8:26:14 AM CDT To: Terry Haas <<u>thaas@harvarddruggroup.com</u><<u>mailto:thaas@harvarddruggroup.com</u>>> Subject: RE: Oxy & Harvard

Now that is funny ! You made my day!

David F. Liming Senior Vice President - Finance & Administration Chief Financial O fficer The Harvard Drug Group, L.L.C. 734-743-6060 Fax 734-743-7060 <<u>mailto:DLiming@HarvardDrugGroup.com</u>>DLiming@HarvardDrugGroup.com<<u>mailto:DLiming@HarvardDrugGroup.com</u>> <<u>http://www.harvardDrugGroup.com</u>> WWW.HarvardDrugGroup.com<<u>http://WWW.HarvardDrugGroup.com</u>>

From: Terry Haas Sent: Thursday, June 07, 2012 9:18 AM

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To: David Liming Subject: Re: Oxy & Harvard

Thanks Dave. It is a great pleasure to be mentioned in the same article as two convicted felons. Be well! Th

Sent from my iPad

On Jun 7, 2012, at 7:20 AM, "David Liming" <<<u>mailto:dliming@harvarddruggroup.com</u>><u>dliming@harvarddruggroup.com</u><<u>mailto:dliming@h</u> <u>arvarddruggroup.com</u>>> wrote:

Business Week Article, short quote from Terry.

David F. Liming American Pain: The Largest U.S. Pill Mill's Rise and Fall By Felix Gillette<a href="http://www.businessweek.com/authors/1050-felix-gillette">http://www.businessweek.com/authors/1050-felix-gillette</a> on June 06, 2012

Christopher George and his twin brother Jeffrey opened their first pain clinic in a strip mall on the outskirts of Fort Lauderdale in 2008. There were a couple of rooms and a handful of doctors. No appointment was necessary.

It was a good year to be in the business of servicing people in pain. The economy was tanking. The real estate market was in free fall. People were losing their homes, businesses, savings, and jobs, and looking for an escape from their discomfort. The George brothers ran an ecumenical clinic. Their doctors didn't discriminate among the causes of human suffering—be it back pain, fibromyalgia, toothaches, cancer, depression, divorce, boredom, mental illness, unemployment, hip replacement, or withdrawal symptoms.

Just about everyone who came through their doors walked away with the same remedy: a prescription for a month-long supply of powerful opioids. More often than not, the pills were small and blue—generic, immediate-release oxycodone-hydrochloride, which everyone called "roxies." The cust omers often left satisfied and frequently

returned.[http://images.businessweek.com/cms/2012-06-

<u>06/feature\_drugs24\_01inline\_202.jpg]Palm</u> Beach sheriff officeJeffrey helped run the nation's largest pill mill operation

The George twins, now 31, grew up in Florida in an entrepreneurial family. Their father, John George, owned M ajestic Custom Homes, a luxury development business that fell into bankruptcy during the recession. While their father's company crumbled, the twins' business flourished. Each of their four clinics—American Pain, Executive Pain, Hallandale Pain, and East Coast Pain—was bigger than the last. Christopher invested in two pharmacies. They charged patients \$50 a referral to visit a mobile MRI business in a parking lot behind a strip club. Jeffrey bought a monster truck, a Lamborghini, and a bunch of boats. They advertised on billboards. They gave their mom a job.[http://images.businessweek.com/cms/2012-06-

<u>06/feature\_drugs24\_02inline\_202.jpg]Palm</u> Beach sheriff officeChris paid doctors up to \$100 a prescription

Oxycodone and hydrocodone are opioids and controlled substances; their active ingredients are derived from the opium poppy. Each year in December, the Drug Enforcement Administration (DEA) announces how much of such controlled substances may be produced in the country in the following year. For 2012, the DEA has set the quota for oxycodone at 98 million grams, or about 108 tons, and for hydrocodone at 59 million grams, or 65 tons. Thousands of businesses participate in the multi-step process by which the opium derivatives are harvested in India, Turkey, and Australia, turned into dozens of different generic and brand-name narcotic medications, distributed throughout the U.S., and resold to individuals via prescriptions. There's lots of money to be made along the way. In 2011, U.S. sales of prescription painkillers amounted to \$9 billion, according to IMS Health.

