21st National Conference on Pharmaceutical and Chemical Diversion

Pill Mills & Pain Clinics
United States v. Volkman
Overview

I. Special Agent Jerrel Smith (1963–2010)

II. Overview of Pill Problem

III. The Story of Paul Volkman

IV. Investigation

V. Charges

VI. Trial

VII. Sentencing
What this is Not!

“When you win don’t say anything … when you lose say even less”

Paul Brown
Football Legend
Cause and Effect

“If you prove the cause, you at once prove the effect; and conversely nothing can exist without its cause

–Aristotle–
Death in Rural America

a Study in Cause and Effect
I. Overview of Pill Problem

Drug overdose death rates in the US have more than tripled since 1990.\textsuperscript{5}
A Nationwide Problem

In 2008, there were **14,800** prescription painkiller deaths.¹

For every **1** death there are...

- **10** treatment admissions for abuse²
- **32** emergency dept visits for misuse or abuse³
- **130** people who abuse or are dependent⁴
- **825** nonmedical users⁵

Source: OH Department of Health
An Ohio Problem

Source: OH Assoc. of County Behavioral Health Authorities
A Problem in Portsmouth

Photo: Cleveland Plain Dealer
Opiates in Scioto County

TOTAL DOSES OF OPIOIDS DISPENSED (LEGALLY) IN OHIO IN 2010

776,163,404

67 PILLS PER 1 OHIO RESIDENT

121 PILLS PER 1 SCIOTO RESIDENT

Each ● represents 1 dispensed opioid

Source: OH Assoc. of County Behavioral Health Authorities
Scioto County

- 1/10 babies born addicted to drugs in 2010
- Admissions for painkiller addiction 5 times national average
- Highest rate of Hep C infection in OH in 2010
- 117 deaths between 2000 and 2008
  - 9/10 caused by prescription drugs
  - 2/3 of dead did not have prescriptions
  - 298 percent increase in OD deaths
  - Saw first decrease in 2010, continue in 2011
The Cause

In June 2003, DEA started receiving complaints from pharmacists and law enforcement from within the State of Ohio, Kentucky and West Virginia regarding Dr. VOLKMAN prescribing multiple prescriptions for Schedules II and III controlled substances.
II. The Story of Paul Volkman
In October 2003, a DEA undercover agent attempts to seek a consultation with VOLKMAN. For that day, the undercover was denied an appointment at the clinic. No reason given as to why the clinic would not see the undercover.

Possible other reasons for failed attempt:

1) The undercover did not have medical records
2) HUFFMAN’s fear of unknowns as being Law Enforcement Operations
In November 2003, the Drug Control Unit of Kentucky informs DEA that they are unaware of any pharmacies that will fill a prescription written by Dr. VOLKMAN.

“Corresponding Responsibility”
21 C.F.R. § 1306.04(a)

DEA regulations provide that pharmacists have a corresponding responsibility to ensure that a prescription that they fill was issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.
Investigation

November 2003, DEA receives a complaint from a patient of Dr. VOLKMAN.

The patient complains that VOLKMAN did not give her an examination and that she had to have all her prescriptions filled at the clinic.

When asked if she (patient) could bring a friend she is warned by HUFFMAN not to bring friends around the clinic because it is a dangerous place.
Investigation

July 2004, Kentucky State Police (KSP) passes information in regards to RX–EXPRESS Pharmacy located in Russell, Kentucky. A KASPER reports indicates for the period of January 2004 through March 2005 indicates that RX–EXPRESS is filling approximately 85 to 95 percent of VOLKMAN’s prescriptions.
Investigation

December 2004, a patient contacted DEA with information that he/she was a patient of VOLKMAN and that after the initial consultation he/she was prescribed

Lorcet, 
Oxycodone 30mg
Xanax
Soma

Investigator’s Note: Lorcet, Xanax & Soma is a noxious combination of drugs that addicts need. Soma which is not a controlled substance metabolizes into meprobamate, a Schedule IV drug with a potential for abuse.
Investigation

TRI–STATE HEALTH CARE CLINIC is a CASH ONLY business.

All payments are due up-front (prior to services rendered).

Pharmacy climate required (refusing to fill scripts) TRI–STATE begins dispensing.

Witnesses have seen lines with 50 to 100 people waiting to be seen at the clinic.
Investigation

VOLKMAN prescribes and dispenses inordinately large quantity of controlled substances.

No physical examination or very cursory examination was given.

Prescriptions are written inconsistent with legitimate medical treatment.
Data Trends (of patient surveys)

18% of VOLKMAN/HUFFMAN customers have drug charges pending.

43% of VOLKMAN/HUFFMAN customers have controlled substances convictions
Starting in February 2005 and continued to April 2005, a DEA Confidential Source participated in three visits to VOLKMAN.

Common factors:

- Pay First “CASH ONLY”
- Blood pressure taken
- Ask level of pain
- See Dr. VOLKMAN
- No medical exam given
- VOLKMAN sits with back to CS when writing prescription
- Prescriptions are filled at clinic or RX
Investigation

August 2003 DEA obtained distribution reports from McKesson Medical and Moore Medical both DEA Registrants, as Distributors of Controlled Substances.

McKesson: Hydrocodone 10/325
7,000 D/U’s for a one week period.

Moore Medical: Hydrocodone 10/325
41,000 D/U’s for a 26 day period.
#1 Practitioner Purchaser of Oxycodone in Nation in 2004

Source: ARCOS Data
#1 Practitioner Purchaser of Oxycodone in Ohio in 2004

Source: ARCOS Data
Purchased 97 times the national average for practitioner purchases of oxycodone.
Purchased 96% of oxycodone bought by practitioner purchasers in Ohio

Remaining 19 Practitioners
19,061 Dosage Units

Paul Volkman, MD
457,100 Dosage Units

Source: ARCOS Data
#1 Purchaser of Oxycodone compared to pharmacies in Portsmouth

Source: ARCOS Data
Purchased 12 times more oxycodone than the average pharmacy in the nation.

Source: ARCOS Data
Volkman by the Numbers

- **Oxycodone**
  - #1 in Ohio among physicians in 7/03–9/05
  - #2 nationwide among physicians in 7/03–12/03
  - #1 nationwide among physicians 1/04–9/05
  - #1 in Portsmouth among pharmacies 7/03–12/04

- **Hydrocodone**
  - #1 in Ohio among physicians in 7/03–9/05
  - #1 in Portsmouth among pharmacies 7/03–12/04

- **Oxycodone & Hydrocodone**
  - #1 nationwide among physicians 7/03–12/03
  - #2 nationwide among physicians 1/04–12/04

Source: ARCOS Data
Volkman’s Four “ Clinics”

- **TriState:** 4/03 – 9/05
  - Gay St. (4/03 – 10/03)
  - Findlay St. (10/03 – 1/06)

- **Center Street:**
  - 9/05 – 10/05

- **Chillicothe:**
  - 10/05 – 2/06
Volkman’s Co–Conspirators

Denise Huffman

Alice Huffman
Investigation

“Individuals who are not medical professionals with a license such as clinic owner or managers and pharmacy owners who are not pharmacists may be charged with unlawful distribution of controlled substances or conspiracy to distribute controlled substances “outside the scope of professional practice.”
Cash–Only Business
Investigation

HUFFMAN has told patients that if they don’t like the fee increases, that for $500.00 she could get them cocaine, grass, anything.
Law Enforcement Waiver

“I am not appearing to seek care from Paul H. Volkman, M.D., PhD as part of an ongoing investigation...”
Investigation

United States v. Moore
423 U.S. 122(1975)

“[R]egistered physicians can be prosecuted under [21 U.S.C.] § 841 when their activities fall outside the usual course of professional practice.” at 124
Dear Dr. Hurwitz:

Thanks for getting back to me. It is a pleasure to make contact with another professional of like mind and approach. I am new to the pain business, about 7 months, and have had to develop dosing schedules and strategies in total isolation (amidst scorn, vilification, and disapproval). It is reassuring to find that the approach that I have adopted appears similar to yours. Of course, you have been thrown in jail for your efforts, so I’m not sure why I am reassured.

Paradoxically, due to Denise's former and continuing contact with area DEA and FBI agents, our clinic has been well insulated from local corrupt officials and police. Denise once told me, when I asked if we were in any real danger, that the likes of Proctor and his cronies would never face anyone, and were frankly nervous about confrontations. In any case, she and her daughter and niece all have guns in their purses.

As far as security, we have 3 to 4 large armed men in the clinic, and video and infrared cameras all about the building. Whenever the police hang out and take down patient license plates (to find out house addresses and send people over to steal prescriptions) our guys go out and entreatiously take pictures of the cops, who drive away in a huff. I sell the patients to buy a heavy safe for their pills. I have an apartment in the town which has a security system and is about 3 minutes from the clinic. I always carry a cell phone and essentially never go out except to and from the clinic. I always wear my seat belt so I won't get stopped and harrassed by the Portsmouth police.

We are striving to be totally self contained, by having our own pharmacy so it really doesn't matter what the local pharmacists think of me and whether they fill any of my scripts. I think that is the only way for a pain clinic to operate.