Opioids are not only profitable, they're addictive and dangerous. They can depress respiration. Take too many or mix them with other drugs, such as alcohol, and a patient can stop breathing altogether. According to the Centers for Disease Control and Prevention, 14,800 Americans died from overdosing on opioids in 2008, the most recent year data is available—more than the number of deaths from heroin or cocaine.

Most opioids are Schedule II drugs, subject to regulatory restrictions from state and federal agencies. But the regulations are not always clear. Sell too many, too fast, with too much marketing or too little discretion, and suddenly the veil of social acceptability is yanked away. The resulting exposure can be perilous. Those who cross over the sometimes hazy line separating legal from illegal handling of the pills often watch as federal agents suspend their licenses, seize their products, and arrest them in high-profile busts with gothic code names. Recent crackdowns have included Operation Snake Oil, Operation Pill Nation, and Operation Juice Doctor 2

In the spring of 2010, the George brothers were the target of Operation Oxy Alley. Local and federal cops raided their businesses, confiscated their opioids, and seized millions of dollars of assets, including safes full of cash stashed away in their mom's attic, according to prosecutors. In August 2011 the Department of Justice unsealed a five-count indictment outlining a range of charges, from racketeering to possession with intent to distribute controlled substances, against 32 individuals, including 13 doctors and one wholesaler involved with the Georges' clinics. From 2008 to 2010, according to the federal agents, the George twins were the largest illegal dispensers of oxy codone in the U.S.

"The significance of today's takedown is that we have dismantled the nation's largest criminal organization involved in the illegal distribution of painkillers," said John Gillies, special agent in charge for FBI Miami. "Up until today, efforts focused on the demand by targeting individual users. Today, we attacked the source and choked off the

supply."[http://im ages.businessweek.com/cms/2012-06-

<u>06/feature\_drugs24\_03inline\_405.jpg]The</u> Palm Beach Post/Zuma PressIn West Palm Beach, a George brothers clinic

In the fall of 2011, Jeffrey George pleaded guilty to one count of racketeering conspiracy, a federal charge in which the members of an organization can be held responsible for crimes committed on behalf of the organization. He is serving a 15½-year sentence. He is also currently awaiting sentencing in a separate state criminal action in which he pleaded guilty to second-degree murder in the overdose death of a pain clinic patient. His lawyer did not respond to an interview request. Christopher George pleaded guilty to one count of racketeering conspiracy. He is now serving 17 ½ years in prison. The twins' mother, Denice Haggerty, pleaded guilty to one count of conspiracy to commit wire fraud and is now serving a 30-month sentence.

People at all levels in the opioid industry tend to shy away from talking about their role in the supply chain. On May 17, however, Christopher George agreed to speak on the record for the first time.

"People ask me why I didn't get out when I made all that money," he says during a telephone interview from prison in Atlanta. "I had multiple lawyers telling me that I was OK. I really didn't feel like I was going to get in trouble for it. We opened two offices in Georgia. I was opening one in Missouri and one in Texas also. I was expanding."

He says he never considered giving it up. "People don't just suddenly stop doing something they are doing really well at," says George. "I liked the work. I liked the challenge of it."

To move large amounts of prescription painkillers in America, you need somebody to write the prescriptions. You need doctors. Hiring doctors to sell drugs is easy, says George. He found his doctors by posting ads on Craigslist. At their peak, when they were running the largest pill mill operation in the U.S., the George twins had roughly a dozen doctors working for them.

George says not a single doctor he interviewed ever turned down a job offer. Although he was always younger than the doctors he was interviewing—he was in his late twenties at the time—George says he made a professional impression. "I had such a big office; it was an easy sell," says George. "They didn't walk into some hole-in-the-wall place. The hours were good. The pay was good."

What the jobs lacked in prestige, they made up for in wages. According to George's indictment, doctors at his clinics were paid a flat fee for each opioid prescription they wrote—typically, \$75 to \$100 a pop. To help maximize their efficiency, doctors were given prescription stamps they could use quickly, over and over. It was common for physicians at American Pain to see 100 patients a day, he says. At that rate a doctor would earn roughly \$37,500 a week—or \$1.95 million a year.

It was a doctor who first advised him to go into the industry. At the time, he and his brother were running a hormone-replacement therapy business and selling steroids online. Along the way they got to know a doctor who told them that painkillers were a much bigger market and advised them on how to get started. The doctor later died in a car crash overseas, but he left the George brothers with a lucrative business model. According to prosecutors, the twins' pain clinics, over their two-year run, sold 20 million oxycodone pills and brought in \$40 million.

One of the doctors George eventually hired was a plastic surgeon named Patrick Graham. A police wiretap captured a conversation between George and Dr. Graham that touched on the topic of employee compensation. "You make a lot more money doing this than you do doing plastic surgery," said Dr. Graham, according to court documents. In October 2011, Dr. Graham, 64, pleaded guilty to one count of conspiracy to commit money laundering. He is now serving a four-year sentence. His lawyer declined to comment.

George typically charged his walk-in patients \$200 for the first visit, and \$150 a visit thereafter. He says about hal f his revenue in the pain clinics came from such consultation fees. The other half came from buying opioids wholesale and then reselling them at a markup. In most states, after a patient gets a prescription for painkillers from a doctor, he then has to go to a pharmacy. Not so in Florida in 2008, when George was launching his business.

From the get-go, George wanted to sell painkillers directly from his clinics, but he needed someone to sell him the pills. Due to the legal and public-relations risk of handling large amounts of opioids, people in the business tend to be tight-lipped about their suppliers, especially with people they don't know. At first, George checked out the major national pharmaceutical wholesalers, such as Cardinal Health

(CAH<<u>http://investing.businessweek.com/research/stocks/snapshot/snapshot.asp?ticker=CAH</u>>), AmerisourceBergen

(ABC<<u>http://investing.businessweek.com/research/stocks/snapshot/snapshot.asp?ticker=ABC</u>>), and McKesson

(MCK<<u>http://investing.businessweek.com/research/stocks/snapshot/snapshot.asp?ticker=MCK</u>>) . He soon realized that was a dead end. The top distributors had too many rules, he says. To take one example, according to George, they refused to sell you an order that was 100 percent controlled substances. At least half the order, he says, had to be other medications. George had no way of reselling large amounts of, say, aspirin. It would crimp any potential profits. "They were tough to get set up with," says George. "I tried. It was too much of a pain."

Eventually, hunting around online, George found a list of businesses in Florida that had DEA registration numbers. The list didn't specify which were retailers and which were wholesalers. So George had an employee sit down, call every business, and ask whether they sold controlled substances to medical clinics—and if so, under what conditions. Before long, George had identified a couple of potential regional dealers. From there, says George, it was surprisingly easy. "All I had to do when I started was call up a wholesaler, say I had a medical office, and fax in the doctor's DEA registration and medical license," says George "Then I would basically tell them what I wanted, send in the order forms, and they'd ship to me. They didn't know who I was. They didn't talk to the doctor. I could have been someone with a doctor's stolen information. There is really little due diligence."

George soon learned one of the quirks of the opioid market. In most wholesale negotiations, the more you buy, the less you pay per unit. With opioids, the inverse is true. The more opioids you order, the more a wholesaler will charge you per pill. "It's backwards from a normal free market," says George. That's because the more a wholesaler agrees to ship to someone like George, the higher the risk that it will trigger a red flag at the DEA. As a result, the wholesalers have to be cautious when dealing with new clients.