Just 2 days ago a local drug mill (Iron Rock) where 200 to 300 people a day paid $250 to get in and get a handful of pain pill scripts (never seeing a doc), and where the local police got $50 for anyone entering was shut down by the feds. By the way, all of these bogus scripts were cheerfully filled by the local druggists, but not mine!

Regards, and good luck.

Paul Volkman, MD

“Dear Dr. Hurwitz” (10/03)

“It is a pleasure to make contact with another professional of like mind and approach . . .

It is reassuring to find that the approach that I have adopted appears similar to yours. Of course, you have been thrown in jail for your efforts, so I’m not sure why I am reassured.”
Investigation

FACTORS

No Doctor – Patient Relationship

Lack of [Complete] Medical Records

No cursory physical exam & medical history

Prescriptions for people not present
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“I am new to the pain business, about 7 months, and have had to develop dosing schedules in total isolation (amidst scorn, vilification, and disapproval).”

“We are striving to be totally self-contained by having our own pharmacy.”
“A brilliant, tough matriarch”

“Our clinic was started . . . by Denise Huffman, a brilliant, tough matriarch…

“Denise and I realized that the only way to continue was to start our own pharmacy and dispense all the scripts that I wrote…”
“Guns in their purses”

“[Denise] and her daughter and nieces all have guns in their purses.

“As far as security, we have 3 to 4 large armed men in the clinic, and video and infrared cameras all about the building.”
Volkman’s Prescriptions

- Wrote for “the best and the most”
- Euphoria-inducing drugs:
  - Oxycodone
  - Hydrocodone
  - Benzodiazepines (Xanax or Valium)
  - Soma
- Large numbers of pills
- High doses of pills
- The more you came, the more you got
Narcotic prescribed 98% of time
Two Immediate Release Narcotics Prescribed 85% of time in Same Visit

- Two Prescribed: 85%
- Two Not Prescribed: 15%
Oxycodone Prescribed 89% of time

- Oxycodone Prescribed: 89%
- Oxycodone Not Prescribed: 11%
30 mg prescribed 74% of the time

- 74%: Strongest Tablet (30 mg)
- 26%: Other Tablet (5 mg, 15 mg)
Hydrocodone prescribed 81% of time

- Hydrocodone Prescribed: 81%
- Hydrocodone Not Prescribed: 19%
Strongest hydrocodone 100% of time

Strongest Tablet

100%
Benzodiazepine prescribed 85% of time

- 85% Benzodiazepine Prescribed
- 15% Benzodiazepine Not Prescribed
Strongest Valium – 99.6%

- Strongest Tablet (10 mg): 99.6%
- Other: 0.4%
Strongest Xanax – 97.6%
Pharmacist Concerns

- Concerned about prescriptions
  - Types of pills
  - Strength of pills
  - Number of pills
  - Combination of pills

- Concerned about patients
  - Travelled long distances
  - No visible signs of pains
  - Young
  - Arrived in groups
  - Not concerned about cost
Effects

Death by Multi Drug Intoxication
Operation of Dispensary
"I am also identifying and witnessing all of the dispensed medications. I initial the back of each prescription and verify each filled medication before it is dispensed."

Result: 1 million missing pills
Inside Tri-State – 1/04

61 Minutes
Waiting Room

6 Minutes
“Assessment” by Staff

36 Minutes
Wait for Doctor

9 Minutes
“Examination” by Doctor
No Medical Examination

- No one
  - took pulse
  - listened to breathing
  - took blood pressure
  - weighed her

- Received Oxy 30, Percocet, Norco, Soma, Xanax
Basic Exchange: Cash for Scripts
Trend: More Drugs over Time

Mg/Day

Prescription Date

Apr-03  May-03  Jun-03  Jul-03  Aug-03  Sep-03  Oct-03  Nov-03  Dec-03  Jan-04  Feb-04  Mar-04

Benzodiazepines
Oxycodone
Hydrocodone
b) The patient has currently improved in these areas compared to the time when she has been on drug holidays from controlled substances.
Problem: Risks of Opiates

- **Benefits**: Pain Relief

- **Risks**
  - Addiction
  - Diversion
  - Patient Safety
    - Frequency (“stacking”)
    - Combination (“synergistic”)
    - Interaction with health conditions
Toxicological Chaos

3–5 pills every 2 hours
30 pills per day
Sham Controls

- Prior Records
- Pill Counts
- Urine Screens

ALL NEW PATIENTS MUST HAVE THE FOLLOWING:
COPIES OF X-RAY, MRI, CT-SCANS etc.... THE PAIN
MUST BE DOCUMENTED BY OTHER PHYSICIANS FOR
AT LEAST 1 YR. PRIOR TO BEING SEEN AT THIS
OFFICE. YOUR PREVIOUS PHYSICIAN MUST
DOCUMENT OTHER FORMS OF PAIN CONTROL USED;
ALSO A SPECIALIST MUST HAVE SEEN YOU, A
REFERRAL FROM A PHYSICIAN IS PREFERRED. WE
NEED THE NAMES & CURRENT NUMBERS OF ALL
PHYSICIANS THAT HAVE TREATED YOU FOR YOUR
CONDITION.