Opioid crackdowns often start with a tip from a wholesaler. On Sept. 29, 2010, agents at the DEA office in New Orleans received a phone call from D&H Wholesale Medical in Ruston, La. According to court documents, the wholesaler reported to the DEA that a new customer with no established relationship had just tried to order 20,000 oxycodone pills. The tip triggered an investigation. In the fall of 2011, DEA agents raided more than a dozen businesses, homes, pain clinics, and pharmacies around Atlanta and arrested multiple individuals for their alleged involvement in a racketeering conspiracy to illegally sell large amounts of oxycodone.

George says that as his business in Florida expanded, he struggled to buy enough opioids to keep up with the demand His stable of almost a dozen wholesalers ranged from tiny local operations, such as Medical Arts Pharmacy in St. Petersburg, to a couple of national distributors, including Harvard Drug Group, based in Livonia, Mich., one of the 10 largest wholesalers of generic drugs in the country.

George guarded the names of his wholesalers from the hundreds of other pain clinics that were popping up in Florida. In retrospect, George says the reason he was able to operate with such volume is because he forged more deals with more wholesalers than his competitors. "I worked real hard at getting wholesalers and keeping them secret," says George "That's why we were able to buy so many more pills than other pain clinics. We did a lot more work in finding out who was selling the medication."

When the cops descended on American Pain and its sister clinics in the spring of 2010, several wholesalers found themselves in trouble for selling to George. Among the defendants was Steven Goodman, the owner of Medical Arts. Earlier this year, Goodman pleaded guilty to one count of conspiracy to defraud the U.S. He is currently awaiting sentencing. His lawyer declined to comment.

On June 15, 2010, the DEA suspended Harvard Drug's license to distribute controlled substances on the grounds that the company had endangered public safety by selling oxycodone to pain clinics in Texas and Florida—including American Pain and Executive Pain. In response, Harvard Drug filed suit against the Department of Justice seeking injunctive relief. According to Harvard Drug's complaint, the company already had in place a "suspicious order system," designed to monitor orders for controlled substances and, on average, was faxing the DEA five warnings a day. The company argues that in January 2010—months before the DEA revoked its license— Harvard Drug had reached out to the DEA, specifically seeking guidance about whether it was OK to sell oxycodone to the pain clinics in question. In April 2011, Harvard Drug announced on its website that the company had reached a settlement with the federal government resolving all of the DEA's claims. Harvard Drug admitted no wrongdoing and agreed to pay an \$8 million fine. Chief Executive Officer Terry Haas, who joined Harvard Drug in January 2011, says the company has stop ped selling oxycodone in the U.S.

In the meantime, recent court cases show that pharmaceutical wholesalers continue to be vexed by what they describe as ambiguity at the DEA. In February, the DEA suspended Cardinal Health's license to ship controlled substances from its distribution facility in Lakeland, Fla., alleging that the company had endangered public health in part by selling enough oxycodone to two CVS Caremark

(CVS<<u>http://investing.businessweek.com/research/stocks/snapshot/snapshot.asp?ticker=CVS</u>>) pharmacies in Sanford, Fla., to supply a population eight times the city's size. The move came just a few years after Cardinal Health settled over similar allegations from the DEA, paying a \$34 million fine in 2008 without admitting liability. This time, Cardinal Health promptly filed suit against the federal government seeking relief.

Lawyers for the Healthcare Distribution Management Association (HDMA)—a trade group for wholesalers—filed a brief in support of Cardinal, arguing that the system for policing wholesalers is broken and that the DEA has "failed to provide meaningful guidance" to wholesalers.

In May, Cardinal Health settled with the DEA, agreeing to halt shipping of controlled substances from the Florida facility for two years. In the meantime, the fog surrounding opioid distribution lingers, creating e nough uncertainty in the market for retailers like the George twins to accumulate vast a mounts of oxycodone in a piecemeal fashion by cobbling together smaller

orders from a network of wholesalers, each unaware of what the others are doing. In the absence of a centrally maintained database of the sales of controlled substances, some distributors, like Harvard Drug, have decided it's no longer worth the risk of participating in the market.