Paul H Williams

* Dr. Volkman’s new Cell # 1-740-357-9270 *
“Levels” and “Clinical Trials”

- “Levels” = numbers showing whether taking medicine as prescribed
- “Clinical trials” = take pills and sit in waiting room
Observations of Tri-State – 6/05

- No equipment to view X-rays
- No equipment to view MRI’s
- No way to wash hands (no soap)
- No thermometer
- Pills in desk drawers
- Urine specimens on floor
- Medical records in kitchen or stove
Center Street: 9/05–10/05

- Run out of his apartment
- Rough part of town
- Parking quickly became an issue
- New day for individuals kicked out of Tristate
- One witness: like a grocery store – people come in and out, very busy
### Physical Examination

#### Date: 9-16-05

**Lungs**

- *Plan:*
  - Oxy 30 9/10
  - Perc 5 9/10
  - Xanax 2 1/2
  - Dicod 61/10
  - Rest 4 hr

### Current Complaints:

- Gone 91%

### Social Status:

- Married/Widowed/Divorced/Lives Alone/Care Taker:

### Work:

- Oxy 30 9/10
  - Perc 5 9/10

### Any New Complaints:

- OTC medication in past month: Yes

### Last Labs/Tests:

- X-ray not filed

### Medications List:

- Oxy 30 9/10
  - Perc 5 9/10

### Patient States takes Medication as Prescribed?

- Yes
  - Date:
  - Pain:
    - Location: 9/10
    - Duration: 9/10
  - Spasms:
    - Location, Intensity, How often occur
  - Sleep:
    - # of hours per night:
    - Type of sleep:
800% increase, no exam

Lungs:

Heart:

GI:

---

**HEART**

- Apical Impulse
- Sounds M1 A2 P2 3rd
- Thrill
- Pulsion
- Shock
- Rale
- Rhythm

---

**OTC medication in past month:** Yes / No: Unavailable

Last seen: Aug. 5, 2005

Last Lab/U/P:

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**Head:**

**Neck:**

**Throat:**

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**Head:**

**Neck:**

**Throat:**
Chillicothe: 10/05 – 2/06

- 6–10 cars waiting at 6:00 am
- Brought in $9,500 in one day
- Video monitoring, but no examination table
- No ability to read X-ray or MRI film
Operations at Chillicothe

- Volkman
  - Didn’t want to see x-rays
  - Didn’t listen to heart or lungs
  - Didn’t even have a stethoscope
  - Complained patients made more than he did
  - Said patients would “limp in an dance out”

- Wheelchair by day / dancing by night
- Workers there past 1:30 am
- “Strong but irregular heartbeat” – a concern, but not at that office
“Informed Consent”

“... Pt may experience respiratory depression due to combination of Xanax, Soma, Oxycodone, Hydrocodone. Pt. accepts risk of resp. depression + premature demise because of improved qualify of life with this pain medication.”
## A first-time patient – 10/21/05

<table>
<thead>
<tr>
<th>Drug</th>
<th>Amount</th>
<th># Pills / Day</th>
<th># Pills / Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxycodone</td>
<td>30 mg</td>
<td>8</td>
<td>240</td>
</tr>
<tr>
<td>Lortab</td>
<td>10 / 325 mg</td>
<td>8</td>
<td>240</td>
</tr>
<tr>
<td>Xanax</td>
<td>2 mg</td>
<td>3</td>
<td>90</td>
</tr>
<tr>
<td>Soma</td>
<td>350 mg</td>
<td>3</td>
<td>90</td>
</tr>
</tbody>
</table>

**Total**          | 22          | 660           |
At least 12 patient deaths

- 9 under age of 40
- All prescribed combination of opiate and sedatives
- 11 received increase on last visit
- 8 died within 3 days of visit
IV. Charges

- Conspiracy – 1 count
- Illegal Distribution – 13 counts
- Deaths – 11 instances
- Firearms – 2 counts
- Drug House – 4 counts

THE GRAND JURY CHARGES THAT:

At all times material to this indictment:

Introduction

1. Beginning on or about October 1, 2001, and continuing up to and including the date of the Indictment, the defendants, DENISE HUFFMAN (hereinafter referred to as “HUFFMAN”), operated two pain clinics: Tri-State Health Care & Pain Management (hereinafter referred to as “Tri-State”), and South Point Pain Management (hereinafter referred to as “South Point”). Tri-State was originally opened in South Shore, Kentucky, on or about October 1, 2001. Tri-State was later relocated to 200 Gay Street, Portsmouth, Ohio, on or about April 1, 2003. HUFFMAN then relocated Tri-State to 1219 Findlay Street, Portsmouth, Ohio, on or about December 30, 2003, where it was operated until being relocated by HUFFMAN on or about February 1, 2008 to South Point, Ohio. The South Point location is still in operation.
Illegal Distribution

- United States must prove physician acted outside course of professional practice and not for legitimate medical purpose

- Instructions on good faith:

  “Good faith” in this context means good intentions and an honest exercise of professional judgment as to a patient’s needs. It means that the Defendant acted in accordance with what he reasonably believed to be proper medical practice.
“Death resulted”

- United States must prove that “death resulted from use of the substance distributed”

- Instructions on death charges:

  ... the Government need not prove that the death was foreseeable to the Defendant. But the Government must prove beyond a reasonable doubt that the death would not have occurred had the mixture and substance ... Dispensed by the Defendant not been ingested by the individual.”
V. Trial

- 110 potential jurors

- 10 weeks: 3/1/11–5/9/11
  - 8 weeks of trial
  - 5 ½ days of deliberation (over 2 weeks)

- 80 witnesses
  - Traveled from 8 states
  - 70 called by US
  - 10 called by Defendant

- 300+ exhibits in 28 binders
Fact Witnesses

- 17 patients
- 4 family members
- 2 co-conspirators
- 9 employees
- 2 landlords
- 1 yoga instructor
Medical Witnesses

- 5 experts
- 7 pharmacists
- 8 coroners
- 8 pathologists
- 11 toxicologists
Death Charges – Science

- Types of Drugs
- Effect of Drugs
- Dosing & Metabolism
  - Amount
  - Frequency
  - Number of Drugs
- Patient-Specific Red Flags
  - Physical
  - Psychological
Key Evidence

- Medical Records
- Prescription Records
- Data re: other doctors
- Autopsy Report
- Toxicology Report
- Coroner re: Scene
- Death Certificate
- Family Members
The Defense of Tolerance

- Individual
- Requires proof of regular compliance
- Dynamic – can be gained, can be lost
- Limited – fatal dose does exist
The reality of the “fatal dose”

<table>
<thead>
<tr>
<th>Name</th>
<th>Amount of Increase</th>
<th>Days After Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>B.B.</td>
<td>800%</td>
<td>2</td>
</tr>
<tr>
<td>M.C.</td>
<td>25% + 33%</td>
<td>2</td>
</tr>
<tr>
<td>D.C.</td>
<td>50%</td>
<td>5</td>
</tr>
<tr>
<td>J.E.</td>
<td>33%</td>
<td>1</td>
</tr>
<tr>
<td>A.G.</td>
<td>50% + New Drug</td>
<td>2</td>
</tr>
<tr>
<td>S.H.</td>
<td>300%</td>
<td>1</td>
</tr>
<tr>
<td>S.J.</td>
<td>2 New Drugs</td>
<td>4</td>
</tr>
<tr>
<td>C.J.</td>
<td>100%</td>
<td>5</td>
</tr>
<tr>
<td>D.P.</td>
<td>25%</td>
<td>1</td>
</tr>
<tr>
<td>E.R.</td>
<td>4 New Drugs</td>
<td>2</td>
</tr>
<tr>
<td>K.R.</td>
<td>100%</td>
<td>1</td>
</tr>
</tbody>
</table>
Verdict – 5/9/11

- Conviction on 18/20 counts
  - Conspiracy – Guilty on 1 count
  - Drug houses – Guilty on all 4 counts
  - Firearm – Guilty on 1 of 2 counts
  - Illegal distribution – Guilty on 12 of 13 counts

- Deaths – guilty on 4 of 11 charges
Sentencing – 2/14/12

- Effect of Proving Death
- Drug Amount
- Enhancements
  - Vulnerable Victims
  - Abuse of Position of Trust
- Comparative Sentences
- Consecutive versus Concurrent
February 23, 2012
Email:
From Ohio Department of Health
Subject: Scioto County is Sharing Some Good News

I wanted to let you know that we have had a reduction in overdose deaths…. there has been a 17% decrease in accidental OD’s and a 42% decrease in drug related deaths.
CONCLUSION