Gary Boggs, special agent with the DEA's Office of Diversion Control, says the cases that the DEA has brought in recent years involved wholesalers knowingly making enormous sales to customers that were, per se, in violation of DEA rules. "The notion put out by HDMA that somehow or another the DEA is not providing essential information to them is simply not accurate," says Boggs. "It's a smoke screen. It's a step out of desperation."

George, too, says he is being unfairly punished for regulatory shortcomings. When George got into the business, Florida was one of 15 states in the country without a statewide prescriptionmonitoring program (PMP). It has since put one in place. According to the Alliance of States with Prescription Monitoring Programs, 48 states now have legislation authorizing a PMP, and 41 states currently have PMPs that are operational. Such databases are typically designed so that a retailer can type in a patient's name and see if that individual has recently filled prescriptions for painkillers at other clinics or pharmacies.

George says that in the absence of a state system there was no way he and his employees should be held responsible for failing to differentiate between legitimate patients and reckless purchasers going from doctor to doctor to stock up on painkillers to resell on the street. George also says he doesn't see how he can be held criminally responsible while the majority of the wholesalers who dealt to him have avoided criminal charges. "I don't understand how they're not way more responsible than me," says George. "I'm serving 18 years for it, and they're not even in jail."

[http://images.businessweek.com/cms/2012-06-06/BW23\_feat\_greece\_405.jpg]According to IMS Health, there are 92 different oxycodone-based medications currently on the market in the U.S. and another 218 containing hydrocodone. Only a few are patented. George says he and his brother steered clear of brand-name opioids. He once accidentally ordered Percocet, a brandname opioid, from a wholesaler, when he meant to order generic endocet. Otherwise, he avoided medications like OxyContin, Opana ER, or Vicodin—which generally belong to a parallel world where patients have health insurance, physicians worry about ethical prescribing, industryfunded nonprofit groups advocate for the right of doctors to prescribe opioids to patients in pain, and glowering U.S. senators occasionally broadcast their disapproval.

The George broth ers operated downmarket from all of that. They bought and sold the generics. Their customers paid in cash. At his clinics, doctors typically prescribed around 180 30-mg painkillers per patient at \$2 apiece plus a small amount of generic anti-anxiety medication such as alprazolam. George says the wholesalers usually sold him generic roxies for, on average, around 70¢ a pill. Thus each sale netted roughly \$1 30 profit per pill, or about \$235 for every prescription they filled on site. For brand opioids, on the other hand, says George, wholesalers charged about \$3 a pill. "Nobody buys brand," says George. "Especially when it comes to roxies. I don't even know who makes the brand Roxicodone."

Instead, George says he sold about a half-dozen kinds of generic roxies, including ones marked "A/215," which are made by the Actavis Group, a multinational generic drug manufacturer headquartered in Zug, Switzerland; "V-4812," manufactured by Qualitest, a pharmaceutical company based in Huntsville, Ala., which Endo Pharmaceuticals (ENDP<<u>http://inv\_esting.businessweek.com/research/stocks/snapshot.asp?ticker=ENDP</u>

>) purchased in 2010; and "K-9," created by KVK-Tech, a private company in Newtown, Pa. In general, he sold whatever he could buy in the largest amounts from wholesalers. The most common form of roxy they sold were little blue generics, labeled "M/30." George suspects customers liked them the most because they were the easiest to crush up, mix with water, and inject.

Called "mallies" by aficionados, the M/30s are made by Mallinckrodt, a pharmaceutical company founded in Missouri in the 19th century Mallinckrodt is now the pharmaceuticals business of Dublin-based Covidien

(COV<<u>http://investing.businessweek.com/research/stocks/snapshot/snapshot.asp?ticker=COV></u>), a global health-care products maker with \$11 5 billion in annual revenue. According to the company's website, Mallinckrodt is currently the ninth-largest manufacturer of generic pharmaceuticals in the U.S., with more than 90 million prescriptions dispensed annually. In an e-mail, Stephen Littlejohn, Mallinckrodt's vice president for communications, says the company has less than 20 percent of the market share of 30-mg oxycodone tablets and that "we believe that reducing the abuse, diversion, and misuse of powerful pain medications is necessary to ensure adequate treatment of pain and access to that treatment for legitimate pain patients."</u>

There may be plenty of consumer demand for prescription painkillers in America, but it still pays to advertise, says George. When he was first breaking into the industry, what went on in a stripmall pain clinic was basically unknown. George bought ads in the yellow pages. He took out ads in a local alternative weekly paper, the New Times Broward-Palm Beach, alongside promotions for strip clubs and escort services. "Eventually all the pain clinics put ads in there," says George. "People would know that if you wanted to find one, you just pick one up and look at that paper."

He didn't neglect digital outlets, either. He bought search ads on Google. And he hired a search engine optimization expert to help his websites appear at the top of Google results whenever people typed in queries about painkillers in Florida, pain clinics, pain specialists, pain relief, or prescription drugs. George also advertised by the side of the road. "I was the first one in the business to ever have billboards," says George.

In June 2011, Florida Governor Rick Scott appeared at a press conference in Tampa to sign into law a new bill, HB 7095, designed to curb the distribution of prescription opioids, closing loopholes that allowed "illegitimate doctors and pharmacies" to overprescribe and dispense mass amounts of opioids under the guise of lawful pain clinics. No longer, said Scott, would Florida be ridiculed as the "Oxy Express."

The key provision prohibited doctors from dispensing painkillers directly. And a statewide system now keeps track of how many prescriptions for opioids doctors write and patients receive. There are quite a few. Nationwide, there were 335 million prescriptions written for painkillers in 201 1, according to IMS Health.

Mark Perez, a special agent in charge with the Florida Department of Law Enforcement, says the new regulations in combination with regional strike forces, which the governor and attorney general set up in March 2011, have already significantly reduced the problem. Says Perez, "You can't just arrest these individuals without getting to the root of the matter, which was obviously the suppliers, the prescribers, and the doctors who were dispensing these narcotics." In 2010, according to DEA records, 90 of the nation's top 100 oxycodone-purchasing doctors were located in Florida By March 2011, that number had dropped to 13 of the top 100. During the same period, the mamber of pain clinics around the state declined from 800 to 508, says Perez. In

its first year, the strike force arrested 34 doctors.

The concern now, says Perez, is that the retailers have picked up and moved to states with less stringent regulations and less attention from law enforcement. A recent press release from the DEA touting the progress made in Florida noted that the agency has seen "notable increases in doctors purchasing oxycodone in Georgia, Tennessee, and Kentucky." In 2013, Georgia will begin implementing a statewide PMP similar to Florida's. In the meantime, pain clinics have popped up all over the state, according to the Atlanta Journal-Constitution.

At a recent national conference on prescription drug abuse, Dave Aronberg, a special prosecutor in the Florida Attorney General's office, noted that would-be oxycodone retailers are already coming up with new business models to evade the law. Pain clinics might now be morphing into "wellness centers," "urgent care centers," and "rejuvenation clinics."

In the meantime, the DEA has signed off on the manufacture of 98 million grams of oxycodone in the U.S. in 2012—up 40 percent from 2008, the year the George twins got into the business. Boggs, of the DEA's Office of Diversion Control, says the quotas are designed to provide for legitimate use only, which can increase over time due to new products coming on the market or different formulations of the same product. "There are checks and balances that are built into the system that make sure that people aren't just blindly distributing and people aren't just blindly filling prescriptions," says Boggs.

George, though, says he is skeptical that his arrest—and the subsequent changes in Florida law will put much of a dent in the distribution of opioids. The market is too big, too fractured, too lucrative to lock down. "Really there's no way to stop someone from getting pain medication," says George. "If you limit it because there are drug addicts out there, you're going to hurt the people who really need it. People are good liars. They can say they're in pain, and you can't prove otherwise. There's no way to stop them from getting their medication."

